In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-1899V
Filed: April 7, 2023
PUBLISHED

CARLA DURHAM, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration ("SIRVA"); Table Injury; Cause-in-fact; Influenza ("flu") vaccine

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On December 7, 2017, petitioner, Carla Durham, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that she suffered "injuries, including Shoulder Injury Related to Vaccine Administration ("SIRVA"), resulting from adverse effects of an influenza ("flu") vaccination she received on December 30, 2016." (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is not entitled to compensation.

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 document 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 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] Within this decision, all citations to § 300aa will be the relevant sections 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 vaccine administration. § 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 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 (citations omitted); § 300aa-13(a)(1)(B).

In this case, petitioner stresses that she suffered an injury consistent with a SIRVA Table Injury. Alternatively, petitioner asserts that reliable medical evidence supports a non-Table shoulder injury caused-in-fact by her vaccination. (ECF No. 64.)

II. Procedural History

This case was initially assigned to the Special Processing Unit ("SPU") for expedited resolution based on the allegations of the petition. (ECF No. 5.) Over several months, petitioner filed evidence, including medical records and affidavits, marked as Exhibits 1-8. (ECF Nos. 7, 9, 11.) Respondent then advised as of November 5, 2019, that he intended to defend the case and later filed his Rule 4(c) Report setting forth his view of the case on March 21, 2019. (ECF Nos. 21, 23.) Respondent primarily raised the issue that petitioner had a history of back pain, body aches, and a diagnosis of fibromyalgia, that more likely explained her condition and prevented her from relying on a Table Injury of SIRVA. (ECF No. 23.)

After the filing of respondent's report contesting the claim, the case was reassigned out of the SPU and to Special Master Moran. (ECF Nos. 24-25.) While the case was before Special Master Moran, petitioner filed further medical records marked as Exhibits 9-11. (ECF Nos. 28, 34.) The case was reassigned to the undersigned on August 29, 2019. (ECF No. 36.) Thereafter, petitioner filed an expert report by Uma Srikumaran, M.D., with supporting literature. (ECF No. 43; Exs. 12-18.) Respondent filed a responsive report by Geoffrey Abrams, M.D. (ECF No. 45; Exs. A-B.)[3]

On September 15, 2020, I held a Rule 5 status conference to discuss the expert reports. (ECF No. 46.) I explained that based on their initial reports, it does not appear that either expert believed petitioner's history could be explained by fibromyalgia as had been raised in respondent's Rule 4 report. I noted, however, that respondent's expert had instead raised an issue with respect to cervical radiculopathy and cervical spondylosis. (*Id*.) I further explained:

> While each expert report highlights certain findings that favor the etiology favored by that expert, neither report adequately addresses whether any of the findings or notations in the medical records are potentially confounding. Nor do the experts explicitly discuss the considerations at issue in distinguishing pain associated with a shoulder versus cervical etiology.

(*Id*. at 1-2.) I attached as Court Exhibit I a review article by Bokshan et al. that discussed the challenges at issue and further noted that petitioner's treating physician, Dr. Drabicki, appeared unwilling to rule out either a cervical condition or impingement syndrome. (*Id*. at 2 (citing Ex. 9, p. 3).) I invited both experts to address the Bokshan article and to also specifically address specific notations within the medical records. (*Id*. at 2-3.)

Petitioner then filed a supplemental report by Dr. Srikumaran with further supporting literature on January 6, 2021. (ECF No. 49; Exs. 19-25.) Respondent filed a responding supplemental report by Dr. Abrams on May 6, 2021. (ECF No. 52; Ex. C.) A follow up status conference was held on October 22, 2021. (ECF No. 56.)

During the October 2021 status conference, I advised the parties that I viewed Dr. Srikumaran's supplemental report as conceding that petitioner could not satisfy the requirements of a Table SIRVA due to his agreement that petitioner's presentation was at least partly explained by cervical radiculopathy, albeit cervical radiculopathy he believed to be sequela of her shoulder injury. I indicated that this may prevent petitioner from satisfying SIRVA QAI prong 4 (which discusses evidence of cervical radiculopathy) but would also in any event prevent petitioner from satisfying SIRVA QAI prong 3 (which requires the condition be limited to the affected shoulder). (ECF No. 56, pp. 1-2.) Further to that, I discussed several points the parties should consider with respect to an alternative cause-in-fact claim. (*Id*. at 2-3.)

[3] Respondent did not file the supporting literature, marked as Exhibit A, Tabs 1-8, until October 30, 2021. (ECF No. 57.)

Subsequently, petitioner filed a status report on December 3, 2021. (ECF No. 59.) Petitioner expressed strong disagreement with the undersigned's preliminary analysis but felt legal briefing and an entitlement hearing would be more productive than further expert reports. (ECF No. 59.) In response, I noted that the specific concerns raised in petitioner's status report were primarily legal rather than medical. Accordingly, I indicated that I was not persuaded that a hearing is necessary and instructed petitioner to provide a legal brief in support of her contention that she is entitled to compensation, addressing both her Table and non-Table contentions. (ECF No. 60.) I allowed petitioner to accompany her written brief with a supplemental report by Dr. Srikumaran. I also noted that petitioner could renew her request for a hearing within her brief. However, I advised that if petitioner's request for a hearing is denied, then the brief would constitute her written submission pursuant to Vaccine Rule 8(d). (*Id*. at 2.)

Thereafter, petitioner filed a second supplemental report by Dr. Srikumaran (Exs. 26-27) and a written brief styled as a "prehearing submission." (ECF Nos. 63-64.) Based on my review of that submission, I confirmed in a subsequent order that I would resolve this case without a hearing and that petitioner's written submission shall constitute her opening brief pursuant to Vaccine Rule 8(d). (ECF No. 65.) Respondent subsequently filed his response accompanied by a second supplemental report by Dr. Abrams on August 8, 2022. (ECF Nos. 69-70; Ex. D.) Petitioner then filed a reply accompanied by a third supplemental report by Dr. Srikumaran and four additional medical articles. (ECF Nos. 72, 74-75; Exs. 28-32.)

In light of the above 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

Petitioner was 45 years old at the time of the subject vaccination, which she received in her left arm on December 30, 2016. (Ex. 1, p. 1.) Respondent stresses that at that time she had a history significant for anxiety, depression, lower back problems, pre-menstrual dysphoric disorder, and smoking. (ECF No. 70, p. 4 (citing Ex. 3, p. 23; Ex. 4, p. 1; Ex. 6, p. 1).) Petitioner states in her affidavit that she believed her injection was improperly placed (too high) and that she felt a "strange sensation" when the vaccine was injected. (Ex. 7, p. 1.) She states that she began to feel aching in her deltoid that evening and that her pain and discomfort worsened progressively over several weeks. (*Id*.)

About one month later, on January 26, 2017, petitioner presented to the emergency department with a complaint of left upper arm pain. (Ex. 2, p. 2.) The chief complaint reports that "pt states that she had a flu vaccine at Rite Aid 5 weeks ago. She states that it 'didn't feel right' at the time. She experienced pain immediately.

Today she noticed numbness in her left hand and hot inside her arm." (*Id*. at 4.) The history of present illness further explains that

> Following flu shot 5 weeks ago patient states that she has been getting progressively worsening left-sided shoulder and arm pain with radiculopathy and numbness radiating into her left hand. She states the numbness is most profound in her middle finger. She also states there is a warm feeling inside her left upper arm. She admits to weakness associated with this and she has decreased range of motion in all planes . . . She states that she believes due to compensating for her arm pain her shoulder and left side of her neck have begun to hurt as well.

(*Id*. at 5.) Physical exam by Dr. Joseph Snatchko showed limited active and passive range of motion of the left shoulder in all planes along with diminished sensation in her 1st, 3rd, and 5th fingers consistent with a C6-8 dermatomal distribution. She was also tender to palpation at the deltoid and supraspinatus, but had no point tenderness at the cervical spine. (*Id*. at 7.) Shoulder X-rays were negative. (*Id*.) The assessment was left shoulder pain with "symptoms potentially due to injury to lateral cutaneous axillary nerve, but given degree of pain and limited range of motion with numbness in hand, suspect possible involvement of cervical nerve roots." (*Id.* at 8.)

