In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-1918V
Filed: March 24, 2022
PUBLISHED

DOUGLAS KELLY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration ("SIRVA"); Influenza ("Flu") Vaccine; Ruling on the Record

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Ruling on Entitlement[1]

On December 8, 2017, petitioner, Douglas Kelly, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that his receipt of an influenza ("flu") vaccination on October 26, 2016, caused a left shoulder injury. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to an award of compensation for a significant aggravation of a pre-existing shoulder injury.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In

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

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a flu vaccine. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (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 CFR §100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a 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 ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must demonstrate: (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. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005)

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

Here, petitioner contends that if he did not suffer a Table Injury of SIRVA, then he nonetheless suffered a significant aggravation of a pre-existing shoulder condition. (ECF No. 1, p. 1; ECF No. 53, p. 12-15.) The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a pre-existing injury, petitioners must establish three additional factors. *See Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test.). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Id*.

II. Procedural History

This case was initially assigned to the Court's Special Processing Unit ("SPU") on December 11, 2017. (ECF Nos. 1, 4.) On December 26, 2017, petitioner filed his medical records and an initial statement of completion. (ECF Nos. 7-8.) Further records and affidavits were filed between January 25, 2018, and July 10, 2019.[3] (ECF Nos. 9, 12-13, 21, 31-32.) On April 9, 2019, respondent filed Rule 4(c) report recommending against compensation. (ECF No. 26.)

This case was reassigned to my docket on October 29, 2019. (ECF No. 37.) On October 30, 2019, I ordered petitioner to file an expert report supporting his claim. (ECF No. 38.) Petitioner filed an expert report authored by Uma Srikumaran, M.D., on April 13, 2020. (ECF No. 41.) On October 9, 2020, respondent filed a responsive expert report from Julie Bishop, M.D. (ECF No. 47.) Subsequently, petitioner filed Dr. Srikumaran's supplemental expert report on December 17, 2020. (ECF No. 49.)

On January 19, 2021, the parties filed a joint status report requesting a hearing. (ECF No. 50.) A status conference was held on February 19, 2021, where I advised the parties that, based on the number of SIRVA claims resolved on the record, that this case might also be best resolved on the written record. (ECF No. 51.) The parties agreed. (*Id.*) On May 5, 2021, petitioner filed a motion for a ruling on the record. (ECF No. 53.) On June 21, 2021, respondent filed his response brief. (ECF No. 55.) Petitioner filed his reply on July 21, 2021. (ECF No. 56.)

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record."). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As reflected in the medical records

i. Pre-vaccination

Petitioner has an extensive history of musculoskeletal problems which include approximately 12 surgeries on his left knee (Ex. 3, p. 29), right elbow, hand, and thumb complaints resulting in right elbow and thumb surgeries (Ex. 9, p. 5), two surgeries on the left shoulder and two surgeries on the right shoulder prior to his vaccination (Ex. 12, p. 3; Ex. 6, p. 2-3).

[3] Respondent did also request complete physical therapy records from Comprehensive Physical Therapy, Inc. and petitioner subsequently represented that these records are unavailable. Respondent filed a status report questioning the documentation supporting petitioner's representation, but at no point thereafter specifically re-raised his request for these records and has raised no argument based on the absence of these records. (ECF No. 33, 55.)

On June 4, 2015, petitioner presented to Aaron Shakespeare, PA-C, at The Centers for Advanced Orthopedics complaining of left shoulder pain. (Ex. 5, pp. 31-32.) Petitioner reported that he had "left shoulder pain for the last 3 years" and that "he was reaching back to scratch his back when a friend grabbed his arm and wrenched it up." (*Id.*) At that time petitioner "had a pain in the shoulder develop." (*Id.*) Petitioner tried ultrasound and heat with therapy but described his left shoulder throbbing and feeling weaker compared to the right. (*Id.*) On physical examination petitioner was tender along his biceps, he had full range of motion with pain at flexion and abduction, and his impingement and Speed's signs were positive. (*Id.*) Petitioner was diagnosed with bursitis-rotator cuff syndrome and biceps tendonitis and prescribed physical therapy, a cortisone injection, and recommended NSAIDs for pain management. (*Id.*)

On September 9, 2015, petitioner presented to Thomas McNamara, M.D., for a Medicare preventive visit. (Ex. 3, p. 48-52.) Dr. McNamara noted in the history of present illness arthralgia and failed knee surgery with repeat procedures. (*Id.* at 49.) He further noted that petitioner was on chronic narcotic maintenance. (*Id.*) There is no mention of shoulder or elbow problems. (*See id.*)

On March 11, 2016, petitioner returned to PA Shakespeare complaining of bilateral elbow, knee, and left shoulder pain. (Ex. 5, pp. 27-28.) PA Shakespeare noted "discomfort in the left shoulder that was treated last June with a cortisone shot that gave [petitioner] significant relief." (*Id.*) Petitioner reported that the "pain is mainly at the end range of flexion and abduction" and "lifting seems to hurt the shoulder more." (*Id.*) On physical examination petitioner had some tenderness to palpation of the incised tendon of the left shoulder, with pain in the left lateral epicondyle, full shoulder range of motion and strength. (*Id.*) Petitioner was diagnosed with shoulder bursitis and PA Shakespeare noted rotator cuff tendonitis. (*Id.* at 28.) He was given a cortisone injection and directed to physical therapy. (*Id.*)

On May 17, 2016, petitioner presented to Physical Medicine and Rehabilitation specialist, Dr. Brad Rosen, for an evaluation at Rehabilitation and Sports Medicine Associates. (Ex. 6, pp. 24-26.) On his intake form, petitioner noted past problems with his right thumb, elbow, knees, and shoulders between 1973 and 2014—with surgery on both shoulders in the 1980's. (*Id.* at 2-3.) Petitioner complained of knee and left shoulder pain. (*Id.* at 24.) Dr. Rosen noted that 35 to 40 years ago petitioner suffered "pain up and down [the] neck," though "ortho / MRI" showed "Ø prob[lems]." (*Id.*) Petitioner reported that he has attended physical therapy for an injured left shoulder from three years ago. (*Id.*) He described weakness and numbness in the shoulder while boxing, rating the pain at 2 to 7 out of 10 in the shoulder. (*Id.* at 24, 26.) Dr. Rosen suggested rehabilitation and osteopathic treatments. (*Id.*)

On May 20, 2016, petitioner presented to his primary care physician Seth Garber, M.D., for "chronic conditions." (Ex. 3, pp. 42-44.) In the history of present illness Dr. Garber noted that petitioner had osteoarthritis of the knee (unspecified). (*Id.* at 43.) There is no mention of petitioner's shoulder or elbow problems. (*See id.*)

On June 13, 2016, petitioner returned to Dr. Rosen complaining of left shoulder aches and numbness. (Ex. 6, pp. 22-23.) Petitioner rated his shoulder pain at a 3 to 7 out of 10. (*Id.*) However, petitioner reported that his shoulder condition was improving and that he planned to continue current treatments. (*Id.*) On June 21, 2016, petitioner returned to Dr. Rosen complaining of pain in his knee. (*Id.* at 20.) At this visit petitioner also states that he would like to try physical therapy for his left shoulder. (*Id.*) On June 27, 2016, petitioner returned to Dr. Rosen complaining of knee and left shoulder pain. (*Id.* at 18.) Dr. Rosen indicated that petitioner "improved since dry needling." (*Id.*) Petitioner reported that his "shoulder feels tight in the teres minor area." (*Id.*) On physical examination petitioner was tender to palpation at the infraspinatus and teres minor (rotator cuff muscles). (*Id.*)

On July 19, 2016, petitioner again returned to Dr. Rosen for his knee and left shoulder. (Ex. 6, pp. 15-17.)[4] Dr. Rosen noted that petitioner's "shoulder [is] much better." (*Id.* at 15.) He further noted "sh[oulder] down to just a few spots – best it's felt x 3 y[ea]rs!" (*Id.*) Petitioner complained of an ache and numbness in his shoulder, rating his pain at a 3 to 6 out of 10. (*Id.* at 17.) Dr. Rosen ordered petitioner to return for a follow-up in four weeks. (*Id.* at 15.)

On September 12, 2016, petitioner presented to Dr. Rosen again for his knee and left shoulder, reporting that he "still had pain in the scap area, [though] [he] started swimming two weeks ago [and it] seems like this is helping." (Ex. 6, pp. 13-14.) Petitioner rated his shoulder pain as ranging from 2 to 6 out of 10, but averaging 3-4 and 2-3 at the time of examination. (*Id.* at 14.) He further described the pain as an ache and numbness. (*Id.*) On physical examination, he was noted to be tight in internal rotation and had tenderness along the teres minor. (*Id.* at 13.) Petitioner's shoulder pain was assessed as being "improved," and Dr. Rosen suggested a follow-up in four weeks. (*Id.*)

ii. **Vaccination and subsequent treatment**

On October 26, 2016, petitioner received an influenza vaccination in the left deltoid at CVS. (Exs. 1, 13.) Five days later, on October 31, 2016, petitioner presented to Laura Nowosielski, M.D., complaining of left arm and shoulder pain and a "dull-aching pain" since receiving the influenza vaccine the prior week. (Ex. 7, pp. 1-2.) It was noted in his history of present illness that petitioner:

> presents with a painful left arm and shoulder after receiving a[n] influenza vaccine 4 days ago in Maryland. He has a history of bilateral shoulder surgery and has received multiple injections in the left shoulder recently as well as osteopathic manipulation, [his] shoulder was feeling good prior to his injection. [Petitioner] had a sudden onset of pain with the injection in the area[,] remains with a constant dull aching irritation. The pain causes a decrease in his range of motion but normal grip strength. . . .

[4] The "overall discomfort" charts from this visit list a date of June 19, 2016 as opposed to July 19, 2016, however based on the context and chronology of the medical records, it appears that this was an error and that the charts do in fact apply to petitioner's July 19, 2016 visit to Dr. Rosen.

(Ex. 7, p. 2.)

On physical examination petitioner had limited active range of motion in his shoulder due to pain but normal passive range of motion. (*Id.*) Petitioner also had tenderness over the left biceps. (*Id.*) He was assessed with "musculoskeletal pain after flu vaccination" and a vaccine adverse reaction. (*Id.* at 3.) Dr. Nowosielski prescribed a Medrol dose pack and Naproxen. (*Id.*)

On November 9, 2016, petitioner presented to Dr. Rosen reporting that he "seemed to [be] get[ting] better" but "flared up after a flu shot." (Ex. 6, p. 11.) "Now," petitioner described a "high / sharp pain." (*Id.*) He rated his shoulder pain at a 3 to 7 out of 10 and now described it as an ache and stabbing pain. (*Id.* at 12.) Dr. Rosen assessed petitioner as having a "DOA shoulder" (osteoarthritis) and myalgia after a flu shot. (*Id.* at 11.) Petitioner's plan included physical therapy and NSAIDs. (*Id.*)

On November 28, 2016, petitioner returned to PA Shakespeare complaining of left shoulder pain. (Ex. 5, p. 21.) Petitioner reported "ongoing pain for quite some time but recently had a flu shot a month ago and had significant increase in his pain." (*Id.*) Petitioner rated the pain at 3/10. (*Id.*) PA Shakespeare noted that petitioner had had a cortisone shot and therapy without any significant benefit. (*Id.*) His range of motion was noted to be functional with pain at the end range of motion. (*Id.*) Petitioner's radiographs showed an anchor from prior rotator cuff surgery, AC arthritis, and a preserved joint space. (*Id.*) He was diagnosed with impingement syndrome of the left shoulder and rotator cuff capsule sprain. (Ex. 5, pp. 21-22.) PA Shakespeare advised petitioner to get a new MRI to assess for rotator cuff tear. (*Id.*at 22.)

