In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1736V
Filed: February 24, 2023
PUBLISHED

JOYCE GRUSZKA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration (SIRVA); Influenza (Flu) Vaccine; Dismissal

Michael G. McLaren, Black McLaren et al., PC, Memphis, TN, for petitioner.
Christine Becer, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On November 8, 2018, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that as a result of her August 18, 2017, influenza vaccination, she suffered a left Shoulder Injury Related to Vaccine Administration ("SIRVA"). (ECF No. 1.) Respondent recommended that compensation be denied, arguing, *inter alia*, that there is not preponderant evidence that petitioner's shoulder pain began within a timeframe that would support a finding of vaccine causation, namely 48 hours. (ECF No. 21.) In a prior Finding of Fact, I concluded that there is not preponderant evidence that petitioner suffered onset of new or significantly aggravated left shoulder pain within 48 hours of her August 18, 2017, flu vaccination. (ECF No. 62.) For the reasons discussed below, I now further conclude that petitioner is not entitled to compensation.

[1] Because this finding of fact 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 (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document 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 (2018).

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 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 vaccination. § 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 her 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 show 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 show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *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 her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278; § 300aa-13(a)(1)(B).

Additionally, in some cases a petitioner may allege that the vaccine at issue "significantly aggravated" a pre-existing condition. The Vaccine Act defines a significant aggravation as any change for the worse in a pre-existing 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, the petitioner must establish the three *Althen* prongs along with three additional factors described in the prior *Loving* case. *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

Petitioner filed her petition on November 8, 2018. (ECF No. 1.) This case was initially assigned to the Court's Special Processing Unit ("SPU") on November 9, 2018. (ECF No. 4.) On November 12, 2018, petitioner filed an affidavit, medical records, and a statement of completion. (ECF Nos. 6, 7.) Subsequently, petitioner filed additional medical records and her second affidavit. (ECF Nos. 10, 11, 13.) On November 30, 2019, respondent filed his Rule 4 report, recommending that entitlement be denied in this case. (ECF No. 21.) Respondent raised the issue that "the record does not establish that petitioner suffered SIRVA from a vaccination within forty-eight hours and she had significant underlying chronic shoulder issues[.]" (*Id*. at 5.) Specifically, respondent noted that petitioner's treating physicians had identified advanced osteoarthritis of the affected shoulder and petitioner had reported on multiple occasions during her treatment that she had a prior history of left shoulder pain from 2015. (*Id*. at 4.) On December 10, 2019, this case was removed from the SPU and reassigned to my docket. (ECF No. 23.)

A fact hearing was held on October 6, 2021, and I subsequently issued a Finding of Fact regarding onset of petitioner's alleged shoulder pain on July 7, 2022. (ECF Nos. 58, 62; *see also Gruszka v. Sec'y of Health & Human Servs.,* No. 18-1736V, 2022 WL 3024777 (Fed. Cl. Spec. Mstr. July 7, 2022).) The procedural history leading up to that Finding of Fact is discussed in the Finding of Fact itself. (ECF No. 62, pp. 2-3.) After reviewing the record as a whole, the Finding of Fact concluded that

> [T]he evidence preponderates in favor of a finding that petitioner experienced prior episodes of left shoulder pain and also experienced a gradual onset of similar left shoulder pain with an indeterminate initial onset occurring sometime between late August and early October of 2017. However, there is not preponderant evidence that onset of left shoulder pain, whether new or aggravated, occurred within 48 hours of her August 18, 2017, vaccination.

(*Id*. at 24.)

Following issuance of the Finding of Fact a follow up status conference was held on August 24, 2022. (ECF No. 64.) During the call, petitioner's counsel argued that the Finding of Fact did not foreclose a causation-in-fact claim. Because the parties' experts had submitted their reports prior to the fact hearing and finding of fact, I afforded petitioner the opportunity to determine whether she would file a supplemental expert report accounting for the finding of fact. (*Id*.) However, I indicated that I felt an entitlement hearing to take expert testimony was unlikely to be necessary. (*Id*.)

On September 20, 2022, petitioner filed a status report confirming that "[p]etitioner believes that her expert's report adequately addresses the significance of whether it is material or not to have a sudden or gradual onset in this case. As such, she does not currently anticipate filing a supplemental report." (ECF No. 65.)

Subsequently, on October 21, 2022, I issued a Scheduling Order explaining that based on the prior status conference and subsequent status report the case is presumptively ripe for resolution on the existing record. I provided the parties a short period of time to raise any objection, but otherwise set a briefing schedule pursuant to Vaccine Rule 8(d). (NON-PDF Order 10/21/2022.) Petitioner filed a Motion for a Ruling on the Record on December 5, 2022. (ECF No. 67.) Respondent filed his response on January 4, 2023, and petitioner filed a reply on January 11, 2023. (ECF Nos. 68-69.)

In his response to petitioner's motion, respondent noted that petitioner's expert report from Dr. Srikumaran included language referencing significant aggravation even though petitioner's petition and motion relied on causation-in-fact under *Althen*. (ECF No. 68, p. 8.) Respondent addressed significant aggravation "for the sake of completeness." (*Id*. at 9.) In reply, petitioner states that "[r]espondent arguing against compensation because of significant aggravation issues is premature and not currently at issue before this Court." (ECF No. 63, p. 2.) Petitioner further states that "[t]his Motion [is] seeking a ruling on cause-in-fact (not significant aggravation) based on the current state of the record. Should this Court find Petitioner's record does not establish a pure cause-in-fact claim, Petitioner would still reserve the right to investigate and/or pursue a significant aggravation claim." (*Id*. at 3.)

On January 13, 2023, I issued a scheduling order requiring petitioner to pursue any significant aggravation claim in advance of my entitlement determination or the claim would be waived. (ECF No. 70 (citing Vaccine Rules 8(d) and 8(f)).) Petitioner subsequently filed an amended petition including a significant aggravation claim and a supplemental brief in support of that claim. (ECF Nos. 72-73.) Respondent subsequently filed a status report confirming he would rely on his prior motion response and not provide any further response to petitioner's supplemental filings. (ECF No. 74.) On February 15, 2023, I issued a follow up order confirming that the case is once again ripe for resolution and that a ruling on petitioner's pending motion and supplemental filings would be issued. (NON-PDF Order 2/15/2023.)

In light of the above, I conclude that the parties have had a full and fair opportunity to develop the record of this case and that the case is ripe for resolution on the existing record.[3] No additional evidence was filed subsequent to the July 7, 2022 Finding of Fact. Accordingly, Sections III and IV, below, including recitation of both the

[3] Special masters "must determine that the record is comprehensive and fully developed before ruling on the record." *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012); *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993.)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2). The parties must have a full and fair opportunity to present their case and develop a record sufficient for review. *Id*.

medical records and witness testimony, are repeated verbatim from the Finding of Fact. However, the discussion of the expert reports contained in Section V is more extensive than what was contained in the Finding of Fact. The Finding of Fact addressed the expert reports only to the extent their medical expertise helped inform the factual question at issue. In this decision, the expert reports are assessed in whole, including consideration of both the experts' assessment of the medical records and their ultimate causal opinions.

III. Factual History

a. Medical Records

i. Pre-vaccination records

Petitioner's prior medical history is significant for bilateral knee pain, right foot / ankle pain, osteoarthritis, and ankylosing spondylitis. (Ex. 6, pp. 56-75, 91-149; Ex. 9, pp. 72-74, 76-77; Ex. 21, p. 11.) On October 21, 2015, petitioner presented to Gregory Kirwan, D.O., at Premier Orthopaedic & Sports Medicine Group ("Premier Ortho"), for a right foot assessment. (Ex. 5, p. 1.) Petitioner's past surgical history included carpal tunnel release. (*Id.*) Petitioner was assessed with right foot pain, right ankle pain, cellulitis in her right lower extremity, and rheumatoid arthritis in her foot. (*Id.* at 4-5.)