Petitioner then presented to orthopedist Edward Birdsong, M.D., on February 1, 2017.[4] (Ex. 5, p. 7.) Petitioner provided a history of left shoulder pain following her prior flu vaccination, but this time denied any numbness or tingling in the hand. (*Id.*) Physical exam of the left shoulder showed full strength of the deltoid, rotator cuff, and biceps and triceps, but limited active range of motion and pain with passive range of motion. (*Id*. at 9.) Neer and Hawkins signs were positive.[5] (*Id*.) Petitioner was diagnosed with myositis[6] of the left shoulder and prescribed a Medrol Dosepak and instructed to follow up in two weeks. (*Id*.) Petitioner returned to Dr. Birdsong on February 22, 2017. (Ex. 11, p. 1.) He noted her pain was improving with the Dosepak, but not entirely resolved. (*Id*.) However, he also noted that she was now complaining of "having several different areas of myalgias and some arthralgias as well." She was

[4] In fact, she was seen by a resident, Alan Slipak, M.D., supervised by Dr. Birdsong. (Ex. 5, p. 7.)

[5] The Neer Impingement Test "is a test designed to reproduce symptoms of rotator cuff impingement through flexing the shoulder and pressure application. Symptoms should be reproduced if there is a problem with the supraspinatus or biceps brachii." *Neer Impingement Test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Neer_Impingement_Test (last accessed Apr. 7, 2023). A positive Hawkins-Kennedy test is indicative of an impingement of all structures that are located between the greater tubercle of the humerus and the coracohumeral ligament." *Hawkins-Kennedy test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Hawkins%E2%80%93Kennedy_test (last accessed Apr. 7, 2023). The impinged structures include the supraspinatus muscle, teres minor muscle, and the infraspinatus muscle. *Id.*

[6] Myositis is "inflammation of a voluntary muscle." *Myositis,* DORLAND'S MEDICAL DICTIONARY ONLINE https://www.dorlandsonline.com/dorland/definition?id=32923 (last accessed Apr. 7, 2023).

still tender to palpation at the left deltoid. Dr. Birdsong recommended a consultation with a sports medicine specialist. (*Id*.)

On March 6, 2017, petitioner saw physical medicine and rehabilitation specialist Sarah Hagerty, D.O., for left arm pain. (Ex. 5, p. 13.) Petitioner described left arm pain beginning post-vaccination, but also "report[ed] whole-body pain that has been going on for several years." (*Id*.) On physical exam petitioner reported tenderness over the lateral aspect of the arm along her deltoid, but no cervical spinal tenderness. (*Id*. at 15.) She reported no sensation changes in her extremities and had intact sensation to light touch as well as intact reflexes. She had a negative Spurling's test[7] and no pain with cervical extension. (*Id*.) Dr. Hagerty assessed both left arm pain beginning after the flu vaccination and fibromyalgia. (*Id*. at 16.) She was prescribed gabapentin and recommended to finish the course of steroids initiated by Dr. Birdsong. (*Id*.)

Petitioner was not seen again for several months until she returned to Dr. Birdsong's office on August 2, 2017, and was seen by Physician Assistant Fickner. (Ex. 11, p. 2.) Petitioner reported that she had discontinued the gabapentin because it made her feel sick and was instead managing with ibuprofen. (*Id*.) On physical examination, petitioner continued to be tender over the lateral aspect of her left deltoid and also at some aspects of her right shoulder. She had left deltoid pain with resisted abduction of the shoulder and pain and "near full" range of motion limited by pain at the last 10-15 degrees of forward elevation and lateral abduction. She had full painless internal and external rotation of the left shoulder but painful rotator cuff strength testing. Her diagnosis remained myositis of the left shoulder, but with an additional assessment of fibromyalgia and tendonitis of the long head of the biceps. (*Id*. at 2-3.) She was given a further Medrol Dosepak for inflammation and also prescribed Flexeril to help reduce spastic discomfort. (*Id*. at 3.) A physical therapy referral was provided, and petitioner was otherwise instructed to follow up as needed. (*Id*.)

Petitioner did not seek care for her shoulder complaint again until March 26, 2018, when she presented to orthopedist Raymond Drabicki, M.D. (Ex. 9, p. 1.) In the interim, petitioner was seen by Dr. Neuschwander on August 10, 2017, for her lower back pain and by Jeffrey Hein, M.D., for an annual physical. (Exs. 6, 8.) Although the fact of her shoulder condition is noted in the histories she provided to Drs. Neuschwander and Hein, no relevant evaluations were conducted. (*Id*.)

When petitioner presented to Dr. Drabicki for the first time in March of 2018, she reported a one-year history of left shoulder pain following her vaccination and further indicated that "[i]t radiates at times down from the neck all the way down into the hand." (Ex. 9, p. 1.) Review of systems indicated a history of joint pain along with muscular weakness, stiffness, and pain. (*Id*. at 2.) On physical exam petitioner had positive Spurling's on both the right and left. She was not tender at the acromioclavicular joint and she had full range of motion of her shoulder, but she did have positive Neer and

[7] The Spurling sign is a type of cervical compression test to assess radicular pain. It is positive when pain arises in the neck. *Spurling's test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Spurling%27s_test (last accessed Apr. 7, 2023).

Hawkins tests. (*Id*.) An X-ray of her shoulder was unremarkable, and an X-ray of her cervical spine showed degenerative changes with disc space narrowing at C6-7. The impression was other spondylosis,[8] cervical region, and left shoulder pain. (*Id*.) However, Dr. Drabicki indicated a differential diagnosis including impingement syndrome, Parsonage Turner, and cervical spondylosis with possible mild radiculopathy. He recommended an MRI of both the shoulder and cervical spine, indicating that "[m]y suspicion is she may have some radicular issues due to the arthrosis in the cervical spine and therefore pain may be multifactorial in nature." (*Id*. at 3.)

No further records were filed.

IV. Expert Reports

a. Petitioner's Expert, Orthopedist Uma Srikumaran, M.D., MBA, MPH[9]

As explained in the procedural history, Dr. Srikumaran has provided four reports in this case. (Exs. 12, 19, 26, 28.)

i. First Report

In this first report, Dr. Srikumaran provides his recitation of the relevant medical history and primarily discusses why he opines that petitioner's history satisfies the four criteria for establishing a Table SIRVA. (Ex. 12, pp. 2-6.) He acknowledges petitioner's history of back pain, but asserts that she has no prior history of shoulder dysfunction. Further, he indicates that petitioner consistently reported an immediate onset of post-vaccination shoulder pain. (*Id.* at 4-5.) Dr. Srikumaran asserts that petitioner's condition was limited to her affected shoulder, highlighting findings from Drs. Birdsong's and Hagerty's records that he notes to be inconsistent with cervical radiculopathy. He

[8] Spondylosis denotes "degenerative spinal changes due to osteoarthritis." *Spondylosis,* DORLAND'S MEDICAL DICTIONARY ONLINE https://www.dorlandsonline.com/dorland/definition?id=467&searchterm=spondylosis (last accessed Apr. 7, 2023).