On December 5, 2016, petitioner again returned to PA Shakespeare complaining of shoulder pain "still throughout the left shoulder." (Ex. 5, p. 19.) PA Shakespeare noted that petitioner's "MRI does reveal a significant tendinitis of the subscapularis with questionable partial tear" and "significant supraspinatus and infraspinatus tendinitis." (*Id.*) Petitioner was given a cortisone injection and prescribed dedicated shoulder physical therapy. (*Id.* at 20.) The plan was for petitioner to return in four months. (*Id.*)

On December 14, 2016, petitioner returned to his primary care physician Dr. Garber for a preventative medicine visit. (Ex. 3, p. 36.) Dr. Garber noted in the history of present illness that petitioner complained of receiving an influenza vaccine in the left upper arm that resulted in "immediate pain" followed by "persistent chronic pain since then in the area of the vaccination." (*Id.* at 38.) Dr. Garber further noted that petitioner had been seeking consultation with his orthopedists and receiving cortisone injections. (*Id.*) Finally, Dr. Garber noted that petitioner was not sure of the working diagnosis or the cause of his pain, and further noted that petitioner "did not want an eval[uation] for this issue here." (*Id.*)

On December 22, 2016, petitioner presented to Sam Sydney, M.D., with recurring "pain in the left shoulder following a recent flu shot[.]" (Ex. 5, p. 17.) Petitioner noted that the "pain has changed in quality from previous left shoulder pain" and that he had minimal improvement with cortisone injections and physical therapy. (*Id.*) On physical examination, Dr. Sydney noted tenderness to palpation in the biceps, supraspinatus, and infraspinatus tendons, with 4/5 strength, functional range of motion

but pain at the end range, and positive impingement signs. (*Id.*) Petitioner's MRI was reviewed, and Dr. Sydney noted significant tendonitis and a questionable partial tear of the subscapularis. (*Id.*) Petitioner was diagnosed with impingement syndrome and a left rotator cuff capsule sprain and surgery was not recommended. (*Id.* at 18.) Dr. Sydney recommended petitioner continue range of motion exercises to avoid developing adhesive capsulitis. (*Id.*)

On March 6, 2017, petitioner returned to PA Shakespeare for a follow-up regarding his left shoulder. (Ex. 5, p. 15.) Petitioner reported that the physical therapy and injections had provided minimal relief. (*Id.*) He described a deep pain, worse with reaching overhead and lifting, and stated that he is ready to pursue surgery. (*Id.*) On physical examination, petitioner was tender to palpation over the AC joint and supraspinatus tendon and PA Shakespeare noted shoulder discomfort with end range of motion. (*Id.*) Petitioner's MRI was reviewed, noting no full rotator cuff tears. (Ex. 5, p. 16.) He was diagnosed with left shoulder impingement and rotator capsule sprain and given a cortisone injection. (*Id.*) At this visit petitioner also complained of, and was diagnosed with, right hand trigger finger and right ulnar nerve lesion. (*Id.*)

On April 20, 2017, petitioner returned to Dr. Sydney complaining of right hand and right elbow pain. (Ex. 5, p. 13.) Petitioner noted a fall during pickleball[5] onto his right shoulder six weeks earlier and feared "something may be torn." (*Id.*) An MRI of the right shoulder was ordered. (*Id.* at 14.) Dr. Sydney reviewed petitioner's EMG / NCV from April 17, 2017. (*Id.* at 13-14; Ex. 9, p. 9.) Dr. Sydney noted "results of the right hand which reveals moderate symptomatic right medial and ulnar neuropathy" as well as a "prior history of chronic traumatic sports injury to the right elbow." (Ex. 5, p. 14.) Petitioner was referred to Dr. Pervaiz for consideration of his right cubital tunnel and carpal tunnel release. (*Id.*)

On April 25, 2017, petitioner presented to Khurram Pervaiz, M.D., with "multiple complaints in both arms." (Ex. 5, p. 9.) In addition to his right elbow and hand, petitioner complained of bilateral shoulder pain worse on the left than on the right. (*Id.*) Dr. Pervaiz noted a history of bilateral shoulder surgery. (*Id.*) He further noted that petitioner "had a vaccination into the left shoulder in October of last year which aggravated his left shoulder pain." (*Id.*) On physical examination, petitioner was noted to have pain on range of motion of both shoulders, with tenderness over the AC joint, with weakness in both rotator cuff with limited motion on the left compared to the right (external rotation of 40 on the left and forward flexion of 90 on the left). (*Id.* at 10.) Dr. Pervaiz reviewed petitioner's left shoulder radiographs, showing an anchor from prior surgery as well as AC joint arthritis. (*Id.*) Upon review of petitioner's April 20, 2017 MRI of the right shoulder, Dr. Pervaiz noted partial thickness tearing of the superior subscapularis tendon along with severe long head of the biceps tendinopathy with medial subluxation of the biceps tendon and mild glenohumeral arthritis. (Ex. 5, p. 9, 73.) Dr. Pervaiz recommended petitioner continue conservative treatment for the shoulders because he was soon scheduled to undergo right hand and elbow surgery.

[5] Pickleball is a paddleball sport similar to badminton. *See Pickleball,* WIKIPEDIA, https://en.wikipedia.org/wiki/Pickleball (last visited Mar. 4, 2022).

(*Id.* at 11.) Dr. Pervaiz also expressed concern that petitioner was developing adhesive capsulitis. (*Id.*)

On May 19, 2017, petitioner underwent right carpal tunnel release and right elbow ulnar nerve transposition. (Ex. 9, pp. 13-15, 33.)

On June 6, 2017, petitioner presented to Dr. Pervaiz for bilateral, but left greater than right, shoulder pain. (Ex. 5, p. 6.) Petitioner's history was the same as documented on April 25, 2017. (*Id.* at 7.) Petitioner's physical exam revealed the same findings as his April 25, 2017, visit. (*Id.*) Dr. Pervaiz recommended an MRI on the left shoulder. (*Id.* at 8.)

On June 21, 2017, petitioner presented to Dr. Pervaiz for a follow-up visit. (Ex. 5, p. 2.) Petitioner's shoulder history remained the same as documented on April 25 and June 6, 2017. (*See* Ex. 5, pp. 2-9.) On physical examination, petitioner's range of motion for the left shoulder improved to 50 of external rotation and 120 of forward elevation—compared to 40 external rotation and 90 forward elevation on April 25, 2017. (*Id.*) Petitioner's radiographs remained unchanged. (*Id.*) Reading petitioner's MRI of the left shoulder from June 7, 2017, Dr. Pervaiz noted a high-grade partial thickness tear / tendinosis of the distal supraspinatus tendon along with a high-grade tear of the infraspinatus tendon, along with tearing of the labrum and moderate AC joint arthritis and biceps tenosynovitis with partial tearing of the biceps tendon with no evidence of a full-thickness tear. (*Id.* at 71.) Petitioner was diagnosed with left and right shoulder impingement syndrome, with AC joint arthritis, high-grade rotator cuff tearing, and possible adhesive capsulitis. (*Id.* at 2.) Dr. Pervaiz recommended surgery involving left shoulder arthroscopy with a distal clavicle excision, biceps tenodesis, possible rotator cuff repair, and possible capsular release. (*Id.*)

On July 14, 2017, petitioner underwent left shoulder surgery. (Ex. 5, p. 67.) Dr. Pervaiz noted that after a long history of conservative treatments, petitioner continued to have significant discomfort. (*Id.* at 67-68.) Petitioner's pre- and post-operative diagnoses were: 1) left shoulder impingement syndrome with a type 2 acromion, 2) severe bursitis, 3) acromioclavicular joint arthritis, 4) partial thickness bursal surface sprain of the rotator cuff, 5) slight chondral wear in the humeral head, 6) severe delaminated superior labral tear with instability of the biceps tendon anchor, and 7) mild adhesive capsulitis. (*Id.*) In the operative description section, Dr. Pervaiz noted that petitioner was found to have a severe tear of the superior labrum and tearing of the proximal biceps tendon. (*Id.* at 67.) He further noted that the "adhesions that were found were from the prior surgery." (*Id.*) There was no evidence of a full thickness rotator cuff tear, and Dr. Pervaiz noted that overall the rotator cuff was intact. (*Id.*) The following procedures were enumerated as having been performed during surgery: 1) left shoulder arthroscopy with extensive debridement including a capsular release, 2) subpectoral biceps tenodesis, 3) subacromial decompression / acromioplasty, 4) distal clavicle excision/Mumford procedure. (*Id.*)

On August 3, 2018, petitioner presented for a post-operative follow-up with Dr. Pervaiz. (Ex. 10, p. 6.) Petitioner showed excellent range of motion. (*Id.*) Dr. Pervaiz noted that petitioner had "similar pathology in the right shoulder as well," and may need right shoulder surgery in the future. (*Id.*)

On August 10, 2017, petitioner presented to Dr. Pervaiz with severe right shoulder pain. (Ex. 10, p. 2.) Petitioner's left shoulder was now one-month post-op and "improving nicely." (*Id.* at 4.) His records indicate that petitioner underwent right elbow ulnar nerve transposition and a right carpal tunnel release on May 19, 2017, and that his symptoms were improving. (*Id.*) During this visit petitioner received a right trigger thumb injection. (*Id.*) Dr. Pervaiz decided to proceed with right shoulder surgery, including a right shoulder arthroscopy, subacromial decompression, distal clavicle excision, subpectoral biceps tenodesis, capsular release, debridement, and possible rotator cuff repair. (*Id.*)

Also on August 10, 2017, Veronica Wilson, PT, issued a letter indicating that petitioner was being treated for his knee at Comprehensive Physical Therapy Inc. ("CPT") while he was in the process of moving to Florida.[6] (Ex. 4, p. 3.) The letter further indicated that "[n]ear the end of October, 2016, when [petitioner] came to our office for treatment of his knee, he told us that he had a very painful shoulder following a flu shot the previous day." (*Id.*) Petitioner further indicated that "the shot was given high in his shoulder, not in his arm." (*Id.*) "Each time" petitioner attended physical therapy at CPT "he stated that he was still having difficulties with his shoulder." (*Id.*)

On September 22, 2017, petitioner underwent right shoulder surgery. (Ex. 10, p. 12.) Petitioner's surgery revealed 1) right shoulder severe tearing of the superior labrum as well as longitudinal tearing at the proximal biceps tendon with slight chondral wear in the glenoid, 2) synovitis in the rotator interval, 3) slight capsular contracture / slight adhesive capsulitis with partial thickness, 4) bursal surface slight tearing of the rotator cuff, 5) synovitis, 6) severe bursitis, 7) type 3 acromion and 8) AC joint osteoarthritis. (*Id.*) The same procedures as the left shoulder were performed on the right: 1) right shoulder arthroscopy with extensive debridement as well as capsule release, 2) subacromial decompression, 3) distal clavicle excision, and 4) subpectoral biceps tenodesis. (*Id.*)

b. As reflected in petitioner's affidavits

Petitioner filed an affidavit on January 25, 2018. (ECF No. 9.) Petitioner states that he received a flu shot on October 26, 2016, that was "administered very high up" on his left shoulder and he "immediately experienced a great deal of pain." (Ex. 8, p. 1.) He describes worsening pain throughout the day which "radiated down into [his] forearm." (*Id.*) The next few days petitioner describes taking morphine, hydrocodone, and naproxen to relieve the pain (medications he was prescribed for chronic knee pain). (*Id.*) On October 31, 2016, petitioner presented to Physicians Regional, where he was prescribed a Dosepak of an anti-inflammatory drug. (*Id.*) Petitioner avers that Dr. Nowosielski reported his adverse vaccine reaction. (*Id.*)

Petitioner states that "[o]ver the next couple weeks," his pain and discomfort persisted, and he continued to take morphine, hydrocodone, and naproxen. (Ex. 8, p.