On March 27, 2017, petitioner presented to Mariclaire Schultz, D.C. for an initial exam. (Ex. 3, p. 1.) In her initial findings Dr. Schultz noted posterior right knee pain in extension, cervical instability with a prior cervical fracture, and bilateral ankle swelling. (*Id.*) There was no mention of shoulder or arm pain. (*See id.*) However, on physical examination, petitioner showed reduced range of motion in her shoulders bilaterally, and in her cervical and thoraco-lumbar regions. (*Id.* at 2.) Subsequently petitioner returned to Dr. Schultz for additional adjustments on April 3, April 10, June 5, July 18, and August 7, 2017. (*See id.* at 2-3.)

On May 22, 2017, petitioner presented to Michael S. Rosen, M.D., complaining of ongoing paresthesia in her legs, left greater than right. (Ex. 6, p. 46.) She reported a history of diabetes. (*Id.*) Dr. Rosen observed that her ankylosing spondylitis was otherwise well managed. (*Id.*) He ordered an ultrasound to rule out a Baker's cyst and ordered petitioner to return in 6 weeks. (*Id.* at 47.)

On June 7, 2017, petitioner underwent an EMG evaluation, complaining of burning pain in her calves. (Ex. 6, p. 41.) Extensive EMG evaluations were completed in the muscles of both lower extremities, innervated by lumbar nerve roots L2 through S2. (*Id.*) Daniel Kane, M.D., indicated that the electrodiagnostic testing in conjunction with petitioner's history and physical exam revealed "electrical evidence of a very mild generalized peripheral neuropathy." (*Id.* at 41-42.) He further noted that this condition was both demyelinating and axonopathic, affecting both petitioner's motor and sensory nerves. (*Id.* at 42.) However, Dr. Kane observed that "[t]here is really not a lot of evidence to suggest a significant lumbar radiculopathy" and while there were some

reinnervation potentiate noted throughout her legs, he concluded that the results were "really not too bad for patients 74 years old [*sic*]." (*Id.*) There was no evidence of lumbosacral plexopathy nor myopathy contributing to petitioner's symptoms. (*Id.*)

On July 28, 2017, petitioner presented to Nicholas Giuliani, M.D., for a follow-up visit, with no pain or stiffness, and no further paresthesia in her right leg. (Ex. 6, p. 38.) On examination Dr. Giuliani noted no synovitis, and no change in range of motion in petitioner's lumbar spine. (*Id.* at 39.) Petitioner's routine labs were normal, and she was ordered to return in four months. (*Id.* at 39-40.)

ii. Vaccination and post-vaccination records

Petitioner received an influenza vaccination in her left arm / deltoid on August 18, 2017. (Ex. 2, p. 4.) On August 22, 2017, petitioner presented to Richard Ziegler, M.D., at Premier Ortho for chronic right foot pain. (Ex. 9, pp. 28-29.) In addition to right foot pain, petitioner complained of decreased mobility, difficulty sleeping, joint tenderness, limping, night pain, swelling, and weakness. (*Id.* at 28.) Dr. Ziegler noted that petitioner was previously seen for her right foot on 10/21/15 with Dr. Kirwan. (*Id.*) Petitioner also mentioned that she saw Dr. Rosen for treatment of her arthritis. (*Id.*) There was no mention of left shoulder pain. (*Id.* at 28-29.)

On August 31, 2017, petitioner returned to Premier Ortho to Spencer Monaco, DPM, for right ankle pain. (Ex. 5, p. 14-19.) Dr. Monaco reviewed her right foot MRI and assessed petitioner with a mild ankle varus deformity. (*Id.* at 18-19.) There was no mention of shoulder pain. (*Id.* at 17-22.) Petitioner returned to Dr. Monaco again on September 28, 2017, complaining of right foot pain. (*Id.* at 20-23.) Dr. Monaco recommended an ankle brace and noted that petitioner was doing well with nonsurgical treatment. (*Id.*) Still, there was no mention of shoulder pain. (*Id.* at 23-26.)

On October 5, 2017, petitioner returned to Dr. Schultz complaining of left shoulder discomfort. (Ex. 3, p. 3.) Petitioner "[r]eported just receiving flu shot in left arm a few weeks ago (8/18/17)." (*Id.*) Dr. Schultz noted decreased range of motion to flexion, extension, hyperabduction, adduction, internal rotation, external rotation. (*Id.*) No shoulder range of motion measurements were provided. (*Id.*) Dr. Schultz performed a deep tissue massage on petitioner's left shoulder and adjusted her proximal humerus and superior / lateral scapula. (*Id.*) On November 2, 2017, petitioner returned to Dr. Schultz still experiencing pain in her shoulder. (*Id.* at 4.) Dr. Schultz repeated the same adjustments on petitioner's left shoulder. (*Id.*)

On November 28, 2017, petitioner returned to Dr. Rosen complaining of bilateral knee pain and "left shoulder pain for the past 2 months with abduction." (Ex. 6, p. 35.) Dr. Rosen further remarked that petitioner was "doing better taking the Remicade every 4 weeks instead of every 5 weeks. She has ankylosing spondylitis along with osteoarthritis." (*Id.*) On physical examination, Dr. Rosen observed "[h]er upper and lower extremities reveal no loss of strength or motion. [Range of motion] is full." (*Id.* at 36.) Furthermore, he observed crepitation of the knees bilaterally and impingement in

the left shoulder, with abduction at 160 degrees. (*Id.*) Petitioner's updated diagnoses included ankylosing spondylitis of multiple sites in the spine and primary generalized osteoarthritis. (*Id.*) Dr. Rosen ordered x-rays of the left shoulder and physical therapy, noting that if her pain continued, he planned to inject the left shoulder with steroids. (*Id.*)

On December 6, 2017, petitioner presented to Jonathan Mayer, PT, DPT, at Excel Physical Therapy. (Ex. 4, pp. 5-17.) She presented with left shoulder pain, mostly in the lateral deltoid region and worse when raising her arm overhead, reaching in overhead cabinets, reaching behind back for dressing, bathing, groom, and lifting/carrying. (*Id.* at 13.) She described her pain as a dull ache, rated at 3/10 at best and 8/10 at worst. (*Id.*) Petitioner's pain "began back in August and came on gradually." (*Id.*) Mr. Mayer further indicated that she had "a similar pain in the past about 5 years ago of [left] shoulder that responded very well with physical therapy." (*Id.*) On examination, petitioner's impingement, Empty Can, Hawkin's – Kennedy, Neers, painful arc, and infraspinatus tests were positive. (*Id.* at 14.) Mr. Mayer assessed petitioner with rotator cuff tendinitis and degenerative changes. (*Id.* at 16.) She completed ten physical therapy sessions.[4] (Ex. 4.)

On December 7, 2017, petitioner underwent x-rays of her left shoulder which revealed no fractures or dislocations, a large osteophyte overlying the inferior portion of the humeral head; degenerative changes and subchondral cysts in the region of the ureter and lesser tubercle; mild cortical irregularity overlying the lesser tubercle; no abnormal soft tissue calcifications; and mild degenerative changes in the acromioclavicular joint. (Ex. 6, p. 14.)

On December 11, 2017, petitioner presented to Dr. Schultz for a deep tissue massage and left shoulder adjustment. (Ex. 3, p. 4.) Petitioner complained of shoulder pain on passive range of motion, especially in flexion at 80 degrees and hyperabduction at 80 degrees. (*Id.*) She noted that she could not put dishes away overhead. (*Id.*) Dr. Schultz further noted "[c]urious is there a correlation between flu shot and pain / [decreased range of motion]."[5] (*Id.*)

On February 26, 2018, petitioner presented to a rheumatologist, Nicholas Giuliani, M.D. (Ex. 6, p. 10-12.) She reported that she had shoulder pain for about one year, and that PT had helped but she still had pain on abduction. (*Id.*) Petitioner described the pain as burning, and worse with movement, better with rest. (*Id.*) She also complained of right knee pain, and previous injections in both knees. (*Id.*) Dr.

[4] Petitioner's final treatment session was on January 11, 2018. (Ex. 4, pp. 57-64.) In her discharge summary Mr. Mayer noted that petitioner's "shoulder was feeling much better overall. Only slight discomfort when reaching for heavier items." (*Id.* at 62.) She demonstrated "great improvements of [left] shoulder ROM, strength, stability" and was discharged home with an independent home exercise program. (*Id.* at 64.)