[9] 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. 10, 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. 11, 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 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. (Ex. 10, pp. 1-2.) Dr. Srikumaran was selected to serve on the Shoulder and Elbow Content Committee for the American Academy of Orthopaedic Surgery. (*Id.*)

stresses that Dr. Birdsong diagnosed myositis of the left shoulder, which is a localized condition. (*Id*. at 5.) He further stresses that Dr. Hagerty's fibromyalgia diagnosis constituted a separate condition from the shoulder condition. (*Id*.) He opines that neither back pain nor fibromyalgia would explain petitioner's shoulder symptoms. (*Id*.) Further to this, Dr. Srikumaran lays out, at least briefly, an opinion based on the *Althen* test for causation in fact. (*Id*. at 6-7.)

ii. Second Report

In his second report, Dr. Srikumaran responds to Dr. Abrams's first report as well as my Scheduling Order of September 15, 2020. (Ex. 19, p. 1.) First, Dr. Srikumaran agrees that fibromyalgia was present (or at least diagnosed) but reiterates his contention that it does not explain petitioner's shoulder symptoms. (*Id*.) Second, Dr. Srikumaran agrees that "there is some inconsistent evidence suggestive of cervical radiculopathy in the medical record and this can complicate diagnosis." (*Id*.) Again, however, he opines that it does not explain petitioner's shoulder symptoms and he further notes that it would not be unusual for both cervical and shoulder conditions to exist simultaneously. (*Id*. at 1-2.) Dr. Srikumaran notes that the Bokshan article at Court Exhibit I indicates that shoulder impingement may occur in up to 24% of patients with cervical radiculopathy. (*Id*. at 2.)

Further to this, Dr. Srikumaran provides a list of the types of findings one would expect in cases of shoulder pathology on the one hand and cervical or neurologic pathology on the other. (*Id*.) He quotes language from Bokshan that "[i]n more diagnostically complex cases, patients with cervical pain may have positive provocative shoulder test results" and further notes that the proposed mechanism in such cases is spasming in the muscles connecting the neck and shoulder. (*Id*. at 3.) He opines that it is typical for patients with shoulder pain to adjust their shoulder in response to pain such that these muscles are activated and result in neck pain. (*Id*.) He cites papers by Hawkins et al., and Manifold and McCann, and Gorski and Schwartz, that he indicates show a majority of cases with coexisting neck and shoulder pain were alleviated by treatment of the shoulder rather than the neck. (*Id*. at 3-4 (citing Richard J. Hawkins et al., *Cervical Spine and Shoulder Pain*, 258 CLINICAL ORTHOPAEDICS & RELATED RSCH. 142 (1990) (Ex. 21), Stephen G. Manifold & Peter D. McCann, *Cervical Radiculitis and Shoulder Disorders*, 368 CLINICAL ORTHOPAEDICS & RELATED RSCH. 105 (1999) (Ex. 25), and Jerrold M. Gorski & Lawrence H. Schwartz, *Shoulder Impingement Presenting as Neck Pain*, 85-A J. BONE & JOINT SURGERY 635 (2003) (Ex. 20)).)

In petitioner's case, Dr. Srikumaran cites the following as supportive of a shoulder-related etiology for her symptoms: aching, constant pain high in the deltoid affecting sleep (citing Ex. 7, p. 1; Ex. 2, p. 5); a physical exam inclusive of limited active and passive range of motion in all planes, decreased sensation, and tenderness at the deltoid and supraspinatus but not the cervical spine (citing Ex. 2, p. 7 and Ex. 5, p. 9; Ex. 5, p. 15 (for tenderness)); denial of numbness or tingling in the hand (citing Ex. 5, p. 7); and positive Neer and Hawkins tests, but negative Spurling's test (citing Ex. 5, p. 9; Ex. 9, p. 2). He cites the following as more consistent with cervical radiculopathy:

radiating pain to the wrist (citing Ex. 7, p. 2); numbness in the left hand and specifically the middle fingers (citing Ex. 2, p. 5); complaints of neck pain and stiffness (citing Ex. 2, p. 6 (review of systems)); diminished sensation in the fingers on physical exam (citing Ex. 2, p. 8); a physical exam inclusive of a positive Spurling's test with full range of motion of the shoulder (citing Ex. 9, p. 2); and X-rays showing cervical spinal degeneration with disc narrowing at C6-7 (citing Ex. 9, p. 2). (Ex. 19, p. 4.)

Thus, Dr. Srikumaran opines that petitioner had both cervical radiculopathy and shoulder pathology. (*Id*. at 4.) However, he disagrees that cervical radiculopathy explains all of her symptoms. He notes that the medical records document that petitioner herself reported her shoulder pain as leading to subsequent neck pain. (*Id*. at 4-5.) Dr. Srikumaran asserts that "it is not simply the presence of another condition (cervical radiculopathy) that invalidates a SIRVA claim, but rather that the other condition can explain the patient's constellation of symptoms." (*Id*. at 5.) However, he also opined that "I believe the vaccination triggered and exacerbated a pre-existing cervical degenerative condition." (*Id*.) Specifically, he opines that the vaccine antigen initiated inflammation at or near the bursa or synovium of the joint. This caused the shoulder pain. The shoulder pain in turn aggravated the previously asymptomatic cervical disc degeneration due to petitioner's compensating posture. (*Id*.)

Dr. Srikumaran continues to contend that petitioner's history meets the Table requirements for SIRVA, but also provides a more detailed explanation of the literature supporting the idea that a vaccine can cause-in-fact shoulder pain. (*Id*. at 7-10.)

iii. Third Report

In his third report, Dr. Srikumaran responds to Dr. Abrams's second report as well as the Scheduling Order of October 22, 2021. Dr. Srikumaran further stresses that the presence of both shoulder pathology and cervical radiculopathy does not automatically preclude the presence of a discrete SIRVA. (Ex. 26, p. 1.) He indicates that he interprets the fourth SIRVA criterion as allowing for some overlapping conditions so long as they do not explain all of the relevant symptoms or constitute a better explanation of the constellation of symptoms. (*Id.* at 1-2.) He indicates that "I acknowledge that cervical radiculopathy and fibromyalgia are possible complicating diagnoses in this case, however they are far less likely than SIRVA to be the cause of petitioner's shoulder pain when considering all the facts of the case including timing. Based on the record as a whole, I am very comfortable placing the probability of a SIRVA injury in this case being well over 50%." (*Id*. at 2.) Further, Dr. Srikumaran opines that petitioner met the third SIRVA criterion because her pain and reduced range of motion were initially limited to her shoulder and only later led to the additional cervical radiculopathy symptoms. (*Id*.)

Finally, Dr. Srikumaran also provides an explanation of why he does not find the American Association of Orthopedic Surgeons ("AAOS") position statement cited by Dr. Abrams to be authoritative. (*Id*. at 4.) That position statement suggests there is a lack of good evidence that vaccines cause shoulder injuries and charges the concept as post

hoc, ergo propter hoc fallacy. (Ex. C, Tab 2.) However, Dr. Srikumaran stresses that the AAOS itself disclaims its position statements as "not a product of a systematic review." (Ex. 26, p. 4.)

iv. Fourth Report

The fourth and final report prepared by Dr. Srikumaran is in response to Dr. Abrams's final report as well as to respondent's response to petitioner's opening brief on entitlement. (Ex. 28.) In this final report, Dr. Srikumaran suggests that the major point of disagreement in the case is whether SIRVA can occur in the presence of coinciding fibromyalgia and cervical radiculopathy. He asserts that the presence of these conditions "does not mean that SIRVA would be impossible to occur" and further stresses that he believes the time course of events is more consistent with SIRVA. (*Id*. at 1.) Dr. Srikumaran summarizes his view of the case as follows:

> In conclusion, it is my position based on the totality of medical record evidence, that the vaccination is the most likely cause of intrinsic shoulder pathology (bursitis, subacromial impingement, and capsulitis) and that in turn activated a previously asymptomatic cervical radiculopathy due to compensatory muscle use, muscle imbalances and postural changes. I believe that there is a strong temporal relationship that is supported by the medical record, as I have highlighted above. The temporal relationship is always considered when taking a history from a patient and in complex cases such as this, it cannot be dismissed in determining which structure is responsible for the sequela of events.

(*Id*. at 4.)

b. Respondent's Expert, Orthopedist Geoffrey Abrams, M.D.[10]

Dr. Abrams has prepared three reports for this case. (Exs. A, C, D.)

