In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-478V
Filed: November 1, 2019
PUBLISHED

ADINA SMALL,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Dismissal; Ruling on the Written Record; Influenza (flu) Vaccine; Shoulder Injury Related to Vaccine Administration; SIRVA; Injection Injury; Direct Nerve Trauma

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Lynn Christina Schlie, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On May 11, 2015, petitioner, Adina Small, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that she suffered a Shoulder Injury Related to Vaccine Administration or "SIRVA" caused-in-fact by her February 12, 2013 influenza ("flu") vaccination. A SIRVA is a musculoskeletal, rather than neurological, injury manifesting as shoulder pain and reduced range of motion. *E.g.* 42 C.F.R. §100.3(c)(10). Subsequently, however, although she did not amend her petition, petitioner later submitted expert opinion indicating that petitioner's shoulder injury was a direct result of a nerve injury. For the reasons set forth below, I conclude that petitioner is not entitled to an award of compensation under either theory.

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

[2] Throughout this decision all references to "§ 300aa-" refer to specific sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Procedural History

As noted above, petitioner commenced this action on May 11, 2015, alleging that she suffered a SIRVA in her left shoulder that was caused-in-fact by her February 12, 2013 flu vaccination. (ECF No. 1.) Based on the allegations in the petition, the case was assigned to the Special Processing Unit ("SPU"). (ECF No. 5.) The SPU "is designed to expedite the processing of claims that have historically been resolved without extensive litigation." (*Id*. at 1.) Cases assigned to the SPU remain on the Chief Special Master's docket.[3]

Initially, petitioner supported her petition with medical records marked as Exhibits 1-14 and affidavits marked Exhibits 15-17. (ECF Nos. 6-8.) A statement of completion was filed on May 18, 2015. (ECF No. 9.)

Respondent filed a Rule 4 Report on September 15, 2015. (ECF No. 16.) Respondent recommended against compensation, noting (1) there is no contemporaneous medical documentation demonstrating that petitioner received the flu vaccination in her left arm; (2) petitioner received both a vaccine covered by this program (flu) and a non-covered vaccine (shingles) at the same time and the vaccination record does not identify the site of either vaccination; (3) petitioner did not report her alleged vaccine-caused shoulder pain until ten months after her vaccination despite seeing her primary care doctor twice during that period; (4) petitioner had a years-long history of recurring neck pain radiating to both extremities; and (5) petitioner was diagnosed by a neurologist as having neuritis, which is not consistent with SIRVA. (*Id*. at 8-9.)

Within the SPU, the Chief Special Master held a Rule 5 status conference[4] to provide the parties with her preliminary assessment. (ECF No. 24.) The Chief Special Master preliminarily found preponderant evidence that petitioner received her February 12, 2013 flu vaccine in her left arm and that her flu vaccine was a more likely cause of her injury than her shingles vaccine. (*Id*. at 1-2.) She also noted that petitioner had provided evidence of an extenuating circumstance that could explain petitioner's delay in seeking treatment. (*Id*. at 2.) For this reason, she felt that respondent maintained litigative risk, suggesting an onset ruling could potentially favor petitioner. (*Id*.) Nonetheless, the Chief Special Master cautioned that petitioner also maintained litigative risk due to her diagnosis of neuritis, her history of cervical pain, and references in her medical records to a possible lifting injury. (*Id*.)

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[3] At the time this petition was filed, the Chief Special Master was Denise Vowell. (ECF Nos. 4-5.) However, shortly after the case was filed, Nora Beth Dorsey became Chief Special Master and the case was reassigned to her docket. (ECF No. 14.)

[4] Vaccine Rule 5 provides that following respondent's filing of his report setting forth his position regarding entitlement (in accordance with Vaccine Rule 4), the special master may hold a status conference to "(1) afford the parties an opportunity to address each other's position; (2) review the materials submitted and evaluate the parties' respective positions; and (3) present tentative findings and conclusions." Vaccine Rule 5(a). Such findings are not final; rather, the conference allows the special master the opportunity to "issue a scheduling order outlining the necessary proceedings for resolving the issues presented in the case." Vaccine Rule 5(b).

Following the Chief Special Master's review, respondent confirmed that he intended to continue defending the case. (ECF No. 26.) As a result, the case was removed from the SPU and reassigned to Special Master Millman on April 27, 2016. (ECF No. 28.)

On May 17, 2016, Special Master Millman held a status conference with the parties in which she reviewed petitioner's medical records and concluded that petitioner did not suffer a SIRVA, but agreed to allow petitioner the opportunity to file an expert report from a neurologist. (ECF Nos. 29, 31.) In a subsequent status report, however, petitioner expressed concern that Special Master Millman's impression of the case was in contrast to the Chief Special Master's prior preliminary findings which were suggestive of a SIRVA. (ECF No. 30.)

On June 29, 2016, Special Master Millman issued an order addressing petitioner's concern and explaining at length why petitioner's injury does not constitute a SIRVA. (ECF No. 31.) Following a comprehensive review of the medical records, Special Master Millman disagreed with the Chief Special Master's tentative conclusion regarding onset. (*Id.* at 2, 7.) She also stressed, as the Chief Special Master had observed, that petitioner's injury had been treated by a neurologist as a nerve injury rather than a musculoskeletal injury. (*Id*. at 2-3.) She recommended that petitioner either dismiss her claim or provide an opinion by a neurology expert supporting her claim. (*Id*. at 7.)

Subsequently, on August 23, 2016, petitioner filed a letter from her treating neurologist, Nicholas Szumski, M.D., marked as Exhibit 18. (ECF No. 33.) Dr. Szumski indicated that petitioner experienced a nerve injury to the lateral cutaneous nerve of the arm directly caused by her injection which led indirectly to "frozen shoulder."[5] (Ex. 18, pp. 1-2.) Special Master Millman subsequently required a supplemental report by Dr. Szumski which was filed as Exhibit 19 on November 11, 2016. (ECF Nos. 34, 36.)

On February 9, 2017, respondent filed a responsive expert report by neurologist Jeffrey Allen Cohen, M.D., marked as Exhibit A. (ECF No. 42-1.) Dr. Cohen opined that petitioner's clinical course is not consistent with the nerve injury proposed by Dr. Szumski, that the flu vaccination would be unlikely to cause such an injury, and that petitioner's course is instead consistent with her documented cervical and radicular symptoms. (Ex. A.)

On May 8, 2017, petitioner filed a second supplemental report by Dr. Szumski responding to Dr. Cohen's report (ECF No. 45-1; Ex. 20) and respondent filed a further report by Dr. Cohen on June 14, 2017 (ECF No. 48; Ex. C). Thereafter, on July 6, 2017, the parties requested a hearing. (ECF No. 49.)