[5] Subsequently, petitioner returned for 18 additional deep tissue and left shoulder adjustments between February 27, 2018, and May 14, 2019. (Ex. 3, pp. 4-9; Ex. 12.) By July 23, 2018, Dr. Schultz observed that petitioner "continues with shoulder exercises, but no real progress seen." (*Id.* at 8.) No mention of petitioner's vaccination is made in the records from the remaining visits. (*See* Ex. 3, Ex. 12.)

Giuliani remarked that her ankylosing spondylitis was otherwise doing well on Remicade. (*Id.*) On examination, petitioner had limited range of motion in the left shoulder with fluid in the joint. (*Id.*) The fluid was aspirated and showed rare white blood cells and crystals. (*Id.*) Petitioner was given a steroid injection. (*Id.*)

On June 4, 2018, petitioner returned to Dr. Rosen for a follow-up for left shoulder pain. (Ex. 6, pp. 2-4.) Petitioner had a transient response to the bursa steroid injection in her left shoulder, but the pain returned. (*Id.*) Dr. Rosen remarked that she had "known osteoarthritis of both joints" and physical therapy had not been very helpful. (*Id.*) On physical examination, petitioner could abduct the left shoulder to only 60 degrees. (*Id.*) Dr. Rosen noted that "[he] believe[d] the shoulder is significantly affected with osteoarthritis so a repair of the rotator cuff would not be practical" and referred her to Dr. Towsen for evaluation for a left total shoulder arthroplasty. (*Id.*) Dr. Rosen further observed petitioner's "ankylosing spondylitis is doing well with Remicade[.]" (*Id.*)

On June 18, 2018, petitioner presented to Adrienne Towsen, M.D., for a left shoulder evaluation. (Ex. 5, p. 24-28.) Petitioner described her symptoms as "chronic non-traumatic." (*Id.* at 24.) Dr. Towsen noted that petitioner "had an injection of the left shoulder in 2015 which gave her good relief and "she notes left shoulder pain for a few months." (*Id.*) Dr. Towsen's assessment was primary osteoarthritis of the left shoulder. (*Id.* at 28.) Her impression was that petitioner had:

> [v]ery advanced [degenerative joint disease] in her shoulder and her [range of motion] is limited. This is her non-dominant arm, but she is still very functionally limited with this arm. Her pain is constant. She did have an injection a few year[s] ago which helped her for a while. We discussed option[s] including TSA. I think she would be a great candidate for this. She has done PT in the past as well, which helped a little but I think it would only aggravate it now.

(*Id.*) Petitioner received an injection in her left shoulder and Dr. Towsen ordered her to follow-up as needed. (*Id.*)

On October 8, 2018, petitioner returned to Dr. Rosen complaining of chronic shoulder pain, reporting that she saw an orthopedic surgeon and "feels she needs a total shoulder arthroplasty." (Ex. 10, pp. 20-23.) In the plan portion Dr. Rosen noted no change to petitioner's treatment regimen. (*Id.*) Subsequently petitioner continued with anti-inflammatory drugs and Remicade for petitioner's ankylosing spondylitis through March 2019. (*Id.* at 5-15.)

On January 3, 2020, petitioner presented to Charles L. Getz, M.D., at Rothman Orthopaedics, complaining of shoulder pain of one week. (Ex. 21, p. 284.) Petitioner reported that she fell onto her left shoulder getting out of a car, resulting in a dislocation. (*Id.*) Dr. Getz observed that petitioner "has had a history of left shoulder problems for quite sometime and had an injection about five or six years ago." (*Id.*) Dr. Getz ordered and reviewed petitioner's x-rays showing a reduced shoulder joint and advanced

osteoarthritis / rheumatoid arthritis of the left shoulder. (*Id.*) On physical examination, Dr. Getz observed active forward flexion elevation on the left to 30 degrees, neutral external rotation, significant crepitation through range of motion, normal internal and external rotation strength testing, normal deltoid strength in the left shoulder, and decreased active and passive range of motion in the right shoulder. (*Id.*) Dr. Getz concluded that petitioner was a candidate for shoulder replacement "based on her preexisting arthritis." (Ex. 21, p. 284-85.)

On January 22, 2020, petitioner presented to rheumatologist Michael R. Lattanzio, M.D., for a follow-up visit. (Ex. 20, p. 7.) Dr. Lattanzio noted that petitioner fell and dislocated her shoulder and was told she needs a left total shoulder arthroplasty. (*Id.*) Petitioner deferred shoulder replacement at this point. (*Id.*) On physical examination, he observed no change in her range of motion of the spine. (*Id.* at 8.) Petitioner was ordered to return in four months for a follow-up. (*Id.*)

b. Letter and Testimony from Dr. Schultz

On May 1, 2020, petitioner filed an undated letter written by Dr. Mariclaire Schultz. (Ex. 17.) Dr. Schultz indicates that her treatment of petitioner began in March 2017. (*Id.* at 1.) During that time, she was treating petitioner for "typical age-related issues." (*Id.*) Dr. Schultz notes that "[o]n October 5, 2017's visit, [petitioner] complained of an acute pain in her left shoulder with marked decrease to her shoulder [range of motion] (induced pain at the end ROM especially in forward flexion and abduction near 75 degrees; she could reach 90 degrees with my assistance." (*Id.*) From that time forward Dr. Schultz began to adjust petitioner's left AC joint, encouraged ADL modification and recommended home/aquatic exercises. (*Id.*) According to Dr. Schultz, the onset was "sudden and did not follow the typical pathway of a normal, systemic degenerative disease." (*Id.* (emphasis in original.)) Dr. Schultz "grew pretty concerned upon hearing that [petitioner] had just received the [flu] shot, especially because it was done at a pharmacy." (*Id.*)

Dr. Schultz also testified at the fact-hearing regarding her records and petitioner's treatment. (Tr. at 57-92.) Dr. Schultz testified that in her first evaluation with petitioner on March 27, 2017, petitioner did not have any significant injuries to her left shoulder. (*Id.* at 61.) She testified that petitioner had "limitation bilaterally, both sides of the shoulder, that, to me, were age-related and pretty typical. It didn't put up a red flag for me." (*Id.*) Petitioner was not in active pain at that visit, though Dr. Schultz testified that petitioner "didn't have full range of motion, but she – it was pretty balanced on both her shoulder, but no pain." (*Id.* at 62.)

Dr. Schultz testified that petitioner discussed neck pain with her in her initial visit, on March 27, 2017, "but that was a history, just to clarify, cervical instability." (Tr. at 66.) Dr. Schultz explained that petitioner would have a sore neck if she slept incorrectly, but nothing alarming. (*Id.*) In her course of treatment, Dr. Schultz testified that she spends about 40 minutes on every patient and she "deal[s] with the primary problem that [they] come in for, if [they] have one, and then [she] work[s] through, from head to toe, every

single joint." (*Id.*) In every visit Dr. Schultz works through range of motion exercises on both sides, "[s]o even though I haven't written that down, that's my protocol for years and years." (*Id.* at 67.) Therefore, "if [she] had seen or felt or observed a change in [petitioner's] range of motion in her shoulders, [she] would have noted that." (*Id.*) Dr. Schultz confirmed that the lack of any notation indicates that petitioner was not complaining about shoulder problems. (*Id.*) On October 5, 2017, Dr. Schultz testified that petitioner presented with left shoulder discomfort, reporting that she had just received the flu shot in her left arm a few weeks prior. (Tr. at 68.) At that time "basically every single range of motion was impeded, and that's the first time I've ever experienced that with her." (*Id.*) Dr. Schultz did not recall having any discussions with petitioner at this visit, or her visit on November 2, 2017, about the administration of the vaccine. (*Id.* at 69-70.) In the November visit, Dr. Schultz testified "[m]aybe I thought, too, that, you know, it was age-related, that it was taking her a little bit longer to recover from it." (*Id.* at 70.) However, in the November visit she also observed that petitioner's active range of motion was between 80 and 90 degrees, which was "something she had never experienced before with me in any of her prior visits." (*Id.* at 71.) Dr. Schultz testified that this change was atypical, "when somebody would go through a typical degenerative process or an autoimmune disease, [her] experience over 24 years is that it's more of a progressive occurrence, especially with RA…[b]ut this was more this isn't getting better at all," she noted that "it's only on one side and it's extreme." (*Id.* at 74.)