[6] This letter was also filed as Exhibit 16. (*See* Ex. 4, 16.) Petitioner also filed a letter dated June 4, 2019, stating that petitioner was a patient at CPT intermittently over a period of years for revision of his left knee surgery. (Ex. 15, p. 1.) The June 4th letter further indicates that petitioner complained to his physical therapist of pain and stiffness in his left shoulder after a flu shot "in late October or early November," and indicating that CPT "do[es] not have any records on [petitioner's] shoulder." (*Id.*)

1.) He further states that he made an appointment to see his orthopedic doctor for the pain and reduced range of motion in his shoulder. (*Id.*) On November 9, 2016 he presented to Rehabilitation and Sports Medicine to begin physical therapy. (*Id.*) He continued physical therapy for the next several months. (*Id.*) "Eventually, the pain began to lessen," but petitioner avers that his range of motion remained "restricted because of [his] frozen shoulder." (*Id.*)

Petitioner underwent left shoulder surgery on July 14, 2017. (Ex. 8, p. 1.) Since the surgery, petitioner's pain "has mostly subsided" and his range of motion "is starting to return." (*Id.*) He continued physical therapy after the surgery, including at-home exercises. (*Id.*) Petitioner avers that "[b]efore the surgery, I was in constant pain." (*Id.* at 2.) Before surgery, petitioner further avers that he had difficulty reaching for objects and was unable to lift objects overhead. (*Id.*) He further described difficulty dressing and difficulty sleeping. (*Id.*)

Petitioner filed a supplemental affidavit on July 10, 2019. (ECF No. 31.) Therein petitioner avers that he was "experiencing a dull pain, low in the posterior of [his] left shoulder/upper back" prior to receiving his flu shot. (Ex. 17, p. 1.) He further avers that he first experienced this pain in 2014, and "because it was a dull pain," he did not visit Dr. Sydney until June of 2015, when he received a cortisone shot in the "left shoulder area." (*Id.*) At this time, petitioner states that he continued to participate in boxing fitness classes three times a week, in addition to strength and weight training five times a week. (*Id.*) However, "[o]nce [he] received the flu shot, [he] immediately stopped" participating in the boxing workouts and reduced his strength training. (*Id.*) He also "suffered from a lack of motion in my shoulder." (*Id.*)

Petitioner further stated that, prior to the flu shot in 2016, he underwent two surgeries on his left shoulder—one orthoscopic and one open surgery. (Ex. 17, p. 1.) However, "the pain [he] experienced after the vaccine was completely different in type and severity." (*Id.*) Lastly, regarding his medical records, petitioner avers that the orthopedic record on November 28, 2016 which states that he had "a cortisone shot and therapy without significant benefit" – references an earlier cortisone shot he received on October 10, 2016 (over two weeks prior to his flu vaccination on October 26, 2016). (*Id.* at 2*; see* Ex. 5, p. 21.) Petitioner states that that particular cortisone shot "was administered for symptoms in [his] right elbow, not [his] shoulder." (Ex. 17, p. 2.)

IV. Summary of Expert Opinions

a. Petitioner's Expert, Uma Srikumaran, M.D., M.B.A., M.P.H

Dr. Srikumaran currently 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. (Ex. 18, p. 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. (Ex. 19, p. 1.) 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 has published numerous articles in the field of shoulder surgery, though none specifically related to SIRVA. (Ex. 18, p. 1.) He also 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.*)

Noting that petitioner has a "complicated and extensive musculoskeletal history including pathology involving both shoulders," Dr. Srikumaran initially indicates that petitioner suffered *both* a Shoulder Injury Related to Vaccine Administration (SIRVA) and a significant aggravation of his pre-existing left shoulder condition. (Ex. 18, p. 2.) However, his reports focus mainly on significant aggravation. He opines that petitioner's left shoulder condition was "significantly aggravated by the October 26, 2016 influenza vaccination." (*Id.* at 5.) Prior to vaccination, Dr. Srikumaran notes that petitioner's physical therapy records show a steady improvement, from June of 2016 through September 2016. (*Id.* (citing Ex. 6, pp. 13-22.)) This improvement, according to Dr. Srikumaran, establishes the state of his shoulder health prior to the vaccination. (Ex. 18, p. 5.) He further notes that "the exacerbation that began in May of 2016 was resolved and [petitioner] returned to a high level activity such as swimming." (Ex. 18, p. 5.)

Dr. Srikumaran notes that petitioner consistently reported worsening pain and function within 48 hours after vaccination, which "strongly supports a significant aggravation claim." (Ex. 18, p. 5.) Furthermore, he opines that the character and quality of pain petitioner reported is distinctly different than his baseline pain. (*Id.*) If the shoulder pain was simply a continuation of petitioner's chronic shoulder problem, Dr. Srikumaran explains, "there should be evidence in the record that the pain was similar" prior to the vaccination and not related to the timing of vaccination. (*Id.*) However, he opines that this is not the case. (*Id.*)

Dr. Srikumaran opines that the scientific literature also supports a theory of how vaccinations can cause shoulder injuries. (Ex. 18, p. 5.) According to Dr. Srikumaran, Bodor and Montalvo suggest based on two case reports that injection of vaccine antigen into the subacromial bursa led to a "robust local immune and inflammatory response" leading to pathology of the subacromial space, biceps tendon, glenohumeral joint, and capsulitis. (*Id.* (citing Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction,* 25 VACCINE 585 (2007) (Ex. 22.)) The authors further suggest a high position of injection into the deltoid can lead to a subacromial injection rather than an intramuscular injection. (Ex. 18, p. 5-6 (citing Bodor & Montalvo, *supra,* at Ex. 22.) Dr. Srikumaran cites Atanasoff et al., which "lends further support to this causation theory" as the authors conclude that vaccine antigen injected into synovial tissue has the potential for inducing a prolonged immune-mediated inflammatory reaction. (Ex. 18, p. 6 (citing Sarah Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049 (2010) (Ex. 20.)) Dr. Srikumaran stresses that in Atanasoff's series, "all patients had a rapid onset of symptoms isolated to the area of injection."

(Ex. 18, p. 6, (citing Atanasoff et al., *supra,* at Ex. 20).) Arias et al., in a large systematic review, "further establish the time course of injury with a majority of patients reporting pain within 48 hours, and many reporting a high injection location." (Ex. 18, p. 6 (citing L.H. Martin Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations,* 35 Vaccine 4870 (2017) (Ex. 21)).) Lastly, Dr. Srikumaran cites both animal (Dumonde) and human (Trollmo) studies as supporting an autoimmune theory. (Ex. 18, p. 6 (citing D.C. Dumonde & L.E. Glynn, *The production of arthritis in rabbits by an immunological reaction to fibrin,* 43 BRIT. J. OF EXPERIMENTAL PATHOLOGY 373 (1961) (Ex. 23); C. Trollmo et al., *Intra-articular immunization induces strong systemic immune response in humans,* 82 IMMUNOLOGY 384 (1990) (Ex. 24).)

Dr. Srikumaran opines that there is logical sequence of cause and effect demonstrating a proximate temporal relationship in petitioner's case. (Ex. 18, p. 6.) Again, Dr. Srikumaran suggests that petitioner's condition prior to vaccination showed a history of shoulder pathology in both shoulders. (*Id.*) However, he opines that petitioner's visits to Seth Garber (Ex. 3, pp. 42-43) and Bradley Rosen, D.O. (Ex. 6, pp. 13-24) clearly establishes his condition prior to vaccination. (*Id.*) Though petitioner had an exacerbation of pain in May, Dr. Srikumaran insists that this pain was resolved with conservative treatments. (*Id.*) Additionally, he highlights petitioner's affidavit wherein petitioner describes immediate pain after a "very high up" vaccination. (*Id.* (citing Ex. 8, p.1).) Dr. Srikumaran stresses that petitioner consistently reported the onset of immediate pain. (Ex. 6-7 (citing Ex. 7, p. 1; Ex. 6, p. 11; Ex. 5, pp. 9, 17-18, 21; Ex. 3, p. 38).)

Dr. Srikumaran points to petitioner's visit with Dr. Nowosielski on October 31, 2016, five days post-vaccination, where Dr. Nowosielski's assessment included an adverse reaction to vaccination. (Ex. 18, p. 7 (citing Ex. 7, p. 3).) He also highlights a note from Dr. Rosen post-vaccination, on November 9, 2016, which noted that petitioner's pain as "[n]ow some high/ sharp pain." (Ex. 6, p. 11) compared to a note pre-vaccination, on May 17, 2016, which described petitioner's pain as "tight" (Ex. 6, p. 25; Ex. 18, p. 7.) Dr. Srikumaran concludes that petitioner's pre-existing left shoulder condition was well managed with conservative measures prior to vaccine injection, immediately worsened after the injection, failed conservative measures after injection, was confirmed by diagnostic imaging (MRI) and surgical findings consistent with well-known SIRVA pathologies (bursitis, capsulitis), and required surgery. All of this evidences a significant aggravation of petitioner's pre-existing left shoulder condition. (*Id.*) Dr. Srikumaran refutes respondent's claim that petitioner's case represents the natural progression of his condition. (*Id.*) Based on the "temporal relationship alone," he explains that "a chronic condition would not be expected to press so acutely." (*Id.*) Lastly, Dr. Srikumaran opines that conditions such as bursitis, capsulitis, or inflammation can be aggravated by various triggers, and in petitioner's case, "this trigger was clearly the vaccination." (*Id.* at 7-8.) In contrast, petitioner's right shoulder pain was likely triggered by a traumatic fall onto his right shoulder while playing pickleball. (*Id.* at 8 (citing Ex. 5, p. 13).)

b. Respondent's Expert, Julie Y Bishop, M.D.

Dr. Bishop currently serves as a professor in the department of Orthopaedic Surgery at the Ohio State University, Wexner Medical Center, as well as Chief of the Division of Shoulder surgery, and Vice Chair of Finance for the Orthopaedic Department. (Ex. A, p. 1.) As a shoulder specialist, all of Dr. Bishop's research interests, publications, book chapters, and presentations have been on the treatment of shoulder pathology. (*Id.*; Ex. B pp. 9-41.) Dr. Bishop has treated multiple patients with SIRVA in her practice over the years and has published in this area as well. (*Id.*)

Dr. Bishop received her medical degree from Cornell University Medical College in 1997. (Ex. B, p. 1.) She completed fellow training in 2003 specifically in shoulder surgery (fellowship at Mount Sinai Hospital in New York City) and Orthopaedic sports medicine (visiting fellowship at the University of Pittsburg Medical Center). (Ex. A, p. 1.) She is board certified in orthopedic surgery. (Ex. B, p. 2.) Dr. Bishop is also a fellow of the American Academy of Orthopaedic Surgeons, an active member of the American Shoulder and Elbow Surgeons, a member of the American Orthopaedic Society for Sports Medicine as well as an elected member of the American Orthopaedic Association. (Ex. A, p. 1.)