[5] Frozen shoulder, or adhesive capsulitis, is an orthopedic condition of the shoulder characterized by pain and reduced range of motion. The condition can occur idiopathically, but has also been associated with vaccination and often appears as an underlying diagnosis in SIRVA claims. *See, e.g., Gurney v. Sec'y of Health & Human Servs.*, No. 17-481V, 2019 WL 2298790 (Fed. Cl. Spec. Mstr. Mar. 19, 2019).

Over the next four months the parties attempted, but failed, to set a hearing date. (ECF Nos. 49-51.) On November 20, 2017, Special Master Millman held a status conference to discuss the parties' difficulty setting a hearing date. (ECF No. 51.) The parties reported that they "are unable to set a date for an entitlement hearing because petitioner's expert Dr. Szumski cannot confirm a specific date in or after July 2019. Respondent's counsel does not want to move forward with scheduling a hearing without confirmation from petitioner's expert." (*Id*.) Special Master Millman warned that "[i]f the parties do not agree on a date for a hearing, there will be no progress in moving the case to conclusion." (*Id*.)

No further action was taken in the case for ten months. On September 6, 2018, Special Master Millman issued an order noting the parties' failure to act in the case for ten months and advising of her anticipated retirement. (ECF No. 52.) She informed the parties that "[w]hen this case is transferred to another special master upon the undersigned's retirement, the new special master will schedule a hearing date." (*Id*.)

Again, no further action was taken in the case until nine months later when it was reassigned to me following Special Master Millman's retirement. (ECF No. 56.) In light of the parties' apparent inability to timely set a hearing date, and upon my own review of the case, I informed the parties on June 24, 2019, that in accordance with Vaccine Rule 8(d) I intended to issue a decision based on the written record without holding a hearing and set a briefing schedule.[6] (ECF No. 57.)

On July 24, 2019, petitioner filed a brief supporting her claim. (ECF No. 58.) Respondent filed a response on August 22, 2019, and petitioner filed her reply on September 5, 2019. (ECF Nos. 59-60.) Accordingly, this case is now ripe for a decision regarding entitlement.

II. Factual History

a. As reflected in medical records

i. Prior history and pattern of care

Petitioner was born April 25, 1940. (*See, e.g.* Ex. 1, p. 1.) At the time of the vaccination that forms the basis of her petition, she was 72. (*Id.*) Petitioner's prior medical records before 2013 are mostly unremarkable for back or shoulder problems, but she did treat with a number of specialists.

[6] Upon review of this case and for all the reasons described herein, I determined that a hearing was not required to resolve the issues presented by the parties. Moreover, petitioner had a full and fair opportunity to present Dr. Szumski's opinion by filing three expert reports that clearly explain the basis for his opinion. (Exs. 18-20.)

Beginning with records in 2010, petitioner treated with urologist Dino Deconcini, M.D. (Ex. 6.) She described "kidney pains" throughout her adult life, but in February of 2010 reported "there has been increasing right flank pain recently associated with pelvic pressure and urinary frequency." (*Id*. at 1.) Dr. Deconcini felt petitioner's flank pain was likely chondritis,[7] but also noted, *inter alia*, "[b]ack pain – seems to be more musculoskeletal." (*Id*.) Following that assessment, she did not return to Dr. Deconcini until March of 2014. (Ex. 6, p. 7.) Petitioner also treated with a nephrologist. (Ex. 12.)

From 2011 through 2014, petitioner was followed by endocrinologist David Aftergood, M.D., for thyroid nodules. (Ex. 7.) She treated on multiple occasions with a dermatologist in 2011 and 2012. (Ex. 11.) Beginning in 2012, petitioner began seeing gastroenterologist Gil Melmed, M.D. (Ex. 8.) Petitioner also followed up regularly with her gynecologist. (Ex. 9.) None of these treatment records reflect any complaints of neck or shoulder pain and no indication of any relevant physical examination.

Petitioner was also followed regularly by Yaron Elad, M.D. at the Cardiovascular Medical Group of Southern California. (Ex. 2.) Notably, however, petitioner relied on Dr. Elad for the majority of her primary care in addition to her cardiovascular treatment.[8] Although Dr. Elad saw petitioner regularly for hypertension, hyperlipidemia, and chest pain (Ex. 2, pp. 17, 26, 29, 32, 37, 43), petitioner has an established pattern of treating with Dr. Elad for conditions unrelated to cardiology. For example, petitioner saw Dr. Elad multiple times in 2010 with a chief complaint of "green mucus." (Ex. 2, pp. 39, 41.) She has also presented on two separate occasions (in 2010 and 2015) for "cough." (*Id*. at 35, 51.)

Additionally, even when she has presented to Dr. Elad for cardiovascular issues, petitioner has discussed other, unrelated conditions. For example, in June of 2012, she presented with a chief complaint of hyperlipidemia, but indicated that her "[b]iggest problem has been with abdominal pain." (*Id*. at 17.) Petitioner's records reflect only one visit to an internist in March of 2014. (Ex. 10.) Significantly, as described in greater detail below, Dr. Elad was the first physician to whom she described the shoulder pain for which she seeks compensation. (Ex. 2, pp. 5-8.)

ii. Medical records immediately prior to vaccination

Approximately one month prior to her alleged injury-causing vaccination, on January 7, 2013, petitioner presented to her rheumatologist, Dr. Silverman, with a chief complaint of "one year history of neck pain right." (Ex. 13, p. 1.) She also complained of "feeling of ants on body" and "swelling of right posterior trunk." (*Id*.) Past medical

[7] "Chondritis" is inflammation of cartilage. Dorland's Illustrated Medical Dictionary ("Dorland's"), 32nd Ed., p. 352.

[8] In the petition, Dr. Elad is identified as petitioner's cardiologist. (ECF No. 1, p. 2.) In her affidavit, however, petitioner identified Dr. Elad as her primary care physician. (Ex. 15, p. 2.)

history noted "cervicalgia/neck pain" and displacement of an intervertebral disc without myelopathy.[9]

Consistent with the past medical history he recorded, Dr. Silverman assessed petitioner as having cervicalgia and displacement of an intervertebral disc without myelopathy. (Ex. 13, p. 2.) He recommended an x-ray and MRI of the cervical spine. (*Id*.) Petitioner had the recommended x-ray performed the same day and the MRI performed about a week later, on January 15, 2013. (*Id*. at 3-5.)

Petitioner's cervical x-ray showed discogenic disease at C3-4 and C6-7 as well as at C5-6, though to a lesser degree, characterized by decreased height of the disc space. (Ex. 13, p. 3.) Her MRI showed similar results. (*Id*. at 4-5.) The impression from the MRI was (1) "the patient has borderline developmental cervical spinal stenosis[10] and while she only has mild changes of cervical discogenic disease at C3-C4, C4-C5, C5-C6 and to a lesser degree C6-C7, there are mild degrees of cord effacement without evidence of cord signal alteration. There is little CSF space present about the cord from C3-C6;" and (2) "[r]ight C3-C4, left C4-C5, neural foraminal stenoses." (*Id*. at 4.) Notably, at the time of her MRI, petitioner's clinical information was reported as "[r]ecurring neck pain radiating to both upper extremities for many years. There is no history of trauma or surgery." (*Id*.)