In her letter Dr. Schultz noted that petitioner's diagnosis is frozen shoulder syndrome. (Tr. at 86; Ex. 17.) She testified that frozen shoulder syndrome is "when you can't get your arm into full range of motion in almost all ranges of motion, if not all." (Tr. at 86.) In contrast, she explained that "[b]ursitis and tendinitis ha[ve] more range of motion, per se, than a frozen shoulder would." (*Id.*) With a rotator cuff tear, Dr. Schultz opined that "an internal and external rotation will be the greatest deficit that you'll see." (*Id.*) However, she acknowledged that diagnosing a rotator cuff injury is difficult without an MRI. (*See id.*) Dr. Schultz never received or viewed MR images, and petitioner primarily provided verbal updates on her visits with her other doctors. (*Id.* at 87.)

On cross-examination, Dr. Schultz acknowledged that crepitus was not noted in petitioner's records until March 27, 2018. (Tr. at 89; *see* Ex. 3, p. 5.)) However, based on her recollection, Dr. Schultz testified that petitioner's crepitus began around November or December 2017. (Tr. at 89.) She also confirmed that throughout petitioner's treatment, she adjusted petitioner's neck for mechanical improvement. (*Id.* at 90.) Dr. Schultz described petitioner's onset of pain following vaccination as sudden. (Tr. at 82.) However, Dr. Schutlz could not recall petitioner's description of the onset of her shoulder pain. (Tr. at 91.) Regarding her October 2017 visit, Dr. Schultz testified that she "didn't write anything more specific as to, [] where exactly was she injected. We didn't have a discussion on that, just that it was painful afterwards and [] that's all I can recall." (*Id.*) Dr. Schultz further testified that petitioner distinguished the pain at the top of her shoulder versus the pain in her arm: "[t]he initial pain was more of a – like a muscle pain and the – as it advanced, it became more of a deeper pain, situated around the AC joint. So that's where all of my treatments were." (Tr. at 92.) Lastly, Dr. Schultz

opined that osteocytes can cause crepitus, however, it would present as a more gradual presentation. (*Id.* at 94.)

c. Petitioner's Affidavits and Testimony

Petitioner filed her first affidavit on November 12, 2018. (Ex. 1.) Prior to receiving her flu vaccination on August 18, 2017, petitioner avers that she never had any pain or loss of range of motion in her left shoulder, nor had she suffered any significant injuries or trauma to her left arm / shoulder "similar to the persistent pain [she] experienced after this vaccination." (*Id.* at 1-2.) Petitioner contends that the pain began "Immediately, within 48 hours, in [her] muscle after injection." (*Id.* at 2.) Over the next several days, petitioner described pain that "moved from [her] muscle(s) into [her] arm and shoulder with noticeable reductions of range in motion with certain activities." (*Id.*)

Petitioner filed her second affidavit on May 3, 2019. (Ex. 11.) She avers that the prior pain mentioned by her physical therapist in records from December 6, 2017, referred to "neck pain that [she] experienced in 2015." (*Id.* at 1.) Petitioner further avers that she underwent physical therapy for that pain, which helped. (*Id.*) The pain she felt in 2015 in her neck was "very different from the pain in [her] arm/shoulder now, which is in [her] upper arm area." (*Id.*) Petitioner states that she received an injection in 2015 for neck stiffness, which was "not related to shoulder pain at all." (*Id.*) She describes difficulty turning her head from side to side at the time she received the injection in 2015. (*Id.*) Petitioner also underwent physical therapy beginning in December 2017 that was not helpful. (Ex. 11, p. 2.) In the summer of 2017, petitioner avers that she presented to an orthopedic specializing in foot and ankle issues for a torn ligament. (*Id.*) Though she may have mentioned her shoulder at those visits, petitioner stresses that the primary reason for going was for the torn ligament. (*Id.*)

Petitioner filed her third affidavit on January 16, 2020. (Ex. 15.) Petitioner additionally avers that she has arthritis in several joints, and from time to time they flare up, though the pain subsides. (*Id.* at 1-2.) In contrast, her shoulder pain has never subsided, but increased. (*Id.*) Regarding the inconsistencies in her medical records, petitioner explains that when she saw her doctors, especially early on, she had not come to realize that her vaccination was the likely cause of her pain and in her visits, she gave an "approximate time frame" for the onset of her shoulder pain. (*Id.* at 2.) Looking back, she avers that "the injection site was unusually high on [her] arm." (*Id.*) Petitioner describes constant, daily, pain and struggles with activities of daily living. (*Id.* at 2-3.)

During the hearing, petitioner testified that she was in good health in August of 2017. (Tr. at 11.) She has had arthritis for approximately 20 years, and she "can go weeks, months" without any pain, but suffers occasional flare-ups, in particular, in her right knee. (*Id.* at 12.) Petitioner also had a prior history of neck pain—"it was pain upon turning my head sideways[.]" (Tr. at 17-18.) She testified that she would often wake up with neck pain and used a special pillow to help while sleeping. (*Id.*) The references in her medical records to shoulder pain in 2015, treated with an injection,

referred to injections she received "in the back along the shoulder" for her neck pain. (*Id.* (*see* Ex. 5, p. 28.)) She testified that she did not have any shoulder pain prior to the vaccination at issue. (*Id.* at 18-19.) Petitioner also receives Remicade infusions every four weeks to treat her ankylosing spondylitis. (*Id.* at 19.) Most recently, petitioner testified that she underwent back surgery on May 4th, 2021, to treat the degeneration of discs in her back and the nerves that were being impinged upon—which was causing pain in the back of her legs from her hips down to her knees. (*Id.* at 12-13.)

Regarding onset, petitioner testified that her pain and dysfunction began "within a couple of days after the vaccine." (Tr. at 14-15.) She described "[t]he soreness after the vaccination would be a tenderness…[b]ut after a couple of days that you figure you shouldn't feel that anymore if you go to use that arm, and it's a different type of pain. It's not the soreness – or tenderness would be a better word. It's painful." (*Id.* at 16.) Unlike her neck pain, petitioner testified that "[t]he shoulder pain or the arm pain that I've had since the vaccination comes from the top of my arm down to my elbow. I call it arm pain; some people might call it shoulder pain." (*Id.* at 20.) At her first visit post-vaccination, on August 22, 2017, petitioner testified that she presented to her podiatrist for foot pain after a heavy weight fell on her foot. (Tr. at 21-22 (*see* Ex. 9, pp. 28-29)) At the time she was suffering shoulder pain, although she did not discuss it with her doctor because it was not his expertise. (Tr. at 23.) On October 5, 2017, petitioner complained of left shoulder pain to her chiropractor, Dr. Shultz. (*Id.* at 23-24 (*see* Ex. 3, p. 3.)) She waited approximately five to six weeks because she "thought it would go away" and didn't realize "that it was pain from the vaccine, it was just something that I thought would go away." (Tr. at 24.) Petitioner testified, though, that she associated the pain in her shoulder with the flu shot "within a few days" or "after like 24 hours [when] it didn't feel any better, it didn't go away." (*Id.*)

Petitioner testified that she has degenerative changes in her shoulder(s) and was referred to physical therapy. (Tr. at 26.) The physical therapist performed manipulations on petitioner's arm in addition to home exercises. (*Id.*) She described the physical therapy as "[n]ot very good." (*Id.*) Petitioner's medical record from December 6, 2017, indicates that her shoulder pain "began back in August and came on gradually." (*Id.* at 27 (citing Ex. 4, p. 13.)) She testified during the hearing that she described the onset as gradual "because in the fact that the pain was there, but gradually as [she] tried to do different things, then [she] realized the limitations." (*Id.*) Regarding the note indicating that she suffered "similar pain in the past about five years ago," petitioner testified that the pain she was experiencing was in her neck. (*Id.* at 28 (*see* Ex. 4, p. 13.)) When talking about her pain with medical providers, petitioner testified that when she discussed pain from the vaccination, it was in her lower arm, from the shoulder down (gesturing to the bicep), whereas oftentimes she referred to shoulder pain or preexisting shoulder pain in the top of her shoulder, it was through the neck (gesturing along the clavicle). (*Id.* at 28-29.)