Dr. Bishop opines that there is no evidence to support the conclusion that there was a significant aggravation of petitioner's condition due to vaccination. (Ex. A, p. 10.) While petitioner did report an increase in pain after the vaccination, she emphasizes that petitioner reported only one point higher on the pain scale than his previous reports of pain for several months prior to vaccination. (*Id.* at 10-11.) Rather, petitioner's reports of pain "show the more waxing and waning nature" of the pathology in petitioner's left shoulder. (*Id.* at 11.) Dr. Bishop acknowledges that petitioner developed a "new component," adhesive capsulitis, in his left shoulder six months after the vaccination. (*Id.*) While this certainly "added to his pain and symptoms," Dr. Bishop stresses that there is clear evidence presented in petitioner's records that "the pathology in his shoulder was degenerative and thus by definition, progressive in nature." (*Id.*) Therefore, Dr. Bishop opines, surgical intervention was the reasonable conclusion to address petitioner's pathology, "regardless of the vaccination." (*Id.*)

Dr. Bishop observes that at the time of vaccination, petitioner was sixty-four years old and had an extensive past musculoskeletal history that included 19 surgeries on his left knee, bilateral shoulder surgeries and right elbow, hand and thumb complaints (that also led to right elbow and hand surgery), culminating in a third surgery on each of his shoulders at the conclusion of his care records. (Ex. A, p. 2.) She further observes that petitioner had two surgeries on both his left and right shoulders prior to his influenza vaccine, one in the 1980's and one in 2002; he has a history of bilateral shoulder dislocations; and he lives a vigorous lifestyle involving boxing and weightlifting. (*Id.*) Shoulder dislocations likely led petitioner to undergo his surgeries in the 1980's, as Dr. Bishop explains, petitioner would have been in his thirties at the time and surgery for shoulder dislocations is more prevalent in this age group. (*Id.* at 7.) Petitioner also underwent rotator cuff surgery in 2002. (*Id.*) Dr. Bishop notes that petitioner next presented in June 2015 with left shoulder pain, noting he injured the shoulder three years earlier, when he was diagnosed with rotator cuff syndrome and

biceps tendonitis. (Ex. A, p. 7.) Nine months later, in March 2016, petitioner presented with left shoulder pain, again with similar diagnoses. (*Id.*) By May of 2016, petitioner presented again for his shoulder, this time noting that hitting the boxing bag made his shoulder numb and feel weak. (*Id.*) This note, Dr. Bishop explains, is a clear indication that "despite the pain, [petitioner] is still boxing" at this time. (*Id.*) Over the next four months, Dr. Bishop observes that petitioner reported shoulder improvement, though he still rated his pain at a 6/10. (*Id.*) This was down only one point from the 7/10 score petitioner reported at his first visit. (*Id.*)

At the time of his surgery, Dr. Bishop observes that petitioner was found to have chondral wear to the humeral head and was also given the diagnosis of shoulder osteoarthritis by Dr. Rosen in his November 2016 visit post-vaccination. (Ex. A, p. 8.) Given petitioner's history of shoulder dislocations, Dr. Bishop asserts that there is substantial support in the literature that shoulder dislocations lead to arthritis of the shoulder joint. (*Id.*) Citing Hovelius and Saeboe, Dr. Bishop observes that in this 25-year follow-up there was an overall incidence of shoulder arthritis in 56% of the patients studied. (*Id.* (citing Lennart Hovelius & Modolv Saeboe, *Neer Award 2008: Arthropathy after primary anterior shoulder dislocation—223 shoulders prospectively followed up for twenty-five years,* 18 J. SHOULDER ELBOW SURGERY 339 (2009) (Ex. A-1).)) Moreover, the authors found that patients who engaged in high-energy sports (like boxing), had higher rates of arthritis. (Ex. A, p. 8 (citing Hovelius & Saeboe, *supra,* at Ex. A-1.)) In fact, petitioner was found to have AC arthritis at the time of his surgery, which was addressed with a distal clavicle excision. (Ex. A, p. 9.) Petitioner was also found to have a type II acromion (bone spur) and subacromial impingement. (*Id.*) However, Dr. Bishop opines that "an influenza vaccination would not cause these structural findings" because these injuries are "degenerative findings related to age." (*Id.* (citing Steven Needell et al., *MRI Imaging of the Rotator Cuff: Peritendinous and Bone Abnormalities in an Asymptomatic Population,* 166 AM. J. ROENTGENOLOGY 863 (1996) (Ex. A-3)).)

Dr. Bishop observes that at the time of his 2017 surgery, petitioner also suffered from a superior labrum anterior to posterior (SLAP) injury, rotator cuff symptoms, severe bursitis, and adhesive capsulitis. (Ex. A, pp. 9-10.) Petitioner's SLAP injury led to debridement of the labrum and tenodesis of the biceps during his surgery. (*Id.*) Dr. Bishop explains that this finding is considered an age-related degenerative pathology, as well as a common finding in overhead athletes and contact athletes. (*Id.*) Again, Dr. Bishop stresses that an influenza vaccination would not lead to these findings, and they are not a part of the commonly accepted shoulder pathologies for SIRVA. (*Id.* (citing Sandeep Mannava et al., *Prevalence of Shoulder Labral Injury in Collegiate Football Players at the National Football League Scouting Combine,* 6 ORTHOPAEDIC J. SPORT MED. 1 (2018) (Ex. A-4); Lennard Funk & Martyn Snow, *SLAP Tears of the Glenoid Labrum in contact athletes,* 17 CLINICAL J. SPORT. MED. 1 (2007) (Ex. A-5)).) Petitioner's MRI also confirmed a prior history of rotator cuff repair and was read as a possible partial tear. (Ex. A, p. 9.) At the time of his 2017 surgery, petitioner's final diagnosis was partial thickness bursal sprain of the rotator cuff which required only debridement, no formal repair. (*Id.*) Like his SLAP injury, Dr. Bishop notes that rotator cuff pathology is an age-related degenerative finding. (*Id.*) In fact, petitioner underwent rotator cuff surgery in 2002 and Dr. Bishop opines that symptoms would be expected to progress

over the course of 14 years post-op, especially considering petitioner's age and history of boxing and weight lifting. (*Id.*) She also notes that the healing failure rate after prior rotator cuff repair is report as 11% to 94% in the literature. (*Id.* (citing Jieun Kwon et al., *The Rotator Cuff Healing Index,* 47 AM. J. SPORT MED. 173 (2019) (Ex. A-6)).) Thus, the debridement of petitioner's rotator cuff during his 2017 surgery was likely due to the natural progression of this injury and not due to the influenza vaccination. (*Id*.) At the time of petitioner's surgery, Dr. Pervaiz noted "adhesions from the prior surgery" in the operative report. (Ex. A, p. 10.) These findings from a prior surgery likely contributed to petitioner's severe bursitis, as Dr. Bishop explains "they are really one in the same." (*Id.*) If petitioner had bursitis triggered by an influenza vaccination, Dr. Bishop admits that it would be difficult to differentiate it from bursitis due to the adhesions from the prior surgery. (*Id.*) However, based on petitioner's multiple pre-existing pathologies and prior shoulder surgeries, Dr. Bishop opines that petitioner's bursitis was not caused by his vaccination. (*Id.*) Likewise, petitioner was diagnosed with mild adhesive capsulitis at the time of surgery, though Dr. Bishop opines that this injury was also unrelated to petitioner's vaccination. (Ex. A, p. 10.) She also notes that adhesive capsulitis is a disease process that is often bilateral, with a 30% chance of it occurring in the opposite shoulder.[7] (*Id.* (citing Robert Tashjian, *Epidemiology, Natural History, and Indications for Treatment of Rotator Cuff Tears,* 31 CLINICAL SPORTS MED. 589 (2012) (Ex. A-8)).) Given that petitioner's left-sided adhesive capsulitis did not present until April 2017, or six months post-vaccination, Dr. Bishop opines that the component of adhesive capsulitis addressed at the time of surgery was not related to the vaccination. (Ex. A, p. 10.)

According to Dr. Bishop, petitioner's post-operative records reveal that petitioner did "very well after his surgery and that his [range of motion] was excellent." (Ex. A, p. 10.) These results confirm that any component of adhesive capsulitis was resolved after the surgery, Dr. Bishop opines. (*Id.*) One would not expect petitioner to suffer any long-term dysfunction in the shoulder due to adhesive capsulitis component of the shoulder, according to Dr. Bishop, though she notes that petitioner avers in his affidavit that he can no longer workout using his upper body. (*Id.*) Most notably, petitioner underwent a final surgery in his right shoulder, the same as the left shoulder. (Ex. A, p. 10-11.) Dr. Bishop emphasizes that the diagnoses were exactly the same, as were the surgical interventions—providing strong evidence that the flu vaccine was not a substantial factor in petitioner's left shoulder pathology. (*Id.*)

c. Dr. Srikumaran's Supplemental Expert Report

Dr. Srikumaran likewise agrees that many structural findings involving the shoulder are degenerative in nature (related to age and activity). (Ex. 25, p. 1.) He further agrees that these shoulder conditions occur in 30 to 90% of the population, depending on the specific degenerative condition (e.g., labrum tear, AC joint arthritis, rotator cuff tear, etc.). (*Id.*) Additionally, Dr. Srikumaran agrees that these findings are not caused by vaccination. (*Id.*) Rotator cuff symptoms, specifically, progress

[7] In her report Dr. Bishop cites reference 8 (Tashjian *supra*, at Ex. A-8), though it appears that the statistics she is citing actually appear in reference 9 of her report. (*see* Andrew Neviaser and Jo Hannafin, *Adhesive Capsulitis, A Review of Current Treatment,* 38 AM. J. SPORTS MED. 2346 (2010) (Ex. A-9) ("About 20% to 30% of those affected will developed the condition in the opposite shoulder").)

regardless of vaccination. (*Id.*) Like Dr. Bishop, Dr. Srikumaran notes that rotator cuff tears may worsen in severity and become symptomatic over time. (Ex. 25, p. 1.) However, Dr. Srikumaran points to the "tight time course" post-vaccination, during which time petitioner's symptoms worsened, as strong support for the vaccination as the "triggering event." (*Id.*)

Dr. Srikumaran does not dispute Dr. Bishop's summary of petitioner's chronic conditions, the majority of which can be asymptomatic or can wax and wane over time. (Ex. 25, p. 1.) However, Dr. Srikumaran holds the opinion that petitioner's vaccination initiated inflammation "directly related to vaccine antigen being delivered to or near the bursa or synovium of the joint," and the inflammation then initiates pain in previously silent, chronic degenerative condition(s). (*Id.* at 1-2.) The surgical procedures, according to Dr. Srikumaran, address the underlying inflammation "by removing it." (*Id.* at 2.)

Dr. Srikumaran disagrees with Dr. Bishop's opinions regarding petitioner's severe bursitis and adhesions. (Ex. 25, p. 2.) Dr. Srikumaran opines, based on his experience, that during a second surgery adhesions are likely present from prior surgery and quite unlikely to have bursitis (as it is replaced with scar tissue). (*Id.*) Regarding Dr. Bishop's assessment of petitioner's pain on the 10-point pain scale, Dr. Srikumaran asserts that similar pain scores on that scale can be experienced differently. (*Id.*) When assessing pain practitioners consider many factors including severity, duration, consistency, exacerbating and mitigating factors, and radiation. (*Id.*) Pain score alone, therefore, is not a reliable way to ascertain the overall effect of pain an individual, Dr. Srikumaran opines. (*Id.*)

Dr. Srikumaran suggests that there is growing acceptance of a cause-in-fact theory, evidenced by the vaccination guidelines from the CDC and the Journal of the American Pharmacists Association.[8] (Ex. 25, p. 5.) Dr. Srikumaran also stresses that new research has provided epidemiologic evidence supporting the association of subdeltoid bursitis after influenza vaccination. (Ex. 25, p. 5.) According to Dr. Srikumaran, Hesse et al. found an increased risk of 7.78 cases per 1 million vaccinations. (*Id.* (citing Elizabeth M. Hesse et al., *Risk For Subdeltoid Bursitis After Influenza Vaccination: A Population-Based Cohort Study,* 173 ANNALS OF INTERAL MED. 253061 (2020) (Ex. 27).) This epidemiologic evidence can now be "added to the *growing* observational clinical evidence making a strong argument for the validity of shoulder injury related to vaccination." (Ex. 25, p. 5 (citing Elizabeth M. Hesse et al., *Shoulder injury related to vaccine administrations (SIRVA): petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016,* 38 Vaccine 1076 (2020) (Ex. 26).)

[8] citing *New Shingles Vaccine Fact Sheet for Healthcare Providers,* CDC.GOV, https://www.cdc.gov/shingles/multimedia/shingles-factsheet-hcp.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fhcp%2Finfographics%2Fycts-shingrix.html (last updated July 1, 2019); Foster & Davis, *Vaccine administration: preventing serious shoulder injuries,* 53 J. AM. PHARMACISTS ASS'N 102 (2013) (not filed).