Petitioner returned to Dr. Silverman on January 28, 2013. (Ex. 13, pp. 7-8.) Her chief complaint was right shoulder and right lower back pain.[11] (*Id*.) Dr. Silverman reviewed petitioner's MRI and added cervical spinal stenosis, lumbago, and "tender Right QL"[12] to petitioner's assessment. (*Id*. at 8.) At that time she also underwent testing for osteoporosis. (*Id*. at 10-15.)

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[9] "Myelopathy refers to "any of various functional disturbances or pathological changes in the spinal cord, often referring to nonspecific lesions in contrast to the inflammatory lesions of myelitis." Dorland's, 32nd Ed., p. 1220. Although the chief complaint indicated a one-year history, the past medical history listed the date of this exam (January 7, 2013) as the date of onset of these conditions. (Ex. 13, p. 1.) The source of the history is not indicated, but prior to that, petitioner was last seen by her rheumatologist on April 6, 2011. (*Id*. at 23.)

[10] "Stenosis" refers to an abnormal narrowing. Dorland's, 32nd Ed., p. 1769.

[11] Specifically, her record indicates "right sh and right LBP." (Ex. 3, p. 7.) "Sh" and "LBP" are common abbreviations for "shoulder and "low back pain" respectively. *See* Davis, N.M., Medical Abbreviations: 32, 000 Conveniences at the Expense of Communication and Safety, 15th Ed., pp. 186, 297.

[12] In light of the reference to lumbago, "QL" likely refers to quadratus lumborum, an abdominal muscle on either side of the lower back. "Lumbago" is a nonmedical term for any pain in the lower back. *See* Dorland's, 32nd Ed., p. 1076.

iii. Date of vaccination (February 12, 2013)

On February 12, 2013, petitioner returned to Dr. Silverman for a further follow up. (Ex. 13, pp. 16-17.) She also went to Rite Aid Pharmacy for vaccination. (Ex. 1.) The time of day for petitioner's encounter is not indicated in the records of either facility.[13]

Petitioner presented to Dr. Silverman with a chief complaint of "continued neck pain with stiffness, decreased [range of motion]." (Ex. 13, p. 16.) Petitioner was reportedly still symptomatic despite exercises and Aspercreme. (*Id*.) She was placed on Boniva for osteoporosis diagnosed at that visit. (*Id*.) Decreased range of motion in the neck was confirmed on physical exam. (*Id.*) Petitioner declined an injection to treat her neck pain. (*Id*. at 17.) Dr. Silverman recommended physical therapy and provided muscle relaxant. (*Id*.)

At Rite Aid, petitioner received both a Zostavax shingles vaccination and a Fluzone influenza vaccination. (Ex. 1, p. 2.) The influenza vaccine was administered intramuscularly while the shingles vaccine was administered subcutaneously. (*Id*.) The injection site is not listed for either vaccine. (*Id*.)

iv. Medical records immediately following vaccination

On February 13, 2013, the day after her vaccination, petitioner presented to Joint Effort Medical Wellness for physical therapy.[14] (Ex. 5, pp. 16-18.) At her initial evaluation, petitioner presented with a chief complaint of "severe pain c/s[15] [and] upper trapezius muscles and lumbosacral pain." (*Id*. at 16.) She rated her cervical pain as an "8/10" and her lumbar quadrant pain as "7/10." (*Id*.) Her past medical history indicates that she was generally healthy with hypertension under control. (*Id*.) In providing the history of her present complaint, however, petitioner reported that her cervical pain resulted from a strain she suffered lifting her husband, who was suffering Parkinson's disease. (*Id*.) Left upper extremity pain does appear among a list of four problem areas, but it is characterized as radicular pain. (*Id*. at 18.) Petitioner's vaccinations are not discussed in her physical therapy evaluation. Thereafter, petitioner attended physical therapy sessions through February and March of 2013 to improve cervical spine range of motion. (Ex. 5, pp. 10-16.)

On February 21, 2013, petitioner presented to Dr. Elad for a "follow up" visit. (Ex. 2, pp. 13-16.) Petitioner was noted to be "asymptomatic from a cardiovascular point of view," but she discussed the abdominal discomfort she had reported at her previous

[13] A subsequent VAERS report (as further described in Section II(a)(vi) below), drafted by the pharmacy more than a year after the vaccinations, indicates that they were administered at approximately 2:00pm. (Ex. 14.)

[14] This provider's records are all handwritten and are challenging to decipher.

[15] I interpret this abbreviation to refer to cervical spine. *See* Davis, N.M., Medical Abbreviations, 15th Ed., p. 94.

appointment with Dr. Elad in June of 2012. (*Id*.) Petitioner also reported back pain. (*Id*.) Petitioner did not report any shoulder pain at this visit. A review of symptoms recorded that petitioner was "negative for myalgias and joint pain" under musculoskeletal symptoms and musculoskeletal physical exam reflected "[n]ormal range of motion. She exhibits no edema." (*Id*. at 15.) Physical exam of the neck noted "[n]ormal range of motion. Neck supple. No JVD[16] present."[17] (*Id*.)

On August 1, 2013, petitioner followed up with her endocrinologist for a recheck of her thyroid nodules. She was asymptomatic. (Ex. 7, pp. 13-15.) There was no mention of petitioner's shoulder or neck conditions and no indication of any musculoskeletal physical exam. (*Id*.)

Petitioner returned to Dr. Elad on August 8, 2013. (Ex. 2, pp. 9-12.) As with her prior February 21, 2013 visit, her chief complaint for this visit was again listed as "follow up." (*Id*. at 9.) She was again noted to be asymptomatic with regard to her cardiovascular health, but discussed the stress caused by her husband's condition and the fact that she had a viral infection a few weeks prior. (*Id*.) She was noted to be "doing okay." (*Id*.) Again, no mention is made of any shoulder pain. As at the prior February 21, 2013 visit, a review of symptoms recorded that petitioner was "negative for myalgias and joint pain" under musculoskeletal symptoms and musculoskeletal physical exam reflected "[n]ormal range of motion. She exhibits no edema." (*Id*. at 11.) Physical exam of the neck noted "[n]ormal range of motion. Neck supple. No JVD present." (*Id*.)

v. First report and evaluation of post-vaccination shoulder pain

On December 12, 2013, ten months after receiving her vaccinations, petitioner returned to Dr. Elad and reported vaccine-related shoulder issues for the first time. (Ex. 2, pp. 5-8.) Similar to her prior visits, petitioner's chief complaint was listed only as "follow up" and she discussed a number of issues, including the passing of her husband two and a half months prior. (*Id*. at 5.) Her history indicates "[g]ot two vaccines at Rite-Aid last February and can't raise her arm since." (*Id*.) Her record still reflects a lack of musculoskeletal concerns – *i.e*. the review of symptoms recorded that petitioner was "negative for myalgias and joint pain" under musculoskeletal symptoms and musculoskeletal physical exam reflected "[n]ormal range of motion. She exhibits no edema." – however, Dr. Elad recommended that petitioner seek out a neurologist for "persistent pain, weakness in left arm." (*Id*. at 7-8.) Physical exam of the neck also noted "[n]ormal range of motion. Neck supple. No JVD present." (*Id*.)