A record from February 26, 2018, indicates that petitioner suffered left shoulder pain for about one year, or approximately February 2017. (Tr. at 32-33 (*see* Ex. 6, pp. 10-12.)) Petitioner testified that she was "not sure why it would say that. Possibly when

I was giving that information, I was – my timeline was off." (Tr. at 33.) She also testified that it may have had something to do "with the fact that there was a calendar year change[.]" (*Id.*) The primary reason for that visit was for her knee(s), petitioner testified. (*Id.*) When reporting to a specialist, petitioner typically discussed "[w]hatever the body part is that [she's] there to talk about." (Tr. at 36.) She described going to a doctor for the first time, "you've got paperwork to fill out before he even sees you. That's when you can put down everything that is a health issue. But then when you go to see him….you only get to talk about the part that's actually bothering you or hurting, whatever is wrong." (Tr. at 36.)

On cross-examination, petitioner testified that the reference to "shoulder pain for the past 2 months" in Dr. Rosen's report on November 28, 2017, did not refer to the pain in her shoulder post-vaccination. (Tr. at 45-46.) That reference to shoulder pain, according to petitioner, was pain located in the "top and back part of [her] shoulder" and closer to her neck. (*Id.* at 46-47.) She explained that what "[Dr. Rosen's] referring to here is the ankylosing spondylitis is in the spine but it also progresses out to the shoulder area." (*Id.* at 47.) This pain, she testified, was also separate from the neck pain she experienced in 2015. (*Id.*) She maintained that the pain caused by her influenza vaccination was in her upper arm. (*Id.* at 47-48.) Later petitioner returned to Dr. Rosen, on June 4th, 2018, who noted that petitioner had osteoarthritis in her shoulder. (*Id.* at 48 (*see* Ex. 6, p. 3.)) Petitioner testified that she had osteoarthritis in her right shoulder, but not the left shoulder. (Tr. at 48.) She further testified that her treating doctor(s) recommended total shoulder replacement in her left shoulder, but only after she dislocated her shoulder after a fall in 2019. (Tr. at 26-27, 48-49; *but see* Ex. 6, p. 3 (recommending left total shoulder arthroplasty on 6/4/2018).)

When I asked petitioner why she discussed her prior episode of shoulder / neck pain from 2015 – in the context of her post-vaccination shoulder pain – she testified that "it's two totally different things, two totally different areas, and two totally different pains." (Tr. at 54.) Again, when I asked petitioner, why then, she discussed the 2015 injury if it was distinct, she testified that she "[didn't] recall doing that," but suggested that Dr. Rosen "would have notes in his chart – in my chart that would be sent to him from other doctors." (*Id.*) Lastly, she testified that, in her discussions with Dr. Schultz, petitioner told her "about the pain and where it was and then telling [*sic*] her about the flu shot and she then concurred that that was a possibility that that's the reason why I was still having the pain." (*Id.* at 55.)

IV. Witness Statements and Testimony

a. Joesph Gruszka

On January 16, 2020, petitioner filed a statement from her son, Joe Gruszka. (Ex. 13.) Mr. Gruszka indicated that he resides with petitioner, as well as his wife and two children. (*Id.*) He recalls petitioner telling him "right after she received the shot how much it bothered her and that it was more painful then what she remembered from

previous years." (*Id.*) Mr. Gruszka describes petitioner's difficulty performing daily functions, including cleaning, dressing, and cooking. (*Id.*)

Mr. Gruszka also testified during the fact hearing. (Tr. at 97-116.) He testified that petitioner had prior issues with her neck and recalled her receiving trigger point injections for her discomfort. (Tr. at 101.) Mr. Gruszka indicated that petitioner had no prior injuries or previous left shoulder problems prior to the vaccination at issue. (*Id.* at 102.) He testified that after petitioner's vaccination, he observed that the injection site was higher than normal, remarking that the Band-aid was higher up on petitioner's arm as compared to his own vaccination he received a few months later. (*Id.* at 102-03.) Mr. Gruszka observed petitioner's decreased range of motion and recalled pinning petitioner's shirt up because her shoulder was drooping. (*Id.* at 104.) He testified that petitioner's onset of shoulder pain was "pretty sudden," meaning that he "notic[ed] it within, [] a week to, you know, also that she couldn't do a lot of the chores, menial tasks." (*Id.*)

Mr. Gruszka additionally testified that he transported petitioner to some of her appointments. (Tr. at 98, 105.) He recalled that during petitioner's appointments with Dr. Rosen, for complaints involving her foot, petitioner "sa[id] something about her shoulder and the vaccine and he didn't want to discuss that. He was interested in the foot at that time." (*Id.*) Mr. Gruszka testified that, based on his daily observations, petitioner's left shoulder problems began "[l]ike the end of August of 2017." (*Id.* at 108.) Regarding his written statement, Mr. Gruszka testified that by "*right after* the shot" he meant that "in the week or two following, [he] noticed that those things were beginning to take effect." (*Id.* at 110.)

b. Cynthia Kuklinski

On January 16, 2020, petitioner also filed a statement from her daughter, Cynthia Kuklinski. (Ex. 14.) Ms. Kuklinski indicated that "[t]he pain in [petitioner's] arm started instantly, and she lost full use of her arm." (*Id.*) She states that petitioner's pain and limited use did not subside. (*Id.*) She also describes petitioner's limitations which include (1) unable to reach her left arm higher than her wrist, (2) dressing herself is uncomfortable with limited use of her arm, (3) difficulty bathing herself without full use of both arms (4) unable to use a brush and hair dryer at the same time (5) can't put on and take off a necklace and (6) unable to use a drive-thru bank or restaurant since she can't accept items with her left arm through the window. (*Id.*) According to Ms. Kuklinski, petitioner's pain and limited use of her left arm "all started with a flu vaccine." (*Id.*)

Ms. Kuklinski also testified during the fact hearing regarding petitioner's shoulder dysfunction. (Tr. 120-132.) She testified that petitioner complained of soreness in her arm the day of her influenza vaccination, August 18, 2017, or "[i]f not, it was the very next day." (*Id.* at 120.) Ms. Kuklinski recalled that petitioner "felt like [the vaccine] was administered like higher up on the arm than she had remembered in the past." (*Id.* at 121.) She testified that in the years prior to vaccination, petitioner had no left shoulder problems. (*Id.*) Ms. Kuklinski also testified that she speaks with petitioner

every week, sometimes a couple times a week. (*Id.*) Petitioner's pain, she testified, did not subside with icing; and petitioner complained of pain that was unlike the initial soreness of the vaccination. (*Id.* at 123.) Despite the fact that petitioner had several doctors' appointments in the first month to two months post-vaccination where she specifically did not mention shoulder pain to her medical providers, Ms. Kuklinski testified that petitioner was in pain during that time. (*Id.* at 125-26.) She testified that petitioner likely refrained from mentioning her shoulder pain "if it was an appointment for something else, she was focusing on what that appointment was for or she thought [] it was going to go away." (*Id.* at 126.) Ms. Kuklinski did not accompany petitioner to any of petitioner's doctor's appointments in 2017. (*Id.*)

V. Expert Reports

a. Petitioner's Expert, Uma Srikumaran, M.D.[6]

Citing the same literature that underlies the concept of "SIRVA," Dr. Srikumaran opines that petitioner's "needle injection of vaccine antigen inadvertently near the bursa or rotator cuff tendon led to a strong immune mediated inflammatory reaction, causing bursitis and tendinitis in her case." (Ex. 24, pp. 13-14.) He characterizes this as a significant aggravation of a preexisting, but asymptomatic underlying condition. (*Id*. at 14-15.)