V. Party Positions

a. Petitioner's contentions

Petitioner stresses that he suffered a left-sided shoulder injury meeting all four elements demonstrating a SIRVA Table injury. (ECF No. 53, p. 7.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table injury was significantly aggravated by his vaccination. (*Id.* at 10.)

In support of his On-Table claim, petitioner stresses that his left shoulder injury, in its present form, originated after he received the vaccine in question. (ECF No. 53, p. 8.) Any prior history of pain in petitioner's left shoulder, he argues, does not explain the novel symptoms that he experienced after his October 26, 2016 vaccine. (*Id.*) Though petitioner did suffer left shoulder pain prior to vaccination, he asserts that his left shoulder significantly improved prior to his October 26, 2016 vaccination. (*Id.* (citing Ex. 6, pp. 6, 13, 15, 18).) Furthermore, petitioner stresses that his treatment providers consistently report his left shoulder injury as a "distinct injury, with distinct symptoms," which began after his influenza vaccination. (*Id.* at 8-9 (citing Ex. 7, pp. 1, 3; Ex. 5, pp. 17, 21; Ex. 3, p. 38).) Petitioner also stresses that his affidavits are also "entirely consistent" with his medical records. (ECF No. 53, p. 9.) Additionally, Dr. Srikumaran opines that petitioner's left shoulder injury was directly attributable to his influenza vaccination on October 26, 2016. (*Id.* at 10.)

In support of his causation-in-fact claim, petitioner asserts that he has preponderantly established all six *Loving* prongs. (ECF No. 53, pp. 13-18.) Under prong one, petitioner asserts that prior to administration of the vaccine petitioner was able to participate in boxing classes, swim, and train with weights—demonstrating that petitioner's shoulder was in "good condition" prior to his vaccination. (*Id.* at 13-14 (citing Ex. 17, p. 1; Ex. 18, p. 5., 7).) Under prong two, petitioner's condition following vaccination, petitioner stresses that all four of his treating physicians reported that his left shoulder condition deteriorated. (ECF No. 53, p. 14 (citing Ex. 3, p. 38; Ex. 5, p. 17; Ex. 7, p. 1).) Regarding prong three, citing Dr. Srikumaran's report, petitioner argues that his current condition is a significant aggravation of his prior condition because the character and quality of pain he reported was distinctly different than his baseline pain. (ECF No. 53, p. 15 (citing Ex. 18, pp. 5-8).) The medical theory that petitioner presents under the fourth prong is that "vaccine antigen injected into synovial tissue has the potential for inducing a prolonged immune-mediated inflammatory reaction." (ECF No. 53, p. 16.) Finally, petitioner argues that he has met prongs five and six because all of his treating physicians attributed his shoulder pain to his October 26, 2016 vaccination and within a medically acceptable timeframe thereafter. (*Id.* at 16-17.)

In response to respondent's contentions, petitioner stresses that his affidavits must be given credence. (ECF No. 56, p. 4.) Petitioner claims that his affidavits directly address the points challenged by respondent, namely, his continuation of prior shoulder pain. (*Id.*) In his affidavit, petitioner avers that immediately upon receiving his influenza vaccination he experienced new, sharp pain in the median of his left shoulder where the shot was administered. (*Id.* at 4-5.) Regarding his significant aggravation claim, petitioner stresses that a chronic condition would not be expected to progress so

acutely, and therefore cannot be considered a natural progression of his pre-existing condition. (*Id.* at 9-10,14-15.) Therefore, petitioner argues that his current left shoulder condition constitutes a significant aggravation of his prior condition. (*Id.* at 6-15.)

b. Respondent's contentions

Respondent argues that petitioner is not entitled to compensation because he has not met the elements for an On-Table SIRVA nor has he presented preponderant evidence showing that his injury was significantly aggravated by his influenza vaccination. (ECF No. 55, pp. 8, 10.)

Specifically, respondent stresses that petitioner's extended history of shoulder pain is well-documented in the record. (ECF No. 55, p. 9.) Respondent cites petitioner's prior left rotator cuff release (Ex. 3, pp. 43-45); prior left rotator cuff tendonitis (Ex. 5, pp. 31-32); prior shoulder numbness and weakness (Ex. 6, p. 24); and prior physical therapy (Ex. 6, pp. 5, 14). (ECF No. 55, p. 9.) Thus, respondent argues, petitioner's left shoulder pain was "simply a continuation of his chronic shoulder problems that have spanned many years." (*Id.*) Under *Loving* prongs one, two, and three, respondent argues that petitioner's condition was an expected clinical course, not a significant aggravation brought on by vaccination. (*Id.* at 14-18.)

Respondent contends that petitioner has not established significant aggravation of a prior shoulder injury. (ECF No. 55, p. 10.) Respondent disputes the claim that petitioner's shoulder was in "good condition" prior to his vaccination. (*Id.* at 14.) Rather, respondent stresses that petitioner had previously undergone two left shoulder surgeries, two right shoulder surgeries, was diagnosed with left shoulder bursitis, rotator cuff bursitis (treated with cortisone injection), and underwent physical therapy from May to September of 2016 where he rated his shoulder pain at a 2 to 6/10. (*Id.* at 14-15 (citing Ex. 5, p. 27, Ex. 6; Ex. 12, p. 3).) Respondent concedes that petitioner did develop a new, post-vaccination diagnosis of adhesive capsulitis. (ECF No. 55, p. 16.) However, respondent notes that this diagnosis did not appear for six months, placing it well-outside the timeframe for vaccine-mediated causation. (*Id.* (citing Ex. A, p. 11).) Respondent further stresses that petitioner suffered "essentially identical" pathology and symptoms in his non-vaccinated right shoulder. (ECF No. 55, p. 16.)

Under prong four, respondent argues that while it is generally accepted that vaccine administration can cause shoulder pain, petitioner has not shown how this theory specifically applies to his case and that the medical records are inconsistent with a vaccine-mediated injury. (ECF No. 55, p. 12.) Respondent suggests that petitioner's diagnoses are better classified as degenerative findings related to age. (*Id.*) Under prong five, respondent asserts that petitioner's records reflect his own subjective assessment of his injury, and do not indicate that his treating physicians attributed causation to his vaccination. (*Id.* at 13.) Moreover, even if petitioner did report an increase in shoulder pain after his vaccination, respondent proposes that this is more likely attributable to the waxing and waning nature of chronic shoulder pathology. (*Id.*) Finally, under prong six, respondent argues that petitioner has not presented sufficient evidence to show that any significant aggravation occurred within a medically-appropriate timeframe following vaccination. (*Id.* at 14.) Instead, petitioner's presentation demonstrates a long history of left shoulder pain. (*Id.* citing Ex. A, p. 8.)

VI. Analysis

a. Petitioner's Table Injury claim

In this case, petitioner's Table Injury claim hinges on the first SIRVA QAI prong, which requires "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." 42 CFR §100.3(c)(10). Respondent raises no argument that petitioner's alleged post-vaccination pain occurred outside the specified timeframe, that his relevant shoulder pain[9] was not limited to the shoulder in which the vaccine was administered, or that any other condition or abnormality would explain his symptoms—as identified by the Vaccine Injury Table. (*See* ECF Nos. 26, 55.) However, respondent contends that petitioner's post-vaccination left shoulder pain was simply a continuation of his chronic shoulder problems. (ECF No. 55, p. 8-9.) Petitioner alleges that despite his history of prior left shoulder pain, his shoulder had improved in the months prior to his October 2016 vaccination, and that he developed new, worsening pain post-vaccination constituting a Table SIRVA. (ECF No. 53, pp. 7-9.)

Prior to the vaccination at issue, petitioner was still receiving physical therapy for his left shoulder as little as six weeks before the vaccination at issue. (Ex. 6, pp. 5, 14.) Moreover, he avers that he was still symptomatic at the time of his vaccination. (Ex. 17, p. 1 ("[b]efore the flu shot was administered to my left shoulder, I was experiencing dull pain, low in the posterior of my left shoulder/upper back…").) The fact that petitioner experienced some incomplete improvement during the months prior to his vaccination does not in itself meet petitioner's burden of proof on this point. Both parties' experts agree that the symptoms of chronic degenerative changes of the shoulder can wax and wane.[10] Still, petitioner argues that "the medical records make clear that petitioner's left shoulder injury, in its present form, originated after he received the vaccine in question. Any prior history of pain in petitioner's left shoulder does not explain the novel symptoms that petitioner experienced after his October 26, 2016 vaccine." (ECF No. 53, p. 8.) This is not persuasive.

Petitioner did report to his physician that he "feels like this pain has changed in quality from previous left shoulder pain."[11] (Ex. 5, p. 17.) However, even if petitioner's post-vaccination pain was worse, his treating physicians explicitly indicated that they treated petitioner on the basis that his pain complaints were an exacerbation of his prior

[9] Respondent does contend, however, that petitioner's right shoulder condition is relevant to assessing the nature of his left shoulder condition.

[10] Ex A, p. 8 (Dr. Bishop indicating petitioner's presentation of symptoms is "more consistent with the waxing and waning nature of [petitioner's] shoulder pain and pathology that was well documented through the years in the records."); Ex. 25, p. 1 (Dr. Srikumaran indicating that chronic degenerative conditions of the shoulder can be asymptomatic or "can wax and wane over time with activity levels and treatments.")

[11] Petitioner is competent to testify as to the timing and severity of his pain, but not necessarily its cause or medical significance. *See James-Cornelius v. Sec'y of Health & Human Servs.*, 984 F.3d 1374, 1380 (Fed. Cir. 2021).

chronic shoulder pain. On November 28, 2016, Dr. Sydney recorded "ongoing pain for quite some time but recently had a flu shot a month ago and had [a] significant increase in his pain." (Ex. 5, p. 21.) Later, on April 25, 2017, Dr. Pervaiz noted that petitioner "had a vaccination into the left shoulder in October of last year which aggravated his left shoulder pain." (*Id*. at 2, 6, 9.)

In fact, petitioner's argument that onset of post-vaccination pain constituted a new and novel injury is flatly contradicted by his own expert's opinion. In his motion for a ruling on the record, petitioner focuses on the fact that Dr. Srikumaran "concludes from his review of the medical records that petitioner's left shoulder injury was directly attributable to the flu vaccination he received on October 26, 2016." (ECF No. 53, p. 10 (citing Ex. 18 at 5).) However, after describing petitioner's clinical history, Dr. Srikumaran explained that:

> By definition, this course of events describes a significant aggravation of Mr. Kelly's pre-existing left shoulder condition, which typically was well managed with conservative measures, was in good condition prior to vaccine injection, immediately worsened after the injection, failed conservative measures after injection, was confirmed by diagnostic (MRI and surgical findings consistent with well known SIRVA pathologies (bursitis, capsulitis) and required surgery after injection (over 6 months of symptoms and decreased function). The respondent's report claims because Mr. Kelly had similar symptoms and pathology, as well as surgical treatment of his right shoulder, this represents the natural progression of his condition. This is not logical. The temporal relationship alone, with respect to the change in Mr. Kelly's left shoulder symptoms after injection is strong evidence to support a significant aggravation claim; a chronic condition would not be expected to progress so acutely and therefore cannot be considered 'natural progression' of his pre-existing condition.

(Ex. 18, p. 7.)