About a month and a half later, petitioner presented to neurologist Nicholas Szumski, M.D., for the first time on January 29, 2014. (Ex. 3, pp. 2-3.) At that time, petitioner reported "[a]bout a year ago, got her flu and shingles va[ccinations] in L[eft]

[16] Especially given Dr. Elad's specialty, this likely refers to "jugular venous distention." *See* Davis, N.M., Medical Abbreviations, 15th Ed., p. 181.

[17] Of note, these reported findings regarding petitioner's neck and musculoskeletal symptoms appear verbatim across a number of encounters even when they appear inconsistent with Dr. Elad's more detailed notations.

shoulder at the same time and spot. Immediately had pain radiating down lateral upper arm, which she thought was normal at the time. Hasn't changed in the year since, maintaining an ovoid. Advil helps somewhat, but doesn't use it too often – just avoids tasks."[18] (*Id*. at 2.)

On general exam, Dr. Szumski observed "[t]ender to palpation along lateral upper arm with greatest focus just below lateral edge of proximal humerus within deltoid." (Ex. 3, p. 3.) Dr. Szumski noted "normal bulk throughout upper extremities" as well as "[f]ull 5/5 power demonstrated proximally and distally in upper extremities, including the L[eft] deltoid, but pain with abduction." (*Id*.) Based on the history of onset at the time of vaccination, Dr. Szumski concluded that "[o]nset and anatomy correlate strongly with injury to the lateral cutaneous nerve of the arm branching from the axillary nerve within the deltoid." (*Id*.) He diagnosed petitioner with "neuritis" and recommended physical therapy. (*Id*.)

Petitioner returned to Joint Effort Medical Wellness for physical therapy on February 3, 2014. (Ex. 5, p. 6.) She was evaluated for her left shoulder complaints, the pain from which she rated as "9/10." (*Id*.) She attended several physical therapy sessions related to her left shoulder through March 3, 2014. (*Id*. at 1-6.)

During this period, petitioner also presented to Wells Chiropractic Group on February 14, 2014, complaining of left deltoid and upper arm pain with limited movement. (Ex. 4, pp. 1, 5.) She attributed her condition to the flu and shingles vaccines she previously received at Rite Aid and rated her pain as "6" and "7" out of "10." (*Id*.) At this visit, petitioner was marked as having received both a chiropractic adjustment and acupuncture. (*Id*. at 1.) A notation regarding "call back" indicates that petitioner was contacted on February 19, 2014. (*Id*.) Petitioner's response to treatment is recorded as "complete ROM and relief of pain" and petitioner is quoted as having stated she is "Just fine! It's a miracle!" (*Id*.) Notably, however, petitioner's physical therapy records indicate at this time that, while she was progressing as expected, further treatment was warranted. (Ex. 5, p. 2.) Only as of March 3, 2014, did the physical therapist stop recommending further treatment. (*Id*. at 1.)

On March 10, 2014, petitioner visited an internist with a chief complaint of "cough." (Ex. 10, p. 1.) Petitioner made no report of her history of shoulder pain and no findings were reported on physical examination. (*Id*. at 2.) A chest x-ray was completed which showed no abnormalities. (*Id*. at 5.)

On March 13, 2014, petitioner returned to Dr. Szumski. (Ex. 3, pp. 1-2.) Dr. Szumski recorded an interval history indicating that petitioner discontinued physical therapy because it was very painful. (*Id*. at 1.) He recorded that the physical therapist

[18] Dr. Szumski's record indicates that petitioner also "filled out a 14-system review of systems checklist" that is not a part of the record of this case. (Ex. 3, p. 3.) The notation indicates, however, that "[p]ertinent positives and negatives are listed above in the history." (*Id*.)

suspected frozen shoulder.[19] (*Id*.) He also noted that petitioner reported "immediate improvement" after a single session of acupuncture. He noted that petitioner "[n]ow has been doing better, can do her [activities of daily living]." (*Id*.) Upon exam, Dr. Szumski recorded "[i]mproved L[eft] [active range of motion]. Still has focal tenderness on lateral upper arm just below shoulder." (*Id*.) Dr. Szumski's assessment remained neuritis, but he noted it to be "[m]arkedly improved at this point." He noted that petitioner "[m]ay continue acupuncture, PT when ready and needed" and recommended that petitioner return in three months. (*Id*. at 2.)

vi. VAERS report

On March 13, 2014, a Rite Aid Pharmacy employee completed a Vaccine Adverse Event Report System ("VAERS") report regarding petitioner's left shoulder condition. (Ex. 14.) That document describes her condition as follows: "Left arm-pain unbearable at time of injections. 2 months later still experiencing pain + unable to move arm." The form lists both the shingles and flu vaccines. (*Id*.)

vii. Subsequent history

On March 21, 2014, petitioner saw her urologist, Dr. Deconcini, for renal colic, hydronephrosis, and renal cyst. (Ex. 6, pp. 2-4.) She had a renal ultrasound performed. (*Id*. at 7.) No mention is made of petitioner's shoulder.

On June 6, 2014, petitioner returned to Dr. Elad for treatment of her hypertension. (Ex. 2, pp. 1-4.) She reported that Dr. Szumski had diagnosed her with neuritis and that physical therapy had been no help. (*Id*. at 1.) She reported, however, that acupuncture had provided immediate relief with only one treatment, though she still had some residual pain. (*Id*.) Neck and musculoskeletal findings were reportedly the same as during previous encounters. (*Id*. at 3.)

Petitioner returned to Dr. Elad on November 7, 2014, regarding dyslipidemia, and on January 26, 2015, regarding a cough. (Ex. 2, pp. 47-54.) Neither of these encounters include any notation regarding petitioner's left shoulder pain.

On March 4, 2015, petitioner returned to Dr. Elad to discuss her cardiac risk factors. (Ex. 2, pp. 55-58.) At that time, petitioner reported that she was experiencing right arm pain which she associated with her flu shot.[20] (*Id*. at 55.) Petitioner reportedly

[19] The record of petitioner's February 3, 2014 physical therapy evaluation includes a notation that appears to indicate "neg for frozen" under the heading of "MRI/X-ray." (Ex. 5, p. 6.) However, it is not clear to what imaging this notation could be referring. There are no imaging reports for petitioner's shoulder included in her medical records. The same record references "a moderate frozen shoulder" within the history of complaint section. (*Id*.)