Dr. Srikumaran indicates that "like many people of her age, [petitioner] has a chronic condition, osteoarthritis which was clearly asymptomatic for a long period prior to her vaccination." (Ex. 24, p. 10.) Specifically, he cites a March 27, 2017, physical therapy visit that documents essentially normal range of motion. (*Id*. (citing Ex. 3, p. 2).) However, he further indicates that "[petitioner] consistently and reliably reports immediate shoulder pain after vaccination to her varied medical providers, at various clinical settings including office and treatment visits over a long period of time . . . ." (*Id*.) Thus, Dr. Srikumaran bases his assessment on his assumption that petitioner suffered shoulder pain within 48 hours of vaccination. (*Id*. at 11.) He also finds significance in the fact that no other injury or trigger is available to otherwise explain petitioner's symptoms. (*Id*. at 12.) Dr. Srikumaran acknowledges that "[t]here can be many triggers to this inflammation that cause a degenerative condition to become

[6] Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. (Ex. 24, 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. 24, 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. 26, 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.*)

symptomatic. However, in this case we do indeed have a trigger with a strong, reliably and consistently reported, temporal association." (*Id*. at 13.)

Further to this, Dr. Srikumaran notes that petitioner's post-vaccination findings on exam are consistent with tendonitis or bursitis while her radiographic findings indicate arthritis and chronic rotator cuff pathology. (Ex. 24, p. 11.) Thus, Dr. Srikumaran opines that

> Vaccination did not cause these degenerative conditions, but rather was the likely trigger that instigated inflammation in the bursal tissue leading to exam findings consistent with bursitis and tendonitis, and later symptoms more consistent with osteoarthritis. In other words, I believe the vaccination was the trigger that initiated inflammation in her shoulder joint, which we would expect to have underlying age-related degeneration, causing her asymptomatic state to convert to a symptomatic one.

(*Id.*)

Dr. Srikumaran also opines that petitioner's response to physical therapy is more consistent with bursitis or tendonitis as the cause of her shoulder pain. Noting that osteophytes are mechanical blocks, he suggests that physical therapy can make advanced arthritis worse. Importantly, however, he acknowledges that "[c]ertainly, this response can wax and wane over time related to treatments provided as we see in [petitioner's] case as well." (*Id*.) And while he opines there is an inflammatory component, he notes that "she continues to have symptoms consistent with osteoarthritis." (*Id*.)

Dr. Srikumaran opines that "I do not believe it is particularly relevant whether the pain was sudden or gradual in onset, as both can be consistent with a SIRVA injury." (Ex. 24, p. 12.) He suggests the relevant literature (Arias, et al.) allows a latency of up to two months post-vaccination. (*Id*.) Dr. Srikumaran suggests that the amount of antigenic material that is injected into the bursa and various risk factors in the vaccinee may explain the variable timeframes. (*Id*.)

b. Respondent's Expert, Paul J. Cagle, M.D.[7]

[7] Dr. Cagle serves an as assistant professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. (Ex. A, p. 1.) He is a member of the American Shoulder and Elbow Surgeons, and a faculty member of an internationally recognized shoulder surgery fellowship. (*Id.*) His current practice focuses on the shoulder, representing 95% or more of the patients and pathology he treats. (*Id.*) Dr. Cagle conducts clinical, biomechanical, and basic science research. (*Id.*) He has presented scientific work nationally and internationally; and has published over twenty articles related to shoulder injuries and surgery. (Ex. B, pp. 11-12.) Dr. Cagle is a peer reviewer for the Journal of Orthopaedic Research, Techniques in Shoulder and Elbow Surgery, and the Journal of Shoulder and Elbow Surgery. (*Id.* at 13.) He received his medical degree from Loyola University Chicago Stritch School of Medicine in 2008. (*Id.* at 2.) Dr. Cagle completed his orthopaedic residency at the University of Minnesota Academic Health center and Medical School. (*Id.*) He also completed a shoulder and elbow fellowship at Mount Sinai Hospital in New York and is board certified in orthopaedic surgery. (*Id.*)

Dr. Cagle disagrees with Dr. Srikumaran's assessment. (Ex. A.) Whereas Dr. Srikumaran suggested petitioner was asymptomatic pre-vaccination, Dr. Cagle stresses medical records from March of 2017 that show reduced range of motion (Ex. 3, p. 2) as well as x-ray evidence of degenerative changes captured in December of 2017 (Ex. 5, p. 33), and an assessment by Dr. Towsen from June 18, 2018, that recorded "chronic non-traumatic" shoulder pain that was "relieved by physical therapy and injections" (Ex. 5, pp. 27-31). (Ex. A, pp. 6-7.) At that time, Dr. Towsen diagnosed primary osteoarthritis and recommended a total shoulder replacement. (*Id*. (citing Ex. 5, pp. 27-31).) According to Dr. Cagle, petitioner demonstrated a history of degenerative shoulder pain dating back to 2015. (*Id*. at 6-7.) He indicates that "[h]aving subclinical symptoms that eventually cause increasing pain are a hallmark of the disease process." (*Id*. at 6.)

Further to this, Dr. Cagle disagrees that the medical records reflect onset of shoulder pain within 48 hours of the vaccination at issue. (Ex. A, p. 8.) He explains that

> [Petitioner] has clear and undisputed pre-existing shoulder pathology. As such, a failure to report an onset of pain in relation to her flu vaccine prevents a causal link from being drawn, and this is absolutely critical. Without that causal 48 hour link, the pain she experienced subsequently in her shoulder is easily and rationally explained by her severe shoulder arthritis.

(*Id*.)

Dr. Cagle also disagrees that petitioner's post-vaccination physical exams are necessarily indicative of bursitis. (Ex. A, p. 9.) He notes that the abduction finding that Dr. Srikumaran cites is not demonstrably worse than it was pre-vaccination (suggesting it is "within interobserver variability"). (*Id*. (*comparing* Ex, p. 2, *and,* Ex. 6, p. 36).) Additionally, he charges that Dr. Srikumaran overstates the significance of osteophytes, which are themselves indicative of the end stages of osteoarthritis, in impeding motion. Thus, he disagrees with Dr. Srikumaran's assertion that physical therapy does not help arthritis. (*Id*. at 10.)

Dr. Cagle does not go so far as to dispute Dr. Srikumaran's general theory of causation, though he stresses the limitations of the underlying literature. (Ex. A, p. 10.) He does suggest, however, that the risk of needle overpenetration required to cause a SIRVA is "quite low." (*Id*. at 8-9.) (For his part, Dr. Srikumaran likewise acknowledges that "this pathologic entity is quite rare." (Ex. 24, p. 11.))

VI. Party Contentions

a. Petitioner's Motion for a Ruling on the Record

For purposes of her motion, petitioner does not challenge the facts as recited in the Finding of Fact. (ECF No. 67, p. 2.) Petitioner stresses the following language from

the Finding of Fact: "there is not preponderant evidence that onset of left shoulder pain, whether new or aggravated, occurred within 48 hours of [Petitioner's] August 18, 2017, vaccination." (*Id*. (citing ECF No. 63).) Noting that the Finding of Fact further explained that onset of petitioner's shoulder pain was "gradual" and occurred "sometime between late August and early October of 2017," petitioner contends that onset occurred between August 20 and October 14, 2017. (*Id*.) Petitioner further argues that the facts support onset within that period between three and 10 days post-vaccination. (*Id*. at n. 2.) However, petitioner also contends that onset was nevertheless within two months regardless. (*Id*. at 2-3.) Thus, petitioner acknowledges that the Finding of Fact precludes a Table SIRVA claim but argues that onset occurring between three and 57 days post-vaccination supports her cause-in-fact claim. (*Id*. at 4.)

First, petitioner argues that Dr. Srikumaran's expert report satisfies *Althen* prong one. Specifically, she notes that he cites articles by Bodor and Montalvo, Atanasoff, et al., and Arias, et al., that she indicates support the proposed mechanism underlying "SIRVA." (ECF No. 67, pp. 5-6.) (And, indeed, the first two of these three papers were cited in the respondent's proposed rulemaking as supporting the addition of SIRVA to the Vaccine Injury Table (Notice Proposed Rulemaking, July 29, 2015, 80 Fed. Reg. 45132, 2015 WL 4538923, at *45136).) Further to this, Dr. Srikumaran cites studies by Dumonde, et al., and Trollmo, et al., examining the immune response to antigenic material affecting the joints. (*Id*. at 6.) Further still, petitioner notes that Dr. Srikumaran cites a prior study by Hesse, et al., which found a statistically elevated risk of subdeltoid bursitis following influenza vaccination. (*Id*.)