[10] Dr. Abrams serves as Assistant Professor of Orthopedic Surgery at the Stanford University School of Medicine. (Ex. A, p. 1.) He also holds the appointment of Staff Physician at the Veterans Administration Palo Alto Health Care Division. (*Id.*) Dr. Abrams is the Director of Sports Medicine for Stanford University Varsity Athletics as well as Director of the Lacob Family Sports Medicine Center at Stanford University. (*Id.*) He also serves as Team Physician for numerous professional and collegiate sports teams in the San Francisco Bay Area. (*Id.*) Dr. Abrams received his medical degree from the University of California San Diego. (Ex. C, p. 1.) He competed a surgical internship at Stanford University Hospital and Clinics from 2007 to 2008; and completed his residency in 2012 at the same hospital in the Department of Orthopedic Surgery. (*Id.*) Dr. Abrams also has a subspecialty certificate in Orthopedic Sports Medicine. (*Id.* at 2.) He has a surgical practice focused on orthopedic conditions of the shoulder and authored or coauthored over sixty peer-reviewed medical articles on various orthopedic topics. (Ex. A, p. 1; Ex. C, pp. 2-8.)

i. First Report

In his first report Dr. Abrams provides his review of petitioner's medical history and opines that her history is not compatible with the third and fourth SIRVA criteria, requiring that the injury be limited to the shoulder at issue and that no other condition or abnormality is present to explain the symptoms. (Ex. A, pp. 1-4.) With regard to the third criterion, Dr. Abrams simply asserts there is evidence of cervical radiculopathy and fibromyalgia, suggesting her presentation includes conditions affecting parts of the body beyond the shoulder. (*Id*. at 4.) With regard to the fourth criterion, Dr. Abrams explains that cervical radiculopathy is a common cause of arm and shoulder pain in addition to neck pain and that fibromyalgia is likewise an established cause of musculoskeletal pain. (*Id*. at 6.) In responding to Dr. Srikumaran's first report, Dr. Abrams stresses that none of the literature cited by Dr. Srikumaran includes the myositis that was actually diagnosed by Dr. Birdsong. (*Id*. at 8.) Instead, he contends that a diagnosis of myositis is incompatible with the mechanism Dr. Srikumaran proposes of synovial inflammation. Muscle tissue has no synovium. (*Id*.)

ii. Second Report

Dr. Abrams's second report was prepared in response to Dr. Srikumaran's second report. (Ex. C, p. 1.) Dr. Abrams contests Dr. Srikumaran's reliance on Gorski and Schwartz as explanation of how petitioner's vaccination could ultimately have led to cervical radiculopathy. He indicates that all of the study subjects were experiencing conditions that were "qualitatively" different than what is present in this case. (*Id*.) With regard to Dr. Srikumaran's discussion of what signs and symptoms indicate cervical versus shoulder pathology, Dr. Abrams stresses that "[w]hile radiating pain to the hands/fingers or isolated neck pain argue against a shoulder pathology, the presence of shoulder pain does not rule out cervical-mediated pain." (*Id*. at 2.) Dr. Abrams indicates that many of the symptoms deemed "consistent" with shoulder pathology also have "significant overlap" with the symptoms of cervical-mediated shoulder pain. (*Id*.) Dr. Abrams does acknowledge that the finding of tenderness to palpation around the shoulder girdle does argue against cervical-mediated shoulder pain, but contends that this additional finding can be explained by the coexisting fibromyalgia. (*Id*.) In response to Dr. Srikumaran's stressing of the temporal relationship between the vaccination and onset of symptoms, Dr. Abrams cautions against assuming that association implies causation. In that regard, he cites the above-referenced AAOS position statement later criticized in Dr. Srikumaran's third report. (*Id*. at 2-3.)

iii. Third Report

Dr. Abrams's third and final report was prepared in response to Dr. Srikumaran's third report. He notes that he has "no doubt that SIRVA is a real clinical entity," but challenges Dr. Srikumaran regarding his overlooking of two established diagnoses (cervical radiculopathy and fibromyalgia) in favor of an undiagnosed SIRVA as a more likely explanation. (Ex. D, pp. 1, 4.) He stresses that the impingement signs and reduced range of motion that underly Dr. Srikumaran's assessment are "notoriously

non-specific." (*Id.*) In his experience, "[i]t is very common for Orthopedic practitioners to see patients with a likely diagnosis of cervical spine disease who have pain in their shoulder and loss of range of motion on exam." (*Id*.) Noting that Dr. Srikumaran acknowledged that petitioner had symptoms of cervical radiculopathy, he suggests that this necessarily indicates that "at minimum, a component of the shoulder complaints come from her cervical issues." (*Id.* at 2.) Further to that, he suggests that in his own view the majority of petitioner's presenting complaints are explained by cervical spine issues. (*Id*.) He charges that Dr. Srikumaran's alternative explanation, that the injection-related pain in turn resulted in the cervical symptoms, lacks supporting evidence. (*Id*.) Based on his own interpretation of the medical records, Dr. Abrams opines that a more likely explanation is that petitioner initially suffered cervical radiculopathy/spondylosis and then developed a component of fibromyalgia pain. (*Id*. at 3.) Dr. Abrams stresses that cervical spinal mediated symptoms do not require any associated physical event or accident. (*Id*.) Further, Dr. Abrams indicates that the cervical X-rays showed degenerative changes that are the "hallmark" of cervical spondylosis and that are not associated with trauma or event. (*Id*.)

V. Party Contentions

a. Petitioner's Opening Brief

Petitioner's analysis of her alleged Table SIRVA begins with the QAI fourth criterion that requires that "[n]o other condition or abnormality is present that would explain the patient's symptoms." (ECF No. 64, pp. 8-18.) She characterizes respondent as contending that "the mere presence of cervical radiculopathy, or fibromyalgia, entities that can be associated with shoulder pain, act as an absolute bar to petitioner's ability to show a Table injury due to being unable to meet Criterion (iv)." (*Id*. at 10.) However, noting that asymptomatic degenerative spinal changes are incredibly common in older individuals, she asserts that this is far too broad of an interpretation of the regulatory language and would effectively ban broad swaths of the population from demonstrating a SIRVA. (*Id.* at 10-11.) Rather, petitioner argues that the language must be understood more narrowly, precluding a SIRVA only where the other condition is the better or more probable explanation for the shoulder pain. (*Id.* at 11.) "In any given vaccine case, it is the duty and responsibility of the Special Master to carefully review all of the evidence in the record as a whole and determine if the *better* or *more likely* explanation for a petitioner's shoulder pain is the vaccine he received OR the radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy." (*Id*. at 12 (emphasis in original).) From that starting point, petitioner argues at length why Dr. Srikumaran's opinion should be credited and why neither cervical radiculopathy nor fibromyalgia better explains petitioner's symptoms. (*Id.* at 12-18.)

Regarding the third SIRVA criterion, which requires that "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered," petitioner argues that Dr. Srikumaran's opinion "does not run afoul" of this requirement despite invoking cervical radiculopathy within his overall assessment. (*Id*. at 19.) Petitioner contends that Dr. Srikumaran's opinion set forth a "direct insult to

the shoulder, and limited to the shoulder, that is encompassed in her SIRVA shoulder injury." (*Id*.) She argues that "the presence of radiating pain into the neck and hand does not obviate the initial insult to the shoulder. The pain that radiated into the neck was a direct result of the shoulder injury sustained by petitioner. It was not that the vaccine caused a direct injury to the shoulder *and* the neck." (*Id*. (emphasis in original).) Petitioner argues that her understanding of the third SIRVA criterion is supported by the Secretary's response to public comment included within the final rule adding SIRVA to the Vaccine Injury Table. (*Id*. at 19, n.1 (citing 82 Fed. Reg. 6294).) She contends it is also supported by prior cases. (*Id*. at 20 (citing *Werning v. Sec'y of Health & Human Servs*., No. 18-267V, 2020 WL 5051154, at *7 (Fed. Cl. Spec. Mstr. July 27, 2020); *Rodgers v. Sec'y of Health & Human Servs*., No. 18-559V, 2021 WL 4772097, at *6 (Fed. Cl. Spec. Mstr. Sept. 9, 2021)).)