Even if Dr. Srikumaran opines that petitioner's vaccination was a factor in bringing about a specific pattern of post-vaccination pain symptoms, his significant aggravation opinion necessarily and explicitly encompasses a medical opinion that the musculoskeletal dysfunction at the root of petitioner's shoulder pain was the same pre- and post-vaccination. The entire premise of a significant aggravation claim is that the vaccine acted on a pre-existing condition. The Table SIRVA criteria does not necessarily require a spotless prior health history of the affected shoulder. *See, e.g. O'Leary, M.D. v. Sec'y of Health & Human Servs.*, 18-584v, 2021 WL 3046617, at *8 (Fed. Cl. Spec. Mstr. June 24, 2021) (finding petitioner suffered a Table SIRVA despite an "old history of trauma to his shoulder" that had previously resolved). However, given his own expert's assessment, petitioner's assertion of a Table Injury for this case is untenable.

b. Petitioner's Significant Aggravation Claim

i. Petitioner's condition prior to administration of the vaccine (*Loving* prong one)

Petitioner had a long history of shoulder dysfunction, having suffered multiple shoulder dislocations and having undergone two surgeries on the left shoulder and two surgeries on the right shoulder. (Ex. 3, p. 29; Ex. 12, p. 3; Ex. 6, p. 2-3; Ex. 17, p.1.) A rotator cuff release in 2002 appears to have relieved some of petitioner's symptoms, though contrary to petitioner's assertions, it appears that it never fully resolved. (Ex. 3, p. 29.) Petitioner had been diagnosed with left rotator cuff tendonitis as recently as June 2015. (Ex. 5, pp. 31-32.) Additionally, after the date of vaccination, petitioner was also subsequently diagnosed as having the following conditions: impingement syndrome of the left shoulder and rotator cuff capsule sprain (Ex. 5, p. 21); significant tendinitis of the subscapularis with a questionable partial tear and significant supraspinatus and infraspinatus tendinitis (*Id*. at 19). Based on the medical records and expert opinions, there is preponderant evidence that at least some of these conditions were likely chronic and affected petitioner's left shoulder prior to the vaccination at issue. Dr. Srikumaran agrees on petitioner's behalf that "[i]t is not unusual to have chronic degenerative conditions of the shoulder, as by definition, these conditions are age related and extraordinarily common. It is important to understand that the petitioner, like most people his age, will have imaging findings of chronic degenerative conditions such as fayed or partially torn ligaments and tendons and osteoarthritic joints." (Ex. 25, p. 1.)

Petitioner was experiencing reduced pain in the months leading up to his vaccination, but there is also preponderant evidence that petitioner's chronic shoulder dysfunction remained symptomatic at the time of vaccination. Petitioner began reporting improvement in June of 2016, noting in July that he felt the best he had in three years. (Ex. 6, pp. 15-23.) However, even thereafter petitioner continued to report ongoing shoulder pain. (Ex. 6, pp. 13-14.) Petitioner averred that he was experiencing "dull pain, low in the posterior of my left shoulder/upper back" before his vaccination. (Ex. 17, p. 1.) As of September 12, 2016, petitioner reported that he was swimming, but that he still experienced average shoulder pain of between 3-4 on a pain scale. (Ex. 6, p. 14.) However, he had only mild tightness with internal rotation. (*Id*. at 13.)

ii. Petitioner's current condition/condition after administration of the vaccine (*Loving* prong two)

With regard to petitioner's post-vaccination condition, there is no evidence to suggest that any of petitioner's chronic shoulder conditions had fully resolved. Rather, Dr. Srikumaran's causal opinion is premised on three specific factual contentions regarding petitioner's post-vaccination condition. First, Dr. Srikumaran relies on the fact that post-vaccination petitioner suffered an acute worsening of pain from his own prior baseline that he opines is *inconsistent* with the natural progression of his degenerative conditions. (Ex. 18, p. 7; 25, p. 2.) Second, petitioner's subsequent surgery revealed

severe bursitis and adhesions that are best interpreted as developing post-vaccination. (*Id*.) And, third, petitioner's post-vaccination condition failed conservative treatment measures. (Ex. 18, p. 7.) All three of these factual contentions are preponderantly established on this record.

Regarding the first point, petitioner avers that after receiving his vaccination, he "immediately experienced new, sharp pain in the median of [his] left shoulder where the shot was administered." (Ex. 17, p. 1.) This is corroborated by petitioner's contemporaneous medical records. Petitioner sought treatment five days after his vaccination for "sudden" shoulder pain he attributed to his vaccination. (Ex. 7.) On examination he had limited range of motion due to pain and was assessed with a vaccine adverse reaction. (*Id*. at 2.) Petitioner subsequently made similar reports to Dr. Rosen and PA Shakespeare. (Ex. 6, p. 11; Ex. 5, p. 21.) Although Dr. Rosen had recorded only mild tightness with internal rotation prior to vaccination on September 12, 2016 (Ex. 6, p. 13), he recorded a reduction in internal rotation, external rotation, and flexion when petitioner returned on November 9, 2016. (*Id*. at 11). He also recorded end of range pain. (*Id*. at 11.)

There is also some inconsistency in the description of petitioner's pain (petitioner avers "new, sharp" pain whereas his initial treatment record records "dull-aching" pain). (*Compare* Ex. 17, p. 1 *and* Ex. 7, p. 1.) Additionally, petitioner's pain scale rating does not appear to have changed significantly pre- and post-vaccination. (*Compare* Ex. 6, p. 14 (pain of 2-6) and Ex. 6, p. 12 (pain of 3 to 7); Ex. 5, p. 21 (pain 3 out of 10).) However, at least some of these treatment records recorded "sharp" pain and all identified petitioner's pain as new or different. (Ex. 14, p. 12 (describing pain as sharp, burning, dull, stabbing/throbbing, aching); Ex. 6, p. 11 ("Flared up after a flu shot. Now some high/sharp pain"); Ex. 5, pp. 17-18 (pain has changed in quality from previous left shoulder pain"); *Id.* at 21 ("recently had a flu shot a month ago and had significant increase in his pain.").)

Dr. Bishop stresses in particular petitioner's failure to meaningfully describe an increase in pain using the pain scale. (Ex. A, pp. 10-11.) When viewed as a whole, however, it is clear from petitioner's contemporaneous medical records that petitioner complained of increased pain from the time of his vaccination forward and sought care accordingly. The pattern with which petitioner sought care, the reported reason for seeking that care, and the physicians' examinations and conclusions, are more illuminating of petitioner's condition than his specific subjective numerical pain rating. Petitioner sought care from a walk-in center within days of his vaccination for pain he specifically attributed to his vaccination. (Ex. 7.) That is highly suggestive of an acute concern. Additionally, contrary to Dr. Bishop's assessment that petitioner's complaints were consistent with the waxing and waning nature of petitioner's degenerative conditions (Ex. A, p. 8), petitioner's treating physicians treated these pain complaints as a separate, post-vaccination phenomenon (Ex. 5, pp. 9, 17, 21; Ex. 3, p. 38; Ex. 6, p. 11).

In terms of the underlying pathology, Dr. Srikumaran relies on the adhesions and "severe bursitis" documented in petitioner's subsequent surgical report. (Ex. 18, pp. 7-8 (Ex. 5, p. 67).) Although petitioner's prior MRIs taken on November 28, 2016 and June 7, 2017, did not specifically indicate bursitis, petitioner was assessed as having bursitis in his pre-operative assessment on July 7, 2017. (Ex. 3, p. 27.) Severe bursitis was then included as a post-operative diagnosis. (Ex. 5, p. 67.) Dr. Bishop acknowledges this finding but suggests it should be attributed to petitioner's adhesions from his prior surgery and is therefore pre-existing. (Ex. A p. 10.) Dr. Srikumaran disagrees, suggesting that if the finding were related to the prior surgery, it would more likely be reflected as scarring rather than bursitis.[12] (Ex. 25, p. 2.)

Dr. Bishop's interpretation of the surgical report is less persuasive. Dr. Bishop suggests that the "adhesions from the prior surgery" are "really one in the same" as the bursitis. (Ex. A, p. 10.) However, Dr. Pervaiz was aware of the prior surgery, noted the post-surgical adhesions during the procedure, and still included severe bursitis as separate, stand-alone diagnosis both pre- and post-operatively. (Ex. 5, p. 67.) Relatedly, Dr. Pervaiz's description of the actual course of surgery and procedures performed does not appear to bear out Dr. Bishop's view that the two issues were "one in the same." In pertinent part he notes:

> Scope was first placed in the glenohumeral joint and subsequently in the subacromial space. Inside the glenohumeral joint, I found a lot of adhesions from his previous surgery. I released the rotator interval and the anterior and posterior capsules, taking care to protect the rotator cuff tendons and muscles . . . [then discussing other procedures performed] . . . I now placed the scope in the subacromial space, where I performed a complete bursectomy.

(Ex. 5, p. 68.)

Bursectomy is a known treatment for the type of subacromial bursitis commonly seen in SIRVA.[13] Accordingly, Dr. Pervaiz describes two conditions in two different

[12] Following the June 2015 injury petitioner suffered in his left shoulder, there are some references to bursitis among the treating physician impressions indicated in petitioner's treatment records prior to vaccination. (Ex. 5, p. 31 (6/4/2015); Ex. 5, pp 27-28 (3/11/2016).) However, there is no accompanying imaging or surgical report from that period to confirm that diagnosis. Conversely, petitioner's subsequent left shoulder MRIs did not confirm the presence of bursitis. (Ex. 5, pp. 75 (MRI of 11/28/2016), 71 (MRI of 6/7/2017).) To the extent that any of these records could potentially be confounding of either or both expert opinions regarding the origin of the bursitis, neither expert discussed these records in relation to their discussion of the "severe" bursitis they agree is documented in petitioner's July 14, 2017, surgical findings. (Ex. A; Exs. 18, 25.) The discussion between the experts focused exclusively on whether the bursitis was the result of vaccination or petitioner's prior shoulder surgery. Both experts opine that the bursitis was present prior to either of the two MRI studies.

[13] *Compare, bursa,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=7308&searchterm=bursa (last visited Mar. 11, 2022) ("a sac or saclike cavity filled with a viscid fluid and situated at places in the tissues at which friction would otherwise develop."), *and, subacromial bursa,* DORLAND'S MEDICAL DICTIONARY ONLINE,

anatomical locations (adhesions within glenohumeral joint and bursitis in the subacromial space) and an additional procedure in treatment of subacromial bursitis even after having completed the procedure he separately identified as responsive to the adhesions he visualized as residual from the prior surgery. The report is silent as to any link between the post-surgical adhesions and separately treated bursitis. This, coupled with Dr. Pervaiz's separate diagnosis of "severe" bursitis, appears more consistent with (or at the very least remains compatible with) Dr. Srikumaran's opinion that the bursitis is distinguishable from the post-surgical adhesions.[14] (Ex. 25, p. 2.) And in any event, Dr. Bishop acknowledges that "[i]f Mr. Kelly had bursitis triggered by an influenza vaccination, it would be quite difficult to differentiate it from bursitis due to the adhesions from the prior surgery." (Ex. A, p. 10.) Importantly then, Dr. Bishop's ultimate opinion regarding the bursitis is necessarily informed at least in part by her assessment that petitioner did not experience any change in his clinical presentation attributable to his vaccination, a conclusion that I have separately found less persuasive based on the contemporaneous medical records.

iii. Whether the post-vaccination condition is a "significant aggravation" of the prior condition (*Loving* prong three)

As explained above, a significant aggravation is "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."[15] § 300aa-33(4). Here, consistent

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https://www.dorlandsonline.com/dorland/definition?id=62123 (last visited Mar. 11, 2022) ("a bursa located between the acromion and the insertion of the supraspinatus muscle, extending between the deltoid and the greater tubercle of the humerus; usually continuous with the subdeltoid bursa."), *and*, *bursitis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=7315&searchterm=bursitis (last visited Mar. 11, 2022) ("inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon; the most common site is the subdeltoid bursa"), and *bursectomy,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=7314&searchterm=bursectomy (last visited Mar. 11, 2022) ("excision of a bursa"); *See also,* Hesse et al., *supra,* at Ex. 26, p. 1081, Table 6 (reporting 14 bursectomies out of 476 conceded petitions for SIRVA between July 2010-December 2016).