With regard to *Althen* prong two, petitioner relies again on Dr. Srikumaran's opinion. (ECF No. 67, pp. 8-9.) Specifically, Dr. Srikumaran opines that "needle injection of vaccine antigen inadvertently near the bursa or rotator cuff tendon led to a strong immune mediated inflammatory reaction, causing bursitis and tendinitis in [petitioner's] case." (*Id*. at 8 (quoting Ex. 24, p. 14).) Petitioner further highlights Dr. Srikumaran's reliance upon his assessment of the proximate temporal relationship reflected in the medical records as well as on the fact that petitioner's condition was asymptomatic for two years prior to vaccination. (*Id*.) Petitioner further stresses Dr. Srikumaran's explanation of why he believes petitioner's chronic osteoarthritis is not an explanation for her condition. (*Id*. at 9.) Petitioner urges that Dr. Srikumaran's opinion is "quite probative." (*Id*.)

Regarding *Althen* prong three, petitioner acknowledges that the Finding of Fact concluded that onset was outside the period recognized for a Table SIRVA but contends that "onsets falling outside the 'traditional' 48 hours are still supportive of causation in SIRVA cases." (ECF No. 67, p. 10.) Petitioner stresses Dr. Srikumaran's opinion that the Arias article indicates that onset of up to 2 months is medically appropriate and that the variability of latency is determined by a number of factors, including genetics, co-morbidities, tolerance to pain, and the amount of antigenic material errantly injected into the bursa. (*Id*.)

Petitioner contends that respondent has not demonstrated that petitioner's osteoarthritis constitutes an alternative cause of her condition. (ECF No. 67, p. 11.)

b. Respondent's Response

With regard to any Table SIRVA claim, respondent argues that petitioner's history of shoulder pain dating back to 2015 constitutes a condition that would explain her symptoms and that the undersigned's Finding of Fact confirms there was no onset of new shoulder pain within 48 hours of vaccination. (ECF No. 68, pp. 4-5.) Thus, petitioner is unable to satisfy two out of four SIRVA QAI criteria.

With regard to causation-in-fact, respondent stresses his expert's competing assessment that petitioner's clinical history is consistent with her "well documented history of left shoulder osteoarthritis." (ECF No. 68, p. 8.) Respondent suggests that petitioner's symptoms were "classic" findings of arthritis and that even petitioner's own expert, Dr. Srikumaran, factored petitioner's preexisting condition into his overall opinion, noting that he described her alleged vaccine injury as a significant aggravation of her prior complaints. (*Id*. (citing Ex. 24, pp. 14-15). Moreover, respondent notes that petitioner's treating orthopedist characterized her symptoms as "chronic non-traumatic." (*Id*. at 9 (quoting Ex. 5, pp. 27-31).) Respondent further stresses Dr. Cagle's opinion that petitioner had several medical appointments at which she did not report post-vaccination shoulder pain. He argues that "[t]he failure to report shoulder pain temporally related to her vaccination in the presence of a well-documented history of prior shoulder pathology points to the reasonable conclusion that her left shoulder issues are explained by her shoulder arthritis" and that "[t]he severity of her arthritis is supported by two orthopedic surgeons who recommended total shoulder replacement." (*Id*.)

Regarding the possibility that Dr. Srikumaran's opinion has raised a claim for significant aggravation, respondent argues that "Dr. Cagle explains that arthritis evolves over time and it is part of the normal process of the disease for subclinical symptoms to become symptomatic. Accordingly, petitioner's post-vaccination left shoulder symptoms were the 'hallmark' of the natural progression of arthritis, and therefore not a significant aggravation of her underlying condition." (ECF No. 68, p. 11 (internal citations omitted).)

c. Petitioner's Reply and Supplemental Brief Regarding Significant Aggravation

Petitioner contends in her reply that respondent's arguments in response to her motion "muddy the waters" and ignore her cause-in-fact claim in order to focus on significant aggravation. (ECF No. 69, p. 2.) Petitioner stresses that respondent "ignores Petitioner's expert's direct statement that the 'needle injection of vaccine antigen inadvertently near the bursa or rotator cuff tendon led to a strong immune mediated inflammatory reaction, causing bursitis and tendinitis.' Nowhere does Petitioner's expert limit his opinion to aggravation only, as Respondent's Response may suggest." (*Id*. (internal citation omitted).) Petitioner further challenges the persuasiveness of respondent's expert's opinion. Specifically, petitioner charges that "Respondent's expert fails to account for the direct testimony from Petitioner in reaching his conclusions on causation and/or significant aggravation, looking instead at the medical records in a vacuum, discounting her completely asymptomatic condition immediately prior to vaccination." (*Id.*)

Subsequently, in a supplemental brief, petitioner delineates a significant aggravation claim in the alternative. (ECF No. 73.) With regard to *Loving* prongs one through three, petitioner contends that she "had not recently exhibited clinical symptoms of a shoulder injury in the year or more preceding her flu vaccination" and that the prior fact finding in the case concluded that she experienced shoulder pain that arose post-vaccination. (*Id.* at 3.) Thus, because there was an evolution in her condition from asymptomatic to clinical symptomology, she satisfies the showing of significant aggravation under *Loving* prong three. (*Id*.) Regarding vaccine causation of that significant aggravation, petitioner's contentions regarding *Loving* prongs four through six mirror her initial contentions regarding *Althen* prongs one through three. Petitioner argues in effect that the medical theory supporting "SIRVA" necessarily also supports a claim for significant aggravation. Petitioner argues that her medical theory "begins with the simple premise that influenza vaccinations can cause SIRVA." (*Id*.)

VII. Discussion

As explained above, the prior finding of fact patently precludes any Table claim for SIRVA insofar as it specifically confirmed that petitioner did not preponderantly establish onset of shoulder pain within 48 hours of onset as required by the Vaccine Injury Table. *Gruszka v. Sec' of Health & Human Servs.,* No. 18-1736V, 2022 WL 3024777 (Fed. Cl. Spec. Mstr. July 7, 2022). Nonetheless, petitioner argues extensively that this same finding of fact should not preclude a claim that petitioner's vaccine either caused-in-fact a shoulder injury or significantly aggravated her prior shoulder complaints. This decision will not repeat the entirety of the reasoning contained within the finding of fact, but highlighting a few aspects of the reasoning will help to explain why petitioner's arguments are unpersuasive.

As noted above, the finding of fact was not limited to the specific question of a 48-hour onset. It concluded that:

> [T]he evidence preponderates in favor of a finding that petitioner experienced prior episodes of left shoulder pain and also experienced a gradual onset of similar left shoulder pain with an indeterminate initial onset occurring sometime between late August and early October of 2017. However, there is not preponderant evidence that onset of left shoulder pain, whether new or aggravated, occurred within 48 hours of her August 18, 2017, vaccination.

Gruszka, 2022 WL 3024777 at *18. This conclusion was informed by several points directly relevant to the instant analysis. Specifically:

- Petitioner did not initially report shoulder pain during her medical encounters occurring post-vaccination (Ex. 9, pp. 28-29; Ex. 5, pp. 14-23; Ex. 3, p. 3);

- When she did seek care for shoulder pain, petitioner never reported her shoulder pain as vaccine-related to any care provider except her chiropractor who she did not see until two months post-vaccination (Ex. 3, p. 3);

- Petitioner was inconsistent in reporting the timing of onset of her shoulder pain (Ex. 6, p. 35; Ex. 6, p. 10; Ex. 5, p. 24);

- When seeking treatment, petitioner placed her pain in the context of her chronic complaints dating back to 2015 and described her current symptoms as similar (Ex. 4, p. 13; Ex. 5, p. 27);

- Although petitioner's chiropractor testified, she was ultimately unable to corroborate the onset of petitioner's condition from any personal knowledge (Tr. 91); and

- Petitioner confirmed in her own testimony that she perceived the onset of her shoulder pain as gradual. (Tr. 27.)