[20] Dr. Elad's March 4, 2015 record does not indicate to which flu vaccination petitioner is referring. (Ex. 2, p. 55.) In her petition, petitioner asserts that this is a reference to a vaccination administered at Dr. Elad's office on November 7, 2014. (ECF No. 1, p. 4 (*citing* Ex. 2, pp. 47-50.) Although petitioner's November

intended to pursue acupuncture, but Dr. Elad made no findings or recommendations regarding her reported right shoulder pain. (*Id*. at 55-58.)

No further records have been filed.

b. As reflected in affidavits

i. Petitioner's affidavit

In support of her claim, petitioner submitted an affidavit signed April 11, 2015. (Ex. 15.) Petitioner reported having received both of her February 12, 2013 vaccinations in her left arm. (*Id*. at 1.) She averred that "[f]rom onset it was very painful at the injection site. My mobility was very limited, and I moved around as if I were in a sling even though I was not. Over the course of a few months, the pain then spread to my entire shoulder." (*Id*.)

Petitioner further indicated that "a few months" after the vaccine, she was unable to use her arm to dress, do her hair, or prepare food. (*Id*. at 2.) She averred that at that time she returned to Rite Aid to complain about the pain but was told it was normal. (*Id*.) Petitioner reports that she returned to Rite Aid again in the summer of 2013, but was again told the pain was normal and would go away. (*Id*.)

Petitioner's husband died on September 17, 2013. Prior to his death, he experienced a long battle with Parkinson's disease, and petitioner was his caretaker. (Ex. 15, p. 2.)

Petitioner reported that it was only at the end of 2013, at the urging of her family, that she made an appointment with Dr. Elad to address her shoulder pain. (*Id*.) With regard to her subsequent history, petitioner indicated that she became frustrated by a lack of progress she experienced in physical therapy and, as reflected in her medical records, felt that her acupuncture treatment was responsible for her improved condition. (*Id*. at 3.) Nonetheless, as of the date of her affidavit, petitioner indicated that she still experienced tenderness around the area of her vaccination and was still unable to lift her arm over her head. (*Id*.)

ii. Additional witness affidavit

In addition to her own affidavit, petitioner also filed an affidavit by her daughter, Tanya Kramer, signed May 11, 2015. (Ex. 17.) Ms. Kramer indicated that her mother told her about the pain she was experiencing following her vaccinations. (*Id*. at 1.) She also noted that she sees her mother often and was able to see the limitations she was experiencing in her left arm immediately after she received the vaccinations. (*Id*.) Ms. Kramer also described how difficult petitioner's condition was on her daily life and the

7, 2014 encounter record indicates the fact of administration of a flu vaccine, it does not indicate the location of the injection. (Ex. 2, p. 50.)

circumstances that led her to recommend that petitioner seek treatment from an acupuncturist. (*Id*. at 2.)

III. Expert Opinions

a. Petitioner's expert, Nicholas Szumski, M.D.

Dr. Szumski is a neurologist at Cedars-Sinai Medical Group specializing in general neurology and movement disorders. (Ex. 18, p. 1.) He has been a treating physician of petitioner since January 29, 2014, as well as a long-time treating physician for her husband's Parkinson's disease. (*Id*. at 1-2.) Dr. Szumski opined that petitioner experienced two distinct "clusters" of symptoms attributable to two separate conditions.

First, he opined that petitioner suffered an injection injury to her lateral cutaneous nerve, branching from the axillary nerve within the deltoid. (Ex. 18, p. 1.) This resulted in "pain at the site of injection and radiating down the lateral portion of her upper arm in an ovoid shape ending above the left elbow." (*Id*.) He indicated that the lateral cutaneous nerve is susceptible to possible injury from an intramuscular injection and that, with the onset of symptoms being immediate, "[t]his emergence of symptoms due to nerve injury occurred within the medically reasonable time frame expected from the mechanism of injury." (*Id*.)

Second, Dr. Szumski described additional pain and reduced mobility developing over a period of months as petitioner avoided significant use of her arm due to the initial nerve pain. (Ex. 18, p. 1.) Dr. Szumski suggested that this additional pain and reduced range of motion was reflected in petitioner's inability to tolerate physical therapy. (*Id*. at 1-2.) He opined that this second cluster of symptoms constituted a "frozen shoulder," which he also opined occurred in a medically reasonable time frame. (*Id*.)

Dr. Szumski further opined that, since petitioner's shoulder was never completely immobilized, atrophy was not noted in petitioner's physical findings and would not have been expected. (Ex. 19, p. 1.) Dr. Szumski also indicated that "the direct symptoms of her nerve injury were relatively mild compared to the indirect symptoms that developed later and prompted medical attention." (*Id*.) Dr. Szumski suggested that it is impossible to determine when the initial, direct symptoms of nerve injury were supplanted by the symptoms of the indirect frozen shoulder. He indicated that the frozen shoulder symptoms, though distinct, were of insidious onset and that "[t]here was no single day when it became clear that the primary cause of her shoulder pain was changing." (*Id*. at 2.)

b. Respondent's expert, Jeffrey Allen Cohen, M.D.

Dr. Cohen is a Professor and Chairman of Neurology at Geisel School of Medicine at Dartmouth and the Dartmouth-Hitchcock Medical Center. (Ex. B.) He disagrees with Dr. Szumski's assessment of lateral cutaneous neuropathy and also opined that petitioner's symptoms are not a result of her vaccinations. (Ex. A, p. 1.)

Dr. Cohen stressed that a traumatic injection injury to the lateral cutaneous nerve from vaccination would be extremely rare and not consistent with his clinical experience. (*Id*. at 2.) But in any event, he opined that petitioner's "clinical course is not consistent with a nerve injury [,] i.e. a long period of time [of] 10 months before the patient saw a physician. Nerve injuries usually improve over time, they do not worsen. The neurological examinations are normal over time as well which would be very unusual with worsening of a nerve injury." (*Id*. at 3.) He also noted petitioner's history of cervical spinal stenosis, neck pain, and left arm radicular symptoms, and further suggested that an injury to the lateral cutaneous nerve would be at the level of the elbow, not the shoulder. (*Id*. at 2-3.)

c. Responsive supplemental reports

In a supplemental report, Dr. Szumski challenged Dr. Cohen's opinion, contending that Dr. Cohen was failing to distinguish between the lateral cutaneous nerve of the arm, which is the superior lateral brachial cutaneous nerve, and the lateral cutaneous nerve of the forearm, which is the lateral antebrachial cutaneous nerve. (Ex. 20, p. 1.) Dr. Szumski clarified that he has opined that petitioner suffered an injury to the former while asserting that Dr. Cohen's discussion of symptoms at the elbow relates to the latter. (*Id*. at 4.)