[14] Of note, Dr. Bishop stresses that petitioner's later right shoulder surgery, which was obviously unrelated to his left shoulder vaccination, included similar diagnoses. (Ex. A, p. 10.) And, indeed, the same "severe bursitis" was noted during that surgery and petitioner had a bursectomy of his right shoulder as well. (Ex. 10, p. 12.) Dr. Srikumaran noted, however, that conditions such as bursitis or inflammation are subject to various triggers and that prior to onset of the right shoulder symptoms that led to this right shoulder surgery, petitioner had attributed his symptoms to a fall on his right shoulder while playing pickleball. (Ex. 18, pp. 7-8 (citing Ex. 5, p. 13).) Given that petitioner did not experience onset of his right shoulder pain until later, and after a reported fall, it is not clear how valuable his right shoulder findings are to evaluating his left shoulder pathology. Dr. Bishop herself appears to opine that there is in general a causal relationship between structural shoulder dysfunction and the development of bursitis. In this case, each shoulder has been subject to differing histories, traumas, and potential inciting events. Thus, the fact that petitioner ultimately experienced bursitis in both shoulders does not serve as confirmation that all of his shoulder pathology was chronic given petitioner's own specific history.

[15] There are two informative cases, *Locane* and *Sharpe,* that discuss the significant aggravation analysis with regard to the evolution of a petitioner's clinical course. *Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375 (Fed. Cir. 2012); *Sharpe v. Sec'y of Health & Human Servs.*, 964 F.3d 1072 (Fed. Cir.

with the statutory definition, the medical records show for the reasons discussed above that petitioner's post-vaccination condition reflects a change for the worse in petitioner's pre-vaccination condition inclusive of pain and disability as well as a physical deterioration in health.

Dr. Bishop contends on respondent's behalf that petitioner's entire post-vaccination clinical history is explained by the natural progression of his chronic pre-existing degenerative shoulder condition. (Ex. A, p. 10-11.) In effect, she suggests that a degenerative condition should be expected to continue to degenerate and so petitioner's ultimate outcome is not surprising. (*Id.* at 11.) Nor does she assess any significance in petitioner's own initial post-vaccination complaints of increased pain, finding them consistent with the expected overall waxing and waning course of his pre-existing condition. (*Id.* at 10-11.) She opines that petitioner's surgical findings are more consistent with his degenerative condition than with the type of findings typically seen in SIRVA. (*Id*. at 9-11.)

Dr. Srikumaran is persuasive, however, in opining that petitioner suffered an acute change in his condition post-vaccination. (Ex. 18, p. 5.) The medical records clearly document that he was improving, albeit incompletely, prior to his vaccination. This is not necessarily significant in itself for all the reasons Dr. Bishop discussed regarding the waxing and waning nature of chronic degenerative conditions; however, it stands in contrast to his immediate post-vaccination presentation. Petitioner promptly and repeatedly sought care for a "sudden" increase in pain and reduced range of motion following his vaccination. (Ex. 7, p. 2.) Importantly, his treating physicians, who were aware of his prior history, treated his post-vaccination complaints on the basis that his prior condition had been aggravated. (Ex. 5, pp. 9, 17, 21; Ex. 3, p. 38; Ex. 6, p. 11.) Additionally, Dr. Srikumaran's opinion is not limited to a change in petitioner's subjective complaints. He also provides a reasonable explanation of petitioner's surgical findings

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2020). The parties disagree as to the meaning and significance of these two precedents with respect the applicable burden of proof. (ECF No. 55, pp. 10-11; ECF No. 56, pp. 6-7.) In *Locane*, petitioner alleged her Crohn's disease, an inflammatory bowel disease, was significantly aggravated by the hepatitis B vaccine. *Locane*, 685 F.3d at 1377-78. The special master determined that petitioner failed to show "by a preponderance of the evidence that she was entitled to compensation under the significant aggravation theory because the course of her disease was not affected by the vaccination." *Id.* at 1378. The Federal Circuit found no error in the special master's analysis. *Id.* at 1381-82. The *Locane* Court noted that petitioner was "given ample opportunity to develop her significant aggravation claim but 'failed to present persuasive evidence that separates [her] problems from an expected course of Crohn's disease.'" *Id.* at 1382. In *Sharpe,* petitioner alleged L.M. had a pre-existing "seizure disorder" and the administration of the several childhood vaccines at her six-month wellness check-up significantly aggravated L.M.'s pre-existing condition. *Sharpe*, 964 F.3d at 1076-77. The special master denied petitioner's significant aggravation claim because L.M.'s genetic mutation, and not the vaccination, was the sole, substantial cause of L.M.'s seizure disorder. *Id.* at 1080. The Circuit found that the special master's analysis improperly "required [p]etitioner to prove the expected outcome for a child with a DYNC1H1 gene mutation and to show that L.M.'s current, post-vaccination condition was worse than that expected outcome." *Id.* at 1081. The *Sharpe* Court distinguished the special master's decision from *Locane,* explaining that in *Locane* "the special master did not require the petitioner to prove that her significantly aggravated condition was not caused by her preexisting condition. Instead, the special master found that the petitioner's condition 'was not affected by the vaccination.'" *Id.*

that supports the presence of post-vaccination bursitis, providing further evidence of a physical change for the worse and deterioration of health. Even if petitioner's degenerative condition(s) alone could have ultimately led him to become a surgical candidate at some point in the future, petitioner is not obligated under *Sharpe* (*see* n. 15, *supra*) to prove that his post-vaccination condition is worse than the expected outcome of his pre-existing condition.

iv. Medical theory of causation (*Loving* prong four/*Althen* prong one)

Petitioner is also required to present a persuasive medical theory of causation demonstrating that the influenza vaccine could have significantly aggravated his preexisting shoulder condition. *Althen,* 418 F.3d at 1278. It is well-established in the Vaccine Program that compensation may be awarded for shoulder injuries on a cause-in-fact basis. *See, e.g.*, *A.P. v. Sec'y of Health & Human Servs.,* No. 17-784V, 2022 WL 275785 (Fed. Cl. Spec. Mstr. Jan. 31, 2022); *L.J. v. Sec'y of Health & Human Servs.,* No. 17-0059V, 2021 WL 6845593 (Fed. Cl. Spec. Mstr. Dec. 2, 2021); *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) *rev. den.*, 142 Fed. Cl. 329 (2019). However, petitioner's medical theory must be supported by "reputable" scientific evidence and must "pertain[] specifically to the petitioner's case." *Moberly,* 592 F.3d at 1322.

In his motion petitioner confusingly cites primarily to the Vaccine Injury Table as support for petitioner's medical theory with little additional argument.[16] (ECF No. 53, p. 16.) However, especially given the facts of this case, petitioner may not merely rely on the fact that SIRVA was added to the Vaccine Injury Table to establish a medical theory for a cause-in-fact claim. *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[17] The government's recognition of "SIRVA" as a vaccine-

[16] Specifically, petitioner argues that "[t]he theory of how administration of an influenza vaccine can cause SIRVA is so well accepted that the Secretary of Health and Human Services added SIRVA to the Vaccine Injury Table in 2017." (*Id*.) Still more confusing, petitioner continues that "Dr. Srikumaran discusses the three criteria and indicates that petitioner meets all three criteria." (*Id*.) It is not entirely clear what criteria petitioner is referencing; however, as described above, the Table Injury of SIRVA is premised on *four* criteria set forth in the QAI and petitioner has conspicuously failed to meet the first of the four.

[17] In Grant, the Federal Circuit explained the distinction between Table and non-Table claims and quoted the legislative history of the Vaccine Act as follows:

> If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both these cases, however, the *petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine.* Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. (Such a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table.)

Grant, 956 F.2d at 1147-48 (quoting H.R.Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986), reprinted in 1988 U.S.C.C.A.N. 6344, 6356) (emphasis in *Grant*); *see also Schick-Cowell v. Sec'y of*

caused injury was limited by the accompanying QAI criteria. In this case, I have already concluded for the reasons discussed above that petitioner has not met those criteria. Thus, if petitioner's medical theory under *Althen* prong one was limited to taking judicial notice of the government's recognition of SIRVAs as occurring in some contexts, petitioner's case would necessarily have to fail under *Althen* prong two, because the facts of petitioner's case do not fall within the confines of that recognition. *Accord L.J.,* 2018 WL 3083140 (taking judicial notice of the Table Injury of SIRVA under *Althen* prong one and applying the Table SIRVA QAI as the basis for assessing *Althen* prong two); *Tenneson*, 2018 WL 3083140 (same). To hold otherwise would be to expand the causal presumption afforded by the Vaccine Injury Table.

In this case, however, petitioner's presentation is not so limited given that Dr. Srikumaran has included in his reports a discussion of relevant medical literature. Dr. Srikumaran relies on six medical articles addressing the specific context of post-vaccination shoulder pain.[18] (Ex. 25, pp. 2-5.) Three of those articles are closely intertwined with respondent's regulatory rulemaking for SIRVA. Atanasoff et al., and Bodor and Montalvo were both cited as support for the addition of SIRVA to the Vaccine Injury Table. Proposed Rulemaking, 2015 WL 4538923, at *45136 (citing Atanasoff et al., *supra,* at Ex. 20; Bodor & Montalvo, *supra,* at Ex. 22.) Hesse et al. examined the characteristics of a population of cases that were conceded by the government as SIRVAs within this Program. (Hesse et al., *supra,* at Ex. 26.) A fourth study, by Hibbs et al., examined reports of post-vaccination shoulder injuries made to the government through the VAERS.[19] (Hibbs et al., *supra,* Ex. 28.)

Respondent contends that "[w]hile it is generally accepted that vaccine administration can cause shoulder pain, petitioner has not shown how this theory specifically applies to his case, and his medical record is inconsistent with a vaccine-mediated injury." (ECF No. 55, p. 12.) In total, the four studies referenced above (Atanasoff, et al., Bodor and Montalvo, Hess, et al., and Hibbs, et al.) examine 1,711 cases of post-vaccination shoulder injuries. However, all of the studies were descriptive analyses without comparison against background rates or controls and, importantly, all excluded individuals with pre-existing, symptomatic shoulder conditions. To respondent's point, petitioner himself would have been excluded from these studies.

Health & Human Servs., 18-656V, 2022 WL 619839 (Fed. Cl. Spec. Mstr. Feb. 8, 2022); *A.P.*, 2022 WL 275785; *but see L.J.,* 2018 WL 3083140 (taking judicial notice of the Table Injury of SIRVA under *Althen* prong one for case filed prior to inclusion of SIRVA on the Vaccine Injury Table, but decided after); *Tenneson*, 2018 WL 3083140 (same).

[18] Two additional studies address immune reaction without specific reference to SIRVA or SIRVA-like presentations. (Dumonde and Glynn, *supra,* at Ex. 23; Trollmo et al., *supra,* at Ex. 24.)

[19] "VAERS" stands for Vaccine Adverse Event Reporting System. "VAERS is a national spontaneous reporting (passive surveillance) system to monitor vaccine safety. It is administered by the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA). VAERS accepts reports of adverse events (AEs) following vaccination from healthcare providers, patients, parents, vaccine manufacturers, and others." (Hibbs et al., *supra,* at Ex. 28, p. 1138.) The studies authors stressed the inherent limits of the VAERS database as a passive surveillance and noted that this constrained their ability to draw causal conclusions or assess risk. (*Id*. at 1141.)

The Atanasoff study, cited by petitioner himself as "seminal," explains why this is significant. (ECF No. 56, p. 7.) Although some Atanasoff subjects did have MRI evidence of shoulder dysfunction, that study purported to link vaccination and injury on the very basis that the lack of prior shoulder symptoms along with the rapid onset of post-vaccination pain allowed for the suspicion of an immune-mediated inflammatory state that provoked the symptoms. (Atanasoff et al., *supra,* at Ex. 20, p. 8051.) The Atanasoff authors stressed that there is no diagnostic test available to assess whether shoulder dysfunction is vaccine-caused, leaving only this type of clinical qualification to aid in identifying post-vaccination shoulder injuries as a distinct entity. (*Id*. at 8052.)