Regardless of whether this case is addressed as a significant aggravation claim under the *Loving* test or a cause-in-fact claim under the *Althen* test, the dispositive analysis is the same. In light of all of the above, and in consideration of the record as a whole, petitioner has not met her burden of proof with respect to either *Althen* prong two/*Loving* prong five or *Althen* prong three/*Loving* prong six.[8]

Although Dr. Srikumaran included language in his reports that broadly accepted a latency of up to two months for post-vaccination shoulder pain, his actual opinion vis-à-vis this petitioner was based on his assumption of a 48-hour post-vaccination onset. (Ex. 24, p. 11.) In fact, he premised his causal opinion in part on what he characterized as a "strong" temporal association. (*Id.* at 13.) However, this is contrary to the facts as

[8] 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' of Health & Human Servs.,* 956 F.2d 1144, 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"). 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 may support her claim by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

I have found them. *Gruszka,* 2022 WL 3024777, at *13-18. Accordingly, Dr. Srikumaran's opinion is unpersuasive to the extent it is based in part on an unsupported assumption. *Burns v. Sec'y of Health & Human Servs.*, 3 F. 3d 415 (Fed. Cir. 1993) (holding that "[t]he special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner's medical expert."); *see also Rickett v. Sec'y of Health & Human Servs.,* 468 Fed. Appx. 952, 958 (Fed. Cir. 2011) (holding that "it was not error for the Special Master to assign less weight to Dr. Bellanti's conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett's testimony that was inconsistent with the medical records."); *Dobrydnev v. Sec'y of Health & Human Servs.,* 566 Fed. Appx. 976, 982–83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "when an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp*., 509 U.S. 209, 242 (1993)); *Bushnell v. Sec'y of Health & Human Servs.,* No. 02-1648V, 2015 WL 4099824, at *12 (Fed. Cl. Spec. Mstr. June 12, 2015) (finding that "because Dr. Marks' opinion is based on a false assumption regarding the onset of J.R.B.'s condition, and the incorrect assumption of a "stepwise regression" after each vaccine administration, it should not be credited.")

The only other medical professional to offer any suggestion of vaccine causation in this case was petitioner's chiropractor (Dr. Schultz), who, in fact, was the only treating care provider that was provided a history of post-vaccination symptoms. However, as with Dr. Srikumaran, this opinion was based on the assumption that petitioner experienced a sudden onset of symptoms temporally related to her vaccination. (Tr. 82.) But, as explained in the finding of fact, the chiropractor had no personal knowledge of the onset and the assumed onset is not otherwise preponderantly supported. (*Id.* at 91.) This flaw in both Dr. Srikumaran's and Dr. Schultz's opinions defeats petitioner's claim with respect to both the timing element under *Althen* prong three/*Loving* prong six as well as the logical sequence of cause and effect under *Althen* prong two/*Loving* prong five, because it leaves petitioner with no reliable medical opinion supporting her claim based on the actual realities of onset.

Even without treating 48 hours as a bright-line in the cause-in-fact context, Dr. Srikumaran's reliance on Arias, et al., to establish a two-month latency as medically reasonable is also unpersuasive. The Arias authors undertook a review of 67 prior medical articles and 13,717 reports of vaccine-related notifications from the Adverse Reaction Data of the Spanish Pharmacovigilance System or "FEDRA" to assemble a case series of 45 subjects. (L.M. Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations,* 35(37) VACCINE 4870 (2017) (Ex. 26).) The authors assessed 37 cases from the published literature and 8 cases from FEDRA. Among the published cases, post-vaccination onset ranged from immediate to three days. (*Id*. at 3 (Table 2).) Among the FEDRA cases, 6 of the 8 had onset occurring within 7 days of vaccination. Out of all the cases reviewed by Arias, et al., only two cases from FEDRA had latencies beyond one-week post-vaccination. (*Id.* at 3.) The Arias review is a descriptive analysis only, and thus incapable of confirming that the two FEDRA cases with prolonged latencies were vaccine-caused. Nor does

anything in the authors' analysis specifically endorse such a view. Instead, the authors conclude that 48 hours is the likely relevant onset based on the majority of cases falling within that timeframe. (*Id.* at 1 (abstract).) In contrast, a statistical analysis also cited by Dr. Srikumaran examined cases of bursitis occurring within 180 days of vaccination and used the 60 days post-vaccination period as the background rate to find a statistically elevated risk of bursitis occurring within 3 days post-vaccination. (Elizabeth M. Hesse et al., *Risk for subdeltoid bursitis after influenza vaccination: a population-based cohort study,* 173 ANN. INTERN. MED. 253 (2020) (Ex. 30).)

Petitioner's argument that she could prevail on a cause-in-fact basis was based on her assertion that, despite onset being indeterminate, the period of potential onset identified by the finding of fact – between 3 days and 57 days post-vaccination – was entirely encompassed by what petitioner had established as the medically reasonable period of latency. In light of the above, however, this is not true. On the whole, the medical literature makes clear that the expected latency for a post-vaccination shoulder injury is within a matter of days of vaccination, not months as petitioner contends. Thus, petitioner is unpersuasive in suggesting that she has met her burden of proof to establish that her alleged injury occurred within a medically reasonable period of onset. As indicated by the finding of fact, there is not preponderant evidence placing the onset of petitioner's shoulder pain within days of her vaccination. Rather, the finding of fact concluded that onset was indeterminate and possibly as late as about two months post-vaccination. *Gruszka,* 2022 WL 3024777 at *18. Thus, even setting aside the specific 48-hour timeframe, petitioner has not met her burden of proof under *Althen* prong three/*Loving* prong six.

Additionally, even accounting for Dr. Sikumaran's broader acceptance of a gradual two-month onset, this is still not persuasive under the circumstances of this case as evidence supporting a logical sequence of cause and effect under *Althen* prong two/*Loving* prong five. Petitioner stresses that aspect of the finding of fact that indicated an onset of shoulder pain occurring sometime between late August and early October of 2017, which petitioner argues is consistent with Dr. Srikumaran's opinion. (ECF No. 67, p. 10; ECF No. 73, p. 8 (citing Ex. 24, pp. 12-15).) However, petitioner ignores those aspects of the finding of fact that indicated that petitioner had prior episodes of "similar" left shoulder pain and that the shoulder pain ultimately at issue in this case was of both "gradual" and "indeterminate" onset. *Gruszka,* 2022 WL 3024777 at *18. Even before reaching Dr. Cagle's competing opinion, Dr. Srikumaran acknowledges petitioner had a history of degenerative shoulder complaints, acknowledges that symptoms associated with these types of complaints can wax and wane and can be aggravated by many factors, and acknowledges that petitioner displayed symptoms of osteoarthritis subsequent to her vaccination. (Ex. 24, p. 11.) This is consistent with how both petitioner and her treating physicians addressed her condition on the whole. (Exs, 4-6, *passim.*) In that context, it is not persuasive for petitioner to suggest that a "gradual" and "indeterminate" onset of shoulder pain during the months following vaccination is meaningful evidence of a logical sequence of cause and effect implicating petitioner's vaccination in her condition. Indeed, as noted above, the finding of fact was based in part on petitioner's own inability to consistently identify the actual onset of her shoulder

pain, her seeking treatment repeatedly without associating her pain to her vaccination, and her reports to her treating physicians that instead placed her shoulder pain in the context of her "chronic non-traumatic" complaints. (Ex. 5, pp. 14-28; Ex. 6, pp. 10, 35; Ex. 9, pp. 28-29; Ex. 3, p. 3.) Given the continuum on which petitioner's condition existed pre- and post-vaccination, Dr. Srikumaran offers very little additional insight by citing the lack of any other specific injury or trigger to explain petitioner's clinical presentation. It is far from clear that any injury or trigger would be necessary to explain petitioner's condition. Nor, without more, would eliminating alternative causes support petitioner's burden of proof. *Walther v. Sec'y of Health & Human Servs*., 485 F.3d 1146, 1151 (Fed. Cir. 2007); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352 (Fed. Cir. 2006).

VIII. Conclusion

Petitioner has my sympathy for what she has endured. However, considering the record as a whole under the standards applicable in this program, petitioner has not preponderantly established that her August 18, 2017, flu vaccination resulted in a Table SIRVA, a cause-in-fact shoulder injury, or a significant aggravation of a pre-existing condition. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.[9]

IT IS SO ORDERED.

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

[9] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.