Dr. Szumski noted that the rarity of the injury mechanism he proposed does not preclude vaccine-causation. (Ex. 20, p. 1.) He contended that "referring to absence of reports in the clinical literature may grossly underestimate the true incidence of rare disorders" and noted that he has treated patients suffering injection-related injury to the lateral cutaneous nerve of the forearm and to a branch of the suprascapular nerve. (*Id*. at 5.)

Dr. Szumski also challenged Dr. Cohen's assertion that neurological exams were normal in petitioner's case. He indicated that "[i]njuries to purely sensory branches (e.g. the lateral cutaneous nerve of the arm) can only be tested on exam by subjective measures, i.e. touching the areas and asking the patient, 'does this feel normal?', etc. A sensory nerve could only produce objective findings, via an indirect route – if it produced symptoms so severe that mobility was drastically limited, and disuse led to secondary atrophy of nearby muscles." (Ex. 20, p. 4.)

Respondent subsequently filed a supplemental report by Dr. Cohen. (Ex. C.) In his supplemental report, Dr. Cohen stressed that "[i]t is a fact that very obscure clinical problems commonly appear as case reports in the literature. The fact that there is not a single case report of an injection in the shoulder causing a lateral cutaneous nerve injury of the arm is self-evident. In the authoritative texts on peripheral nerve disorders (Dyck Steward) an injection in the shoulder causing solely lateral cutaneous injury is never mentioned." (*Id*. at 1.) He stressed that the prior cases described by Dr. Szumski in his own practice did not involve shoulder injections. (*Id*. at 1-2.) He concluded: "The

simple and clear fact is an injection in the shoulder does not result in a worsening and permanent focal injury of the lateral cutaneous nerve." (*Id*. at 2.)

IV. Findings of Fact

Before reaching the question of entitlement to compensation under the *Althen* test discussed below, I will first address several factual points. A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 300aa–13(a)(1)(A). Although the previously-assigned special masters issued tentative findings of fact during earlier stages of the case, these findings are not binding on me. *Godfrey v. Sec'y of Health & Human Servs.*, 2015 WL 10710961, at *9 (Fed. Cl. Spec. Mstr. Oct. 27, 2015)(noting that "[g]enerally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred."); *see also Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999) (special masters are not bound by their own or other special masters' decisions). Accordingly, I will explain my own findings of fact.

a. Injection site location and vaccination at issue

Of the two vaccinations petitioner received on February 12, 2013, only an injury stemming from the influenza vaccine would be compensable in this program; however, the injection site is not recorded for either vaccine. Accordingly, a threshold question is whether petitioner's vaccinations were administered in such a way that the flu vaccine could have been the cause of her injury (*i.e.* was administered in her left arm) and, if so, would have been a more likely cause of the injury than the shingles vaccine she received at the same time.

Petitioner has averred that she received both her influenza and shingles vaccines in her left arm on February 12, 2013. (Ex. 15, p. 1.) Additionally, although petitioner did not immediately report her alleged shoulder condition to her physicians, once she did, her later medical records are consistent in recording her recollection that her vaccinations were given in her left arm, though these records are all more than ten months post-vaccination. (Ex. 2, pp. 7-8; Ex. 3, p. 2; Ex. 4, pp. 1, 5; Ex. 14.) Additionally, petitioner's medical records note her to be right handed. (E.g. Ex. 3, p. 2.) Vaccinations are often administered in the non-dominant arm.

Also significant is the fact that there is no evidence to suggest that petitioner received either of her vaccinations in her right arm. Importantly, petitioner's vaccination record is silent as to the site of her injections rather than contradictory to her recollection. (Ex. 1.) In that regard, it is also significant that petitioner returned to the Rite Aid pharmacy where she was vaccinated and a pharmacy employee filled out a VAERS report in which petitioner's allegation of a *left* shoulder injury is recorded along with the details of the vaccines she was administered. (Ex. 14.) If the pharmacy had a record of petitioner's vaccines being administered in the opposite arm, that issue likely would have been raised in connection with completion of the form.

For these reasons, there is preponderant evidence that petitioner's February 12, 2013 influenza and shingles vaccines were administered in her left shoulder. However, since both of her vaccines were likely administered in the same shoulder, this raises the additional question of whether one was more likely than the other to have caused a shoulder injury via either of the above-discussed theories.

According to the SIRVA criteria, a SIRVA is limited to injuries following intramuscular injection. *See* 42 C.F.R. §100.3(c)(10); *see also Tenneson, Cooper, Schoonover, infra*. Likewise, both experts in this case opined that a direct nerve injury of the type proposed by Dr. Szumski would be more likely to have been caused by an intramuscular rather than subcutaneous injection. (Ex. 18, p. 1; Ex. A, p. 2.) Petitioner's influenza vaccination was intramuscularly administered and her shingles vaccine subcutaneously administered. (Ex. 1.) Therefore, to the extent petitioner suffered any vaccine-related injury, her flu vaccine would have been more likely than her shingles vaccine to have caused her injury.

b. Onset and nature of shoulder pain

The next question is whether petitioner's alleged shoulder pain arose as an immediate consequence of her flu vaccine as alleged. There are two significant considerations on this point – first, petitioner was actively treating for a preexisting cervical condition at the time of her vaccinations and, second, petitioner did not report any vaccine-related shoulder pain to her physicians until ten months after her vaccination despite returning for regular follow-up primary care.

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (*i.e*., presenting all relevant information on a patient's health problems). *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd,* 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). In this case the contemporaneous medical records do not support petitioner's allegations.

Petitioner's medical records include suspicion of musculoskeletal back pain dating back to 2010. (Ex. 6, p. 1.) She began a course of treatment for back and neck pain beginning in early January 2013 and reported at that time that she had been symptomatic for one year. (Ex. 13, p. 1.) In connection with this history, cervical spinal stenosis was confirmed upon MRI. (*Id*. at 3-5.) It was specifically reported, just one month prior to her February 12, 2013 vaccinations, that pain from this condition radiated into both upper extremities and petitioner complained of *right* shoulder pain approximately two weeks prior to vaccination. (Ex. 13, pp. 4, 7-8.) The day following her vaccination, petitioner reported to physical therapy to treat her cervical pain. (Ex. 5, pp. 16-18.) Consistent with the prior reports, petitioner's assessment included left

radicular shoulder pain[21] as well as a number of symptoms relating to her neck and back. (*Id*. at 18.) To the extent any mechanism of injury was discussed, petitioner attributed her cervical pain to lifting her husband, whom she was caring for as his Parkinson's disease progressed. (*Id*.) In the month following her vaccination, petitioner attended a number of physical therapy sessions for her cervical spinal stenosis. (Ex. 5, p. 10-16.) Shoulder pain following or attributable to vaccination was never mentioned. (*Id*.) She also saw her primary care physician, Dr. Elad,[22] on two occasions (February 21, 2013, and August 8, 2013) for general "follow up." (Ex. 2, pp. 9-16.) At both of these visits, petitioner discussed her general health and prior health complaints, but did not mention her alleged shoulder pain. (*Id*.)