Significant then is the fact of Dr. Srikumaran's further reliance on a large-scale study by Hesse et al., examining the *risk* of post-vaccination subdeltoid bursitis.[20] Instead of examining the characteristics of a population already clinically suspicious for vaccine-caused injury, this study scoured health encounter data of nearly three million people who received the 2016-2017 season flu vaccine and searched for incidences of subdeltoid bursitis diagnosed within 180 days of the administration of the vaccine.[21] (Ex. 27, p. 253.) The authors ultimately concluded that they "identified a small risk for subdeltoid bursitis with new symptom onset after injection of an influenza vaccine. This study provides epidemiologic evidence of an association that was previously supported by clinical evidence from case reports."[22] (*Id*. at 259.)

Taken together, the literature filed in this case supports the theory that the flu vaccine can cause bursitis which in turn can aggravate pre-existing shoulder dysfunction as initially posited by Atanasoff et al. based on clinical suspicion. Specifically, the Atanasoff authors explained that:

> In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions including

[20] Significantly, petitioner had a subacromial bursectomy whereas this article cites subdeltoid bursitis. However, the authors explain that they used the term "subdeltoid bursitis" to refer to both subdeltoid and subacromial bursitis. (Hesse et al., *supra,* at Ex. 27, p. 253.) Bodor and Montalvo explained that the two bursa are contiguous and that injection into the subdeltoid bursa can cause an inflammatory response extending into the subacromial bursa. (Bodor & Montalvo, *supra,* at Ex. 22, p. 586.)

[21] This study also excluded subjects that had prior shoulder dysfunction (Ex. 27, p. 255); however, it is the design of the study, and its ability to detect risk, that is key.

[22] The authors also note that the Institute of Medicine previously concluded that "the evidence convincingly supports a causal relationship between the injection of a vaccine and deltoid bursitis." (Hesse et al., *supra*, at Ex. 27, p. 253.) The Institute of Medicine (known as the National Academy of Medicine since 2015) is the medical arm of the National Academy of Sciences. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (*see* An Act to Incorporate the National Academy of Sciences, ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. When it enacted the Vaccine Act in 1986, Congress directed that the IOM conduct studies concerning potential causal relationships between vaccines and illnesses. *See* § 300aa–1 note.

> 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. Reilly et al reviewed a series of shoulder ultrasound 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.

(Atanasoff et al., *supra* at Ex. 20, p. 8051.) This is further supported by the Bodor and Montalvo case studies that specifically concluded that injection into the subdeltoid bursa likely caused "a robust local immune and inflammatory response" and that "[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, this led to a subacromial bursitis, bicipital tenonitis, and inflammation of the shoulder capsule." (Bodor & Montalvo, *supra,* at Ex. 22, p. 586.) In that regard, the SIRVA medical literature as a whole also finds significance in the presence of bursitis among these subjects. (Atanasoff et al., *supra,* at Ex. 20; Arias et al., *supra,* at Ex. 21; Bodor & Montalvo, *supra,* at Ex. 22; Hesse et al., *supra,* at Ex. 26; Hesse et al., *supra,* at Ex. 27.)

The absence of pre-existing shoulder dysfunction among study subjects was critical to initially uncovering this phenomenon for the reasons discussed by the Atanasoff authors, but with subsequent study confirming an epidemiologic risk of post-vaccinal bursitis, there is no obvious reason why someone with known prior shoulder dysfunction would not also be at the same risk and potentially affected by the same inflammatory process. Nor has Dr. Bishop specifically offered any such opinion. Dr. Bishop opined on behalf of respondent that petitioner's own clinical history is not compatible with a vaccine-related injury. She offers no opinion rebutting Dr. Srikumaran's theory that the flu vaccine can in general cause a significant aggravation of a pre-existing shoulder condition via bursitis.

v. Logical sequence of cause and effect connecting the vaccination and significant aggravation (*Loving* prong five/*Althen* prong two)

The second *Althen* prong/fifth *Loving* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu ex re. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375–77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant v. Sec'y of Health & Human Servs.,* 956 F.2d 1144, at 1148 (Fed. Cir. 1992). However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. §300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y*

of Health & Human Servs., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

Multiple treating physicians attributed petitioner's shoulder pain to his October 26, 2016 vaccination. On October 31, 2016, Dr. Nowosielski noted "musculoskeletal pain after flu vaccination. History indicates sudden onset with likely or irritation of the nerve." (Ex. 7, p. 3.) Dr. Nowosielski further noted a "vaccine[] adverse reaction" under the same section. (*Id.*) On November 9, 2016, Dr. Rosen noted that petitioner "flared up after a flu shot, [n]ow some high sharp pain." (Ex. 6, p. 11.) On November 28, 2016 PA Shakespeare likewise noted in the history of present illness that "[h]e has had ongoing pain for quite some time but recently had a flu shot a month ago and had significant increase in his pain." (Ex. 5, p. 21.) On April 25, 2017, June 6, 2017, and June 21, 2017, petitioner presented to Dr. Pervaiz who noted in the history of present illness—"[h]e had a vaccination into the left shoulder in October of last year which aggravated his left shoulder pain." (Ex. 5, pp. 2, 6, 9.)

Respondent argues that the comments of petitioner's treating physicians largely memorialize petitioner's subjective assessment of his own injury. (ECF No. 55, pp. 12-13.) Alternatively, respondent asserts that these comments reflect the waxing and waning nature of petitioner's chronic shoulder pathology. (*Id.*) While the records from Dr. Nowosielski, Dr. Rosen, PA Shakespeare, and Dr. Pervaiz may include subjective reports from petitioner, I am not persuaded by respondent's suggestion that they also lack considered medical judgment on the part of the treating physicians. For example, in taking petitioner's report of post-vaccination pain, Dr. Nowosielski was careful to note petitioner's prior history of bilateral shoulder dysfunction. (Ex. 7, p. 2.) She also confirmed his report of decreased range of motion by physical examination. (*Id.*) Moreover, in assessing a vaccine adverse reaction, she contemplated both the musculoskeletal pain described by petitioner as well as the possibility of a neurologic etiology. (*Id*. at 3.) Dr. Rosen likewise recorded petitioner's history, but also completed a physical examination and included myalgia of the left shoulder "[status post] flu shot" within his impression. (Ex. 6, p. 11.) Dr. Rosen's assessment is particularly significant as he was the physician that had most recently treated petitioner's left shoulder just six weeks prior to vaccination. (*Id.* at 13.) Other physicians were silent as to whether petitioner's vaccination played any causal role in his presentation, but none contradicted these initial assessments. (Ex. 3, p. 38 (Dr. Garber); Ex. 5, pp. 17, 21 (Dr. Sydney).)

Nonetheless, respondent and Dr. Bishop contend that petitioner's clinical course is better explained by his chronic degenerative conditions. (ECF No. 55, pp. 12-13; Ex. A, pp. 10-11.) Dr. Bishop opines that "[t]here is overwhelming evidence that the final state of [petitioner's] left shoulder, described at the time of his surgery, was pre-existing and dated back to the 1980's, which means he had 40 years of issues with his left shoulder prior to his vaccination." (Ex. A, p. 8.) Thus, Dr. Bishop opines that most of the pathology addressed during petitioner's surgery was ultimately unrelated to his vaccination. (*Id*. at 8-9.) She further opines that "the natural course of the pathology in [petitioner's] shoulder was [progressive,] and surgical intervention was the reasonable conclusion to address this pathology, regardless of the vaccination." (*Id*. at 11.)

There is no question that petitioner had substantial prior shoulder dysfunction as Dr. Bishop explains. As discussed above, however, petitioner is not obligated to prove his condition is worse than his expected outcome. *Sharpe*, 964 F.3d at 1081-82. Additionally, petitioner is not obligated to prove that his vaccination was the sole or predominant cause of his injury. *Shyface*, 165 F.3d at 1352. Dr. Srikumaran is persuasive in opining, with support from the medical records, that petitioner's vaccination was a but-for cause and substantial contributing factor leading to a significant aggravation of his pre-existing shoulder dysfunction via the bursitis demonstrated within petitioner's surgical report.

Given the extent of petitioner's pre-existing chronic degeneration, this represents a close case.[23] Dr. Bishop's competing interpretation of petitioner's history, though ultimately less persuasive, is also plausible. However, petitioner's history contains none of the confounding factual issues from the post-vaccination period that sometimes hinder or defeat SIRVA or SIRVA-like claims (*e.g.*, petitioner did not delay in seeking treatment and did not waver in placing onset at the time of vaccination when speaking with his physicians). Even with pre-existing shoulder dysfunction, petitioner's history is indicative of a logical sequence of cause and effect supportive of vaccine-causation for all the reasons discussed by Dr. Srikumaran and reflected in petitioner's contemporaneous medical records.[24]

vi. Proximate temporal relationship between vaccination and significant aggravation (*Loving* prong six/*Althen* prong three)

The third *Althen* prong/sixth *Loving* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Petitioner stresses that the Atanasoff and Arias articles support the notion that the strong immune mediated inflammatory reaction occurs in most, but not all patients

[23] "The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal 'compensation program' under which awards are to be 'made to vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Knudsen v. Sec'y of Health & Human Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994) (quoting H.R.Rep. No. 99–908, 99th Cong., 2d Sess. 18, *reprinted in* 1986 U.S.C.C.A.N. 6344). Accordingly, the Federal Circuit has suggested that this program represents a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280. I do stress that there is preponderant evidence supporting petitioners' claim. However, I also note that the outcome in this case is consistent with the Federal Circuit's guidance regarding the generous and remedial nature of this program.

[24] In fact, as explained above, respondent's only defense against petitioner's Table SIRVA claim is his pre-existing shoulder dysfunction with no argument advanced regarding the remaining three QAI criteria. Obviously, this is not controlling in a cause-in-fact context, but it illustrates that petitioner's medical history during the post-vaccination period likely would have been suspicious for vaccine-causation (even to respondent) but for the fact of his prior condition.

within 48 hours. (ECF No. 56, p. 11.; Atanasoff et al., *supra,* at Ex. 20; Arias et al., *supra,* at Ex. 21.) A 48-hour onset under *Althen* prong three has been accepted in other cause-in-fact shoulder injury claims. *See, e.g.*, *A.P.*, 2022 WL 2757857; *L.J.*, 2021 WL 6845593; *Tenneson,* 2018 WL 3083140.

Respondent does not argue in favor of any other understanding of what would constitute a medically acceptable timeframe. Respondent argues only that petitioner has not presented sufficient evidence to show that "any significant aggravation occurred within a medically-acceptable timeframe following vaccination." (ECF No. 55, p. 14.) Specifically, respondent argues that petitioner experienced "roughly the same levels of waxing and waning pain both before and after vaccination." (*Id.*)

As explained above, petitioner began presenting for treatment of his post-vaccination shoulder pain only five days after vaccination. At that time, and consistently thereafter, he placed onset of his increased shoulder pain at or about the time of vaccination. (Ex. 7; Ex. 6, p. 11; Ex. 5, pp. 9, 17, 21; Ex. 3, p. 38; Ex. 8; Ex. 17.) When he first presented for care, he described "a sudden onset of pain with the injection" and described having pain "ever since" receiving the vaccination. (Ex. 7, pp. 1-2.) There is preponderant evidence that petitioner's significantly aggravated shoulder pain began within a medically-acceptable period following vaccination such that causation can be inferred.

VII. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this Program, I find by preponderant evidence that petitioner suffered a significant aggravation of his pre-existing left shoulder injury caused-in-fact by his October 26, 2016 flu vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master