Regarding causation-in-fact, petitioner cites nine prior cases that she suggests demonstrate that special masters may take judicial notice of the Table Injury of SIRVA in order to fulfil the medical theory requirement of *Althen* prong one. (*Id*. at 21-22.) However, she also asserts that Dr. Srikumaran's reports include a discussion of general causation that satisfies her burden of proof on *Althen* prong one regardless. (*Id*. at 22.) She argues that the logical sequence of cause and effect required by *Althen* prong two is satisfied in two ways. First, Dr. Srikumaran has explained, consistent with his articulated theory, that petitioner "experienced inflammation in her shoulder resulting in a great deal of pain." Second, petitioner's treating physicians attributed her pain to her vaccination. (*Id*.)

Under either a Table Injury or a causation-in-fact approach, petitioner asserts that there is no genuine dispute in this case as to the fact that petitioner had no prior history of shoulder dysfunction or that she experienced onset of shoulder pain immediately following her vaccination. (*Id*. at 8-9, 23.)

b. Respondent's Response

In contrast to petitioner's view of the record evidence, respondent contends that petitioner's condition is better explained by her cervical region radiculopathy, degenerative disc disease, and fibromyalgia. (ECF No. 70, p. 9.) Respondent asserts that petitioner "has not established an independent SIRVA-like injury" and that her multiple other confirmed diagnoses "more likely than not fully account for her shoulder pain." (*Id*. at 9.) Thus, respondent argues, based on his assessment of the medical records and Dr. Abrams's expert opinion, that petitioner has not preponderantly satisfied SIRVA criterion four. (*Id.* at 9-11.) Relatedly, regarding the third SIRVA criterion, respondent contends that the medical records show that "petitioner's symptoms were never limited to the shoulder, but rather always included symptoms outside the shoulder." (*Id.* at 11-12.)

Regarding causation-in-fact, respondent stresses that "SIRVA" is a term of art used for purposes of creating the Table Injury and not a specific medical condition. (*Id*. at 12.) Respondent asserts that an *Althen* analysis is not possible without the

identification of a specific injury. (*Id*. at 13.) Respondent argues that it is not appropriate for a special master to take judicial notice of a Table Injury in order to establish a causal theory for causation-in-fact. (*Id*. at 14 (citing *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992)).) Respondent contends that the medical literature cited by Dr. Srikumaran does not preponderantly establish a causal theory. (*Id*. at 16-17.) Regarding the logical sequence of cause and effect under *Althen* prong two, respondent contends that petitioner's own clinical course is not consistent with the theory Dr. Srikumaran described, especially given the lack of any diagnosed shoulder pathology and in the presence of other conditions as explained by Dr. Abrams. (*Id*. at 17-22.) With regard to *Althen* prong three, respondent contends that when distinguishing petitioner's arm pain from her shoulder pain, there is not preponderant evidence that her shoulder pain as opposed to arm pain began within 48 hours of her vaccination. (*Id*. at 23-24.)

c. Petitioner's Reply

In response to respondent's position, petitioner suggests that "there is no dispute that petitioner has been diagnosed with cervical radiculopathy, fibromyalgia, and cervical spondylosis. The legal issue is whether these centrally mediated pain syndromes are the *source* of petitioner's shoulder symptomology." (ECF No. 74, p. 2 (emphasis in original).) "Given petitioner's striking symptoms and the close temporal association between those symptoms and her vaccination, a SIRVA injury is the most logical conclusion." (*Id*. at 3.) Petitioner also provides further detail as to why her view of the record evidence contrasts with that of respondent and supports her burden of proof. (*Id*. at 3-10.)

VI. Discussion

a. Table SIRVA

i. Petitioner is required to show there is no history of pain, inflammation, or dysfunction of the affected shoulder

Although respondent does raise petitioner's diagnoses of cervical disc degeneration and fibromyalgia as relevant preexisting conditions that explain petitioner's post-vaccination presentation (ECF No. 70, p. 9), these conditions do not represent prior inflammation or dysfunction of the shoulder itself. Nor does respondent offer any evidence that petitioner ever presented with specific complaints of shoulder pain related to these conditions prior to vaccination. Accordingly, petitioner has satisfied the first SIRVA criterion.

ii. Petitioner is required to show that the pain occurred within the specified timeframe

The specified timeframe on the Vaccine Injury Table for SIRVA is 48 hours post-vaccination. 42 CFR § 100.3(a). Petitioner argues the immediate post-vaccination

onset of her shoulder pain is clear. (ECF No. 64, pp. 8, 23.) Respondent argues that petitioner suffered immediate arm pain, but not necessarily shoulder pain. (ECF No. 70, pp. 23-24.) Respondent's hesitation in equating arm and shoulder pain is understandable in this case given Dr. Birdsong's subsequent diagnosis of myositis. However, when petitioner first presented for care, it was documented that she had been experiencing five weeks of "left-sided shoulder and arm pain." (Ex. 2, p. 5.) This places the onset of both arm and shoulder pain at the origin of her condition. Although her affidavit only specifies "deltoid" pain as of the day of her vaccination (Ex. 7, p. 1), I am not persuaded that the affidavit contradicts this initial treatment record. Petitioner again attributed the onset of shoulder pain to her vaccination when seeking treatment with Dr. Birdsong's office and Dr. Drabicki. (Ex. 5, p. 7; Ex. 9, p. 1.) Thus, considering the record as a whole, petitioner has satisfied the second SIRVA criterion.

iii. Petitioner is required to show that the pain and reduced range of motion are limited to the shoulder

With regard to the third SIRVA criterion, petitioner stresses that the government addressed this QAI criterion in response to public comment. (ECF No. 64, n. 1 (quoting 82 Fed. Reg. 6294 (Jan. 19, 2017)).) For clarity and context, the comment summary and response are worth quoting in full:

> Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.
>
> Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

82 Fed. Reg. 6294, 6296.

As I have indicated in prior cases, the government's comment response reveals that the third SIRVA criterion is intended to ensure that SIRVA claims are limited to

instances in which "*the condition* is localized to the shoulder in which the vaccine was administered" (emphasis added). Thus, it is clear that the gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder. *Grossman v. Sec'y of Health & Human Servs*., No. 18-13V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022). The Chief Special Master has reached the same conclusion on multiple occasions. *E.g., Cross v. Sec'y of Health & Human Servs*., No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023) (finding that "despite the notations of pain extending beyond the shoulder, Petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology"); *K.P. v. Sec'y of Health & Human Servs*., No. 19-65V, 2022 WL 3226776, at *8 (Fed. Cl. Spec. Mstr. May 25, 2022) (holding that "claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body"); *Werning v. Sec'y of Health & Human Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QIA criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder")

Petitioner argues that Dr. Srikumaran's opinion in this case is compatible with the above-quoted public comment response and consistent with prior cases that have allowed SIRVA claims even where there are some symptoms beyond the shoulder itself. I cannot agree.

Petitioner's medical records clearly document that she had both pain and sensory symptoms extending from her neck to her hand and that these were prominent symptoms at both her initial and final presentations. (Ex. 2, p. 5 (reporting "arm pain with radiculopathy and numbness radiating into her left hand" and also that "the left side of her neck [has] begun to hurt as well"); Ex. 9, p. 1 (reporting pain that "radiates at times down from the neck all the way down into the hand").) These symptoms were contemplated by her treating physicians in attempting to arrive at a unifying diagnosis for her condition and, as respondent stresses, there was not ultimately any confirmed final diagnosis of a shoulder joint pathology. In particular, Dr. Drabicki, the final treating physician to assess petitioner's overall history, never cleared a cervical etiology for petitioner's condition from his differential diagnosis and, in fact, appeared to view a cervical etiology either as more likely or as the major part of a multifactorial condition. (Ex. 9, pp. 1-3.) Thus, this is not a case where the medical records reflect that the symptoms beyond the confines of the shoulder are incidental to what was otherwise clearly treated as a shoulder injury.