It was not until ten months after her vaccinations that petitioner mentioned post-vaccination shoulder pain to any physician. (Ex. 2, pp. 5-8.) At that time, petitioner reported to Dr. Elad that she could not raise her left arm since receiving her vaccinations. (*Id*. at 5.) However, this history conflicts with petitioner's prior medical history as reflected in her prior treatment records and is far less contemporaneous to the onset of her condition than her prior medical records. *See, e.g. R.K. v. Sec'y of Health & Human Servs*., No. 03-632V, 2015 WL 10936123, at *76 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) (finding that more remote histories of illness did not have sufficient indicia of reliability to be credited over conflicting contemporaneous medical records); *see also Vergara v. Sec'y of Health & Human Servs.,* 08-882V, 2014 WL 2795491,*4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.").

Dr. Elad advised petitioner to see a neurologist (ultimately Dr. Szumski) without recording any relevant findings. (Ex. 2, pp. 5-8.) Based on her report of chronic pain following vaccination, as well as physical findings of tenderness to palpation and pain with abduction, Dr. Szumski diagnosed neuritis, relying on petitioner's report that onset of her shoulder pain correlated to the time of vaccination. (Ex. 3, p. 3.) Yet there is no indication in either his medical records or any of his subsequent reports that he was aware of, let alone considered, petitioner's history of cervical spinal stenosis and her treatment, contemporaneous to her vaccination, of neck and shoulder pain related to that condition radiating into her upper extremities.[23] (Exs. 3, 18-20.) Respondent's

[21] At base, "radicular" generally means "of or pertaining to a root." Dorland's 32nd Ed., p. 1571. With regard to shoulder pain, it would refer to radiculopathy, which is "disease of the nerve roots, such as from inflammation or impingement by a tumor or bony spur." (*Id*.) Cervical radiculopathy is "radiculopathy of cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." (*Id*.) In his initial report, Dr. Cohen confirmed that petitioner's cervical condition was capable of causing her left radicular arm pain. (Ex. A, p. 2.)

[22] As explained above, Dr. Elad was petitioner's cardiologist, but he also provided her primary care. (Ex. 15, p. 2.)

[23] In his final supplemental report, Dr. Szumski did briefly address Dr. Cohen's assertion that petitioner's condition could have been caused by cervical arthritis, stating that "'cervical arthritis' is such a non-specific and common category that it is a distraction from the core question here." (Ex. 20, p. 4.) But, again, this statement suggests that Dr. Szumski is not taking full account of petitioner's history, which

expert observed that petitioner's cervical spinal stenosis symptoms "are identical" to the symptoms she attributed to her vaccinations in her later reports. (Ex. A, p. 2.)

I have also considered the affidavits petitioner has submitted, but, to the extent they conflict with the contemporaneous medical records, they are not persuasive. (Exs. 15, 17.) First, petitioner does not acknowledge her history of cervical problems or how that was affecting her at the time of her vaccination.[24] (Ex. 15.) Second, petitioner's affidavit does not persuasively address her delay in seeking treatment. Petitioner is very credible in stating that she was prioritizing her husband's care during his end-stage Parkinson's disease; however, petitioner did seek primary care twice during this period for general "follow up" and did not discuss her shoulder pain with her doctor.

Accounting for her very unfortunate family circumstance, minimization of petitioner's self-care is understandable, but prioritization of her husband's care does not explain why active medical concerns were not raised at those general follow up appointments that did occur. This is especially significant, because petitioner has averred that during this same period she returned to Rite Aid multiple times to challenge their assertion that she was experiencing normal, temporary post-vaccination pain. (Ex. 15, p. 2.) Specifically, petitioner saw Dr. Elad on February 21, 2013, and made no mention of shoulder pain. (Ex. 2, pp. 13-16.) She averred that she returned to Rite Aid "[a] few months after the vaccine" to complain about her shoulder pain. (Ex. 15, p. 2.) Petitioner averred that she returned to Rite Aid again "[i]n the summer of 2013" to complain that her pain was persisting. (*Id.*) Petitioner saw Dr. Elad again on August 8, 2013, and again made no mention of her shoulder pain. (Ex. 2, pp. 9-12.)

Ms. Kramer's affidavit lends some support to petitioner's account, but lacks sufficient specificity regarding the ten-month period immediately following petitioner's vaccinations to add significant weight. (Ex. 17, p .1.) Moreover, although she stressed that "[m]y mother and I see each other often" and that she was able to immediately observe petitioner's post-vaccination shoulder pain, she likewise failed to address petitioner's preexisting cervical symptoms. (*Id.*)

With regard to onset of her shoulder pain, petitioner argues that I should follow a number of decisions by the Chief Special Master addressing SIRVA claims within the SPU. (ECF No.58, pp. 24-27.) In such decisions it has been held that neither a delay in seeking treatment in itself, nor a failure to report symptoms to a specialist or emergency room provider prior to later seeking treatment, is necessarily dispositive of whether a petitioner's shoulder pain began within 48 hours of vaccination. *See Forman-Franco v.*

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included detailed description of petitioner's cervical problems, including MRI imaging, as well as an established pattern of treatment seeking to alleviate symptoms related to that condition.

[24] With regard to her past medical history, petitioner indicated only that "[p]rior to receiving a flu shot, I was [a] very health 72 year young lady. I have always tried to be physically active, and I have normal preventative health visits with my doctors for slightly high cholesterol and blood pressure. These are well controlled with minimal medication. I have also had growths on my thyroid, but these were non-cancerous. I have received many flu shots in the past years without issue." (Ex. 15, p. 1.)

Sec'y of Health & Human Servs., No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140 (Fed Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); and *Gurney v. Sec'y of Health & Human Servs.*, No. 17-481V, 2019 WL 2298790 (Fed. Cl. Mar. 19, 2019).[25] This case is distinguishable, however, due to the overall length of delay in reporting vaccine-related shoulder pain, the fact of two intervening medical encounters for general health follow up, and the presence of contemporaneous medical records suggesting petitioner's symptoms are attributable to her pre-existing cervical condition.