In that context, Dr. Srikumaran himself further opines on petitioner's behalf that her cervical signs and symptoms at a minimum "complicate" her diagnosis (Ex. 19, p. 1), but also suggests that the shoulder pathology he opines is present either "activated" or "exacerbated" her degenerative disc condition itself by causing spasming in the muscles extending beyond the shoulder to connect the shoulder and neck (Ex. 19, pp.

3, 5; Ex. 28, p. 4). Thus, Dr. Srikumaran acknowledges a clear role for cervical involvement in petitioner's relevant clinical history. That is, he essentially confirms that he cannot fully explain petitioner's presenting symptoms without invoking her cervical disc degeneration in addition to the shoulder pathology he proposes. Dr. Abrams, for his part, contends that the cervical condition is actually the more likely explanation for the shoulder pain itself. (Ex. D, p. 2.) For these reasons, petitioner has neither established that her outward symptoms of pain and reduced range of motion were strictly limited to the affected shoulder nor alternatively established that the etiology of her condition was nonetheless confined to her shoulder consistent with the above-cited caselaw.

Petitioner argues in effect that she has satisfied the third SIRVA criterion because Dr. Srikumaran opined that her neck complaints were later sequela of the initial shoulder injury rather than directly caused by the vaccine; however, I do not see how this helps petitioner satisfy her burden of proof given the actual language of the QAI. In particular, although prior decisions have indicated that some incidentally reported symptoms beyond the confines of the shoulder may not be dispositive of the nature of the petitioner's injury, the above-quoted comment response confirms that the Secretary was prompted to consider the suggestion of broadening the QAI criteria to include "the shoulder and other parts of the body attributed to that injury," but rejected that comment and maintained the originally proposed QAI language. It is difficult to see how this does not directly answer the argument petitioner advances here.

It is also important to note on this point that the purpose of the SIRVA criteria, and the QAI overall, is not to identify every case that may conceivably be vaccine-caused, but to identify cases that are sufficiently uncontroversial as to warrant a presumption of vaccine causation. Just because petitioner had shoulder pain following vaccination does not mean that her shoulder pain warrants a presumption of vaccine causation given her overall clinical presentation. This is the case with many other Table injuries as well – not every patient diagnosed with a condition listed on the Injury Table will necessarily meet the specific QAI limitations for that condition. *See, e.g.*, *Nuttall v. Sec'y of Health & Human Servs.*, No. 07-810V, 2015 WL 691272, at *10 (Fed. Cl. Spec. Mstr. Jan. 20, 2015) (declining to accept proposed rulemaking as the Table definition of "encephalitis" because QAI definitions are often narrower than the commonly accepted medical definitions), *mot. rev. denied*, 122 Fed. Cl. 821, *aff'd*, 640 Fed. App'x 996 (Fed Cir. 2016).

Thus, considering the record as a whole, petitioner has not satisfied the third SIRVA criterion.

iv. Petitioner is required to show that no other condition or abnormality is present that would explain the petitioner's symptoms

With regard to the fourth SIRVA criterion, petitioner's claim fails for reasons very similar and closely related to the issues discussed with respect to the third criterion. The fourth criterion requires that "[n]o other condition or abnormality is present that

would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 CFR § 100.3(c)(10)(iv).

Petitioner characterizes the issue as whether the "mere presence" of cervical degeneration defeats petitioner's claim, thereby suggesting a danger that scores of older individuals suffering asymptomatic spinal disc degeneration would be needlessly precluded from pursuing SIRVA claims. (ECF No. 64, p. 10.) However, that is clearly *not* the context of this case. Dr. Srikumaran has explicitly acknowledged that in this petitioner's case there is actual clinical evidence of radiculopathy rather than merely evidence of degeneration on imaging (Ex. 19, p. 4) and further that it constitutes at least part of the explanation for her overall presenting symptoms (*id*. at 4-5). Thus, it is not the mere presence of *asymptomatic* cervical radiculopathy that defeats this petitioner's Table claim.

Nonetheless, petitioner argues that this clinical evidence of radiculopathy documented in the medical records and acknowledged by her expert only defeats her Table injury claim if it is the "better" or "more likely" explanation for her own symptoms. (ECF No. 64, p. 12.) However, petitioner's framing of SIRVA criterion four, while not *per se* incorrect, may have the effect of obscuring her actual burden of proof as a matter of emphasis. In order to benefit from a causal presumption as provided by the Vaccine Injury Table, petitioner must prove by preponderant evidence that her injury fits the Table definition of that injury. §300aa-13(a); §300aa-11(c). Thus, under the specific language of the fourth QAI criterion for SIRVA, petitioner herself bears a burden of establishing that any clinical evidence of cervical radiculopathy that is present is not meaningful to the existence of her symptoms. That, is, she must prove by preponderant evidence either (a) that her history is entirely free of, for example, clinical evidence of radiculopathy, or (b) if not, that the radiculopathy would not explain her symptoms. Regarding part (a), not even petitioner herself argues that her history is entirely free of clinical evidence of cervical radiculopathy. (ECF No. 74, p. 2; Ex. 19, pp. 4-5.) Regarding part (b), petitioner's treating physicians never ruled out cervical radiculopathy as a cause of her shoulder pain (Ex. 9) and respondent's expert affirmatively opines that her cervical condition is the best explanation of her shoulder pain given the total clinical picture (Ex. D, p. 2).

On petitioner's behalf, Dr. Srikumaran initially sought to focus on evidence of shoulder pathology, but then when pressed by my prior orders to address whether the evidence of clinical radiculopathy confounded his analysis, he was likewise compelled to incorporate cervical radiculopathy into his overall assessment of petitioner's clinical presentation rather than being able to deny that it is causally relevant to that presentation. (Ex. 19.) Thus, even petitioner's own expert opines that the cervical radiculopathy is an integral part of the overall clinical presentation for which she was seeking treatment and is alleging to have been vaccine-caused. (Ex. 19, pp. 3, 5; Ex. 28, p. 4.) Although Dr. Srikumaran cites signs of impingement as indicators that at least some of petitioner's pain nonetheless originated in her shoulder, Dr. Abrams explains these signs are nonspecific and not entirely reliable (Ex. D, pp. 1, 4), and Dr. Srikumaran does not dispute that cervical radiculopathy can cause shoulder pain.

Whereas the first SIRVA QAI criterion addresses any history of "pain, inflammation or dysfunction of the affected shoulder," the second criterion requires a particular onset of "pain" specifically, and the third criterion addresses only "pain and reduced range of motion," the fourth criterion addresses unspecified "symptoms" more broadly. Additionally, the examples of relevant conditions provided with the fourth criterion include "clinical evidence of" radiculopathy etc. 42 CFR § 100.3(c)(10). This suggests both that the fourth criterion requires a holistic examination of a petitioner's complete clinical presentation, and that this presentation may be explained by clinical evidence of neuropathies that falls short of a confirmed diagnosis. And, again, it is petitioner herself that bears the burden of showing that any evidence of radiculopathy is not meaningful. Thus, I am not persuaded by petitioner's contention that she can satisfy the fourth SIRVA criterion by having her expert, in effect, cherry pick evidence of shoulder pathology out of an overall clinical presentation he otherwise acknowledges to be complicated by a cervical radiculopathy that he agrees is present. But in any event, even accepting *arguendo* Dr. Srikumaran's approach to SIRVA criterion four, his opinion would still be less persuasive when compared against the medical treatment records and Dr. Abrams's competing opinion. (In that regard, see also the discussion of cervical versus shoulder pathology under *Althen* prong two below.)

Balancing all of these considerations, petitioner has not met her own burden under SIRVA QAI criterion four of eliminating her cervical radiculopathy as causally relevant to her symptoms. Petitioner correctly argues that the fact that a patient has a neurologic condition, such as a neuropathy or radiculopathy, does not mean they cannot also suffer a vaccine-caused shoulder injury. (ECF No. 64, p. 12.) However, as explained above, it is simply not the case that every person suffering shoulder pain will benefit from a Table presumption of vaccine causation based on their overall clinical history. Claims involving shoulder pathology in the presence of significant and potentially confounding neurologic signs and symptoms are better addressed on a causation-in-fact basis. The fact that Dr. Srikumaran proposes some explanation for the co-occurrence of cervical and shoulder symptoms in this case does not suggest otherwise.[11]

In the cause-in-fact context, petitioner's claim can more appropriately be assessed based on an affirmative showing of a logical sequence of cause and effect

[11] In the interest of completeness, I note that in *Lang v. Secretary of Health & Human Services*, I indicated that "respondent does not defeat petitioner's claim simply by noting the presence of shoulder dysfunction beyond deltoid bursitis" and further required that the condition raised by respondent "wholly explain [petitioner's] symptoms independent of vaccination" before it would defeat petitioner's Table SIRVA claim. No. 17-995V, 2020 WL 7873272, at *12-13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020). The *Lang* case, however, presented a different context. In *Lang*, respondent argued that petitioner did not suffer a Table SIRVA because she had underlying degenerative changes within the shoulder joint itself; however, respondent's SIRVA rulemaking specifically confirms that SIRVA was intended to capture a broad range of musculoskeletal shoulder injuries without specificity. *Id*. I explained that "[i]n presenting her *prima facie* case under the Vaccine Injury Table, petitioner does not bear any burden of proving causation generally or to show that her shoulder pathology can be directly related to her vaccination as causal. It would be incompatible with the very idea of the Vaccine Injury Table to hold petitioner to a burden of proving causation to establish a Table Injury." *Id*. at n.9. That concern is not implicated in this case.

between her vaccination and a shoulder pathology, balanced against the confounding signs and symptoms, rather than on the process-of-elimination type showing inherent to a Table SIRVA. This is how I have approached prior cases. *Accord Layne v. Sec'y of Health & Human Servs*., 18-57V, 2022 WL 3225437 (Fed. Cl. Spec. Mstr. July 12, 2022) (ruling in petitioner's favor on cause-in-fact, but explaining in the Table context that there is "significant evidence that one or both of petitioner's diagnosed cervical radiculopathy and/or suprascapular neuropathy presented as comorbid conditions that contributed to petitioner's overall presentation" thereby preventing petitioner from satisfying SIRVA QAI criteria three and four); *Colbert v. Sec'y of Health & Human Servs.,* No. 18-166V, 2022 WL 2232210 (Fed. Cl. Spec. Mstr. May 27, 2022) (finding sufficient evidence of radiculopathy to prevent petitioner from relying on a Table SIRVA while finding sufficient evidence of vaccine-caused shoulder pathology to support causation-in-fact). *But see Truett v. Sec'y of Health & Human Servs*., No. 17-1772V, 2022 WL 17348386 (Fed. Cl. Spec. Mstr. Nov. 1, 2022) (finding cervical radiculopathy the most likely explanation under either a Table or cause-in-fact analysis).

Thus, considering the record as a whole, petitioner has not satisfied the fourth SIRVA criterion.

b. Causation-in-Fact

Causation-in-fact is determined by the three-part *Althen* test. Under the first *Althen* prong, petitioner must present a general medical theory explaining that the vaccine in question "can" cause the type of injury in question. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Under the second and third prongs, petitioner must present evidence that the vaccine "did" cause petitioner's own injury. *Id*. The third prong asks whether the timing of injury in this specific case aligns with what would be expected under the general theory presented under *Althen* prong one. *Id.* at 1358. The second *Althen* prong examines the petitioner's own medical history to see if a logical sequence of cause and effect exists to support vaccine causation. *Althen*, 418 F.3d at 1278.

i. *Althen* Prong One

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and

reliable.'" *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen*, 35 F.3d at 548-49).

In this case, Dr. Srikumaran's theory of causation has two parts. First, he opines that overpenetration of an injection needle in or around the bursa can result in a prolonged inflammatory reaction that can cause painful bursitis and/or development of adhesive capsulitis or otherwise cause previously asymptomatic shoulder pathology to become painful. (Ex. 19, pp. 4-5; Ex. 12, p. 6.) Second, he opines that individuals suffering shoulder pain can sometimes adjust their posture in such a way that they aggravate preexisting cervical spine degeneration to provoke symptoms of cervical radiculopathy. (*Id*.) Based on my review of the record as a whole, I conclude that petitioner has preponderantly established a theory sufficient to demonstrate under *Althen* prong one that both of these things *can* happen.

With regard to the first part of Dr. Srikumaran's theory, petitioner requested that I take judicial notice of the Table Injury of SIRVA in satisfaction of her *Althen* prong one burden. (ECF No. 64, pp. 21-22.) Citing Federal Circuit precedent in *Grant v. Secretary of Health & Human Services*, respondent argues that "SIRVA" is merely a term of art derived from his regulatory rulemaking and that such judicial notice is impermissible as support for a cause-in-fact theory. (ECF No. 70, p. 14 (citing 956 F.2d 1144, 1148 (Fed. Cir. 1992)).) In contrast, petitioner cites several prior decisions from other special masters that she asserts have done just that. (ECF No. 64, pp. 21-22.) Specifically, special masters have observed with regard to SIRVA that "the very decision to add a claim [to the Vaccine Injury Table] reflects Respondent's determination that valid science supports revising the Table." *E.g.*, *L.J. v. Sec'y of Health & Human Servs*., No. 17-59V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021).

It is not necessary to resolve this question in this case, because Dr. Srikumaran does base his theory on the ability of a vaccine to cause specific inflammatory conditions such as bursitis or adhesive capsulitis and I conclude that this theory of causation is preponderantly established regardless of respondent's rulemaking based on the record evidence. However, I have cited approvingly to respondent's reliance on the *Grant* precedent in prior cases and noted the importance of not allowing a cause-in-fact analysis to merely constitute a broadening of the causal presumption available to Table SIRVA claimants. *E.g.*, *Layne*, 2022 WL 3225437, at *18. Thus, even if taking judicial notice of the existence of the Table SIRVA Injury under *Althen* prong one, respondent's contention that petitioner must base her claim on a specific shoulder injury in order to prevail would still have relevance with respect to *Althen* prong two given that petitioner must show under that analysis that petitioner's own medical history demonstrates that the vaccine did cause an injury consistent with what Dr. Srikumaran has theorized.

ii. *Althen* Prong Three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. 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). For the same reasons as discussed with regard to the timing element of petitioner's alleged Table injury, I am also persuaded that the onset of petitioner's alleged post-vaccination shoulder pain occurred within a timeframe consistent with petitioner's theory.

iii. *Althen* Prong Two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1280) (stating that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'"). However, medical records and/or statements of a treating physician's views 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* Section 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) (stating that "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"). Ultimately, petitioner may support her claim either through her medical records or by expert opinion. § 300aa-13(a)(1).

Although this petitioner has satisfied *Althen* prongs one and three, the Federal Circuit has cautioned that the second *Althen* prong "is not without meaning." Satisfying *Althen* prongs one and three generally serves largely as a threshold demonstration that a petitioner's claim is even possible. The Court explained that

> There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Capizzano, 440 F.3d at 1327 (emphasis in original). Thus, it is well established that in terms of demonstrating specific causation, temporal association alone is not enough to satisfy petitioner's burden of proof. *See*, *e.g.*, *Veryzer v. Sec'y of Health & Human*

Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury"); *A.Y. by J.Y. v. Sec'y of Health & Human Servs.*, 152 Fed. Cl. 588, 595 (2021); *Forrest v. Sec'y of Health & Human Servs.*, No. 10-032V, 2017 WL 4053241, at *18 (Fed. Cl. Spec. Mstr. Aug. 10, 2017); *Cozart v. Sec'y of Health & Human Servs.*, No. 00-590V, 2015 WL 6746616, at *18 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), *aff'd*, 126 Fed. Cl. 488 (2016); *Crosby v. Sec'y of Health & Human Servs.*, No. 08-799V, 2012 WL 13036266, at *37 (Fed. Cl. Spec. Mstr. June 20, 2012).

Here, the initial part of Dr. Srikumaran's theory is predicated on the existence of an inflammatory reaction affecting the internal structures of the shoulder contiguous to the bursa. (Ex. 12, p. 6 (citing Marko Bodor & Enoch Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 VACCINE 585 (2007) (Ex. 16); S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049 (2010) (Ex. 14)).) However, petitioner's treatment history was not robust, and her treating physicians did not reach clarity regarding the nature of her condition. Moreover, because petitioner sought only limited treatment, there are limited objective findings to rely upon. In particular, there is no evidence petitioner ever pursued the shoulder and spinal MRIs recommended by Dr. Drabicki to narrow his differential diagnosis. (Ex. 9.) Thus, while there are some *potential* signs of shoulder pathology discussed further below, there is very little by way of diagnosis available to preponderantly support a shoulder pathology of the type implicated by the first part of Dr. Srikumaran's medical theory. In fact, those diagnoses that were strongly considered by the treating physicians mostly do not comport with Dr. Srikumaran's theory. Specifically:

- When petitioner first presented to the emergency department, Dr. Snatchko suspected a neurologic condition, likely involving the cervical spinal root. (Ex. 2, p. 8.)

- When petitioner followed up with Dr. Birdsong, he diagnosed myositis, which is inflammation of the muscle rather than the joint. (Ex. 11, p. 1.) Although Dr. Srikumaran opined that this could constitute a relevant condition isolated to the shoulder (Ex. 12, p. 5), Dr. Abrams is persuasive in explaining that it does not point to any suspicion of the type of synovial inflammation that underlies Dr. Srikumaran's theory (Ex. A, p. 8).

- I agree with petitioner that Dr. Hagerty's later diagnosis of fibromyalgia did not subsume her separate left arm pain; however, nothing in Dr. Hagerty's record is any more specific than to note that petitioner had left arm pain evidenced by subjective report as well as tenderness "over the left lateral arm along her deltoid musculature." (Ex. 5, p. 15.) The focus on arm pain is consistent with the prior myositis diagnosis and no specific exam finding or diagnosis otherwise implicated the shoulder joint.

- Well into petitioner's treatment history, Dr. Birdsong's Physician's Assistant added tendonitis of the long head of the biceps to petitioner's

diagnostic assessment. (Ex. 11, p. 3.) This is the only diagnosis petitioner ever received that might generally be viewed as consistent with SIRVA. (*See* Elisabeth M. Hesse et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner Claims to the National Vaccine Injury Compensation Program 2010–2016*, 38 VACCINE 1076, 1080, Tables 4-5 (2020) (Ex. 22) (noting 6.5% of examined SIRVAs had bicep tendon findings on MRI, though biceps tendonitis does not appear on the list of initial diagnoses). However, this assessment was never repeated.

- Dr. Drabicki subsequently indicated that impingement syndrome could be a possibility, but only within the context of a differential diagnosis including several neurologic conditions and further indicating that "[m]y suspicion is she may have some radicular issues due to the arthrosis in the cervical spine and therefore pain may be multifactorial in nature." (Ex. 9, p. 3.) He did specifically include cervical spondylosis in his impression, but only otherwise included unspecified "pain in the left shoulder" in the impression. (*Id*. at 2.)

"[I]n patients with concomitant radiculitis and shoulder disease, signs of both disorders may coexist. The clinician must determine which symptoms are predominant in the patient's presentation." (Manifold & McCann, *supra*, at Ex. 25, p. 108.) While there is no question that there are conflicting indicators with regard to a spinal versus shoulder etiology, Dr. Srikumaran's willingness to accept the limited signs and symptoms of a shoulder pathology as dispositive is less persuasive than Dr. Abrams's suggestion that they are too non-specific to demonstrate a distinct shoulder injury in this overall clinical presentation, especially in light of the diagnoses favored by the treating physicians. The indicators Dr. Srikumaran sees for a shoulder pathology focus in substantial part on the presence and character of petitioner's deltoid and shoulder pain along with limited range of motion and Neer and Hawkins impingement signs. (Ex. 19, p. 4.) However, without entirely discounting the clinical value of these findings, they are far less specific to a shoulder pathology than are those competing signs and symptoms that both experts point to as exclusively indicative of a cervical spinal condition. (Ex. 19, pp. 4-5; Ex. C, p. 2; Ex. D, pp. 1-2.)

It is true that patients with cervical spinal conditions generally will not have point tenderness over the shoulder (Manifold & McCann, *supra*, at Ex. 25, p. 107); however, the significance of the tenderness to palpation findings is tempered by the fact that petitioner has two diagnoses – fibromyalgia and myositis – that could explain that tenderness without implicating the type of inflammatory shoulder joint pathology Dr. Srikumaran theorizes. It is also the case that cervical spinal spondylosis can cause myelopathy in addition to radiculitis. (Manifold & McCann, *supra*, at Ex. 25, p. 107.) Additionally, Dr. Abrams opines that the signs of impingement are nonspecific. (Ex. D, p. 1.) In fact, Dr. Srikumaran himself acknowledges that "[i]n more diagnostically complex cases, patients with cervical pain may have positive provocative test results." (Ex. 19, p. 3 (quoting Bokshan, et al., *supra* at Court Ex. I).) While Dr. Srikumaran clearly offers this statement for the proposition that neck pain can be referred from the

shoulder, he cites literature by Manifold and McCann that also explains that individuals with cervical spinal radiculitis originating at the fifth or sixth cervical roots can present with abduction and external rotation findings similar to a rotator cuff tear because nerve roots at that level innervate the musculature of the cuff and deltoid. (Manifold & McCann, *supra*, at Ex. 25, p. 108.) The record is also clear that petitioner's later positive Spurling test and prominent symptoms of numbness and tingling extending to her fingers are indicative only of a cervical etiology. (Ex. 2; Ex. 9; Ex. 19, pp. 4-5; Ex. C-D.) Moreover, all of this correlates to her cervical spinal X-ray that showed degenerative changes at the C6-7 level and which constitutes the only available objective imaging even potentially suggestive of the etiology of petitioner's condition. To the extent these cervical spine symptoms were not consistently reported, the medical literature confirms that the symptoms of spondylotic cervical radiculitis are generally episodic and with no precipitating event. (Manifold & McCann, *supra*, at Ex. 25, p. 106.)

I do acknowledge that, consistent with Dr. Srikumaran's theory, when petitioner first presented for care she reported that "she believes due to compensating for her arm pain her shoulder and left side of her neck have begun to hurt as well." (Ex. 2, p. 5.) Importantly, however, at the time of her first encounter her cervical spinal symptoms were prominent. Moreover, the assessment from that encounter still favored a cervical etiology for petitioner's condition despite that reported history. (Ex. 2, p. 8.) Nor did any of petitioner's other treating physicians ever offer an opinion reflective of Dr. Srikumaran's two-part theory. And in any event, absent persuasive evidence to support the first part of Dr. Srikumaran's theory, the second part of this theory does not serve to implicate petitioner's vaccination in her condition even if her cervical spinal degeneration was somehow interrelated with a shoulder injury. I have previously observed that some SIRVA claims will present the difficult situation of pitting a clear perception by the petitioner of vaccine-related pain against a confounding medical history that leaves that perception unlikely to be accurate. *Truett*, 2022 WL 17348386, at *15. In that context, as unsatisfying as it may be to accept the presence of a coincidence, a cause-in-fact claim requires petitioner to do the "heavy lifting" of affirmatively proving, *inter alia*, a logical sequence of cause and effect demonstrating petitioner's vaccination to have been the cause of her injury. *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (indicating that in the absence of a Table Injury, "the heavy lifting [of proving causation] must be done by the petitioner, and it is heavy indeed"); *see also Althen*, 418 F.3d at 1280 (clarifying that "heavy lifting" characterizes the preponderant evidence standard and not any heightened burden of proof.) Here, for all the reasons discussed above, she has not done so.

VII. 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 either that her December 30, 2016 flu vaccination resulted

in a Table SIRVA or alternatively caused-in-fact a shoulder injury. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.[12]

IT IS SO ORDERED.

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

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