For these reasons, when viewing the record as a whole, I do not find preponderant evidence that petitioner had onset of post-vaccination left shoulder pain immediately following her vaccination or within 48 hours of her vaccination. Rather, as reflected in her contemporaneous medical records, at the time of her February 12, 2013 vaccinations, a preponderance of the evidence indicates that petitioner had preexisting cervical spinal stenosis with pain radiating into both of her upper extremities and no distinct onset of left shoulder pain related to vaccination. That is, petitioner's cervical condition more likely than not explains all of her shoulder symptoms documented during the period from January through March of 2013. To the extent petitioner later reported left shoulder pain that she contends was distinct from her cervical condition, there is not preponderant evidence that such shoulder pain existed on or before August 8, 2013.

c. Adhesive capsulitis diagnosis

A further question is whether there is preponderant evidence that petitioner experienced adhesive capsulitis as a subsequent consequence of the post-vaccination shoulder pain she alleges. In his expert reports, Dr. Szumski relies on the presence of adhesive capsulitis that he attributes to petitioner's chronic disuse of her arm due to post-vaccination shoulder pain. (Ex. 18, p. 1; Ex. 19, p. 1; Ex. 20, p. 4.)

Petitioner's adhesive capsulitis "diagnosis" is limited to a notation by her physical therapist during her evaluation of February 3, 2014, identifying frozen shoulder based on pain, stiffness, and reduced mobility. (Ex. 5, p. 6.) That notation of frozen shoulder appears in the "history of complaint" section and not in any section related to the physical therapist's findings or observations. (*Id*. at 6-7.) Notably, the physical therapist recorded "neg for frozen" under MRI/X-Ray results.[26] (*Id*. at 6.) Accordingly, while there is some evidence to suggest petitioner may have experienced symptoms

[25] In her brief, petitioner stresses the Chief Special Master's unique authority on the subject matter of SIRVAs due to her accumulated experience in adjudicating SIRVA claims within the SPU. (ECF No. 58, p. 23, n. 14.)

[26] As noted in n. 19, *supra*, it is not clear to what MRI study this notation could be referring. Rather than referring to a prior MRI study, it may be a notation indicating the lack of any MRI or X-ray support for the frozen shoulder suspicion.

consistent with frozen shoulder or that frozen shoulder was suspected, the assertion that she was "diagnosed" as having the condition overstates petitioner's history.[27]

Nonetheless, even assuming *arguendo* that petitioner did have adhesive capsulitis, there is little in the record to connect it to her vaccination. By Dr. Szumski's reasoning, the mechanism of petitioner's development of frozen shoulder was not directly related to the proposed nerve injury, but merely from petitioner "voluntarily" restricting her motion due to localized pain. He indicated that onset of the frozen shoulder would have been insidious over months and that petitioner's shoulder was "never completely immobilized." (Ex. 19, p. 1.) Yet, petitioner was not actively treating for any neck, back or shoulder condition from March of 2013 through December of 2013. Although it is often seen in SIRVA cases, frozen shoulder can occur idiopathically. *See* n. 5, *supra*.

Dr. Szumski's indirect linking of petitioner's alleged adhesive capsulitis to her vaccination is possible only through *post hoc* reasoning based on his reliance on petitioner's reported history of identifiable left shoulder pain beginning at the time of vaccination. However, as noted above, that history is inconsistent with, and less reliable than, her contemporaneous medical records which show active treatment for cervical spinal stenosis radiating to both upper extremities at the time of her vaccination. In that regard, it is worth noting that, although petitioner demonstrated some improvement during her earlier physical therapy related to her cervical condition, none of petitioner's medical records indicate that her cervical pain fully resolved.

For these reasons, assuming *arguendo* that petitioner did have adhesive capsulitis, I do not find preponderant evidence that such adhesive capsulitis occurred as a sequela to any traumatic injection injury to her lateral cutaneous nerve.

V. Discussion Regarding Entitlement

Under the National Vaccine Injury Compensation Program (the "Program"), compensation awards are made to individuals who have suffered injuries after receiving vaccines. To be compensated, the petitioner must 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

[27] In his expert report, Dr. Szumski states that "[a]fter her 1/29/14 appointment, [petitioner] attempted to work with a physical therapist to increase range of motion, reduce pain, and improve function of the left shoulder and arm. However, by that time, she was diagnosed as having a so-called frozen shoulder . . ." (Ex. 18, p. 1.) Dr. Szumski at no point indicated in his treatment records that he diagnosed frozen shoulder himself, but did include in his interval history of March 13, 2014, that petitioner's physical therapist suspected frozen shoulder. (Ex. 3, p. 1.)

other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

In this case, petitioner's allegations include a theory of an injection-related nerve trauma, first raised by her expert, as well as the claim stated in her petition that an influenza vaccination caused her to suffer a Shoulder Injury Related to Vaccine Administration or "SIRVA". As of March 21, 2017, SIRVA has been included on the Vaccine Injury Table for the flu vaccine. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294, Jan. 19, 2017; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321, Feb. 22, 2017 (delaying the effective date of the final rule until March 21, 2017). However, since the filing of petitioner's claim predates this change to the injury table, petitioner must satisfy the burden for establishing causation-in-fact even with regard to her SIRVA claim. *See* § 300aa-14(c)(4) (stating that "[a]ny modification . . . of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation"). Thus, petitioner bears a burden of establishing causation-in-fact under either of her proposed theories.

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

a. *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 v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (citations omitted). To satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549. 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)).

Petitioner's expert asserts a mechanism whereby a direct injection trauma to petitioner's lateral cutaneous nerve initially caused her symptoms only for petitioner to later develop orthopedic sequela in the form of adhesive capsulitis. Both parties' experts agree as a general matter that traumatic nerve injuries from injection are possible. For example, respondent's expert noted that "[t]here are case reports of the very rare event of axillary nerve damage from vaccinations" which do present with shoulder and deltoid symptoms.[28] (Ex. A, p. 2.) He also agreed that traumatic injection injuries to the lateral cutaneous nerve, though extremely rare, do occur.[29]

[28] Dr. Szumski opined that petitioner's injury was to the lateral subcutaneous nerve of the arm, which he indicated branches from the axillary nerve. (Ex. 20, p. 1.)

[29] Dr. Cohen opined, however, that such injuries present at the level of the elbow. (Ex. A, p. 2.) Dr. Szumski challenged that contention, indicating that Dr. Cohen was being imprecise in failing to distinguish between the lateral cutaneous nerve of the arm, which is the superior lateral brachial cutaneous nerve,

Dr. Cohen's competing contentions primarily go to petitioner's clinical course and whether it is consistent with Dr. Szumski's theory. Notably, Dr. Cohen did not challenge, or even address, Dr. Szumski's description of adhesive capsulitis or his opinion that it could theoretically arise as sequela to a traumatic nerve injury. As Dr. Szumski suggested, adhesive capsulitis is known to occur as a result of long term "favoring" or disuse of the shoulder as a pain response. *See, e.g. Tenneson v. Sec'y of Health & Human Servs.*, 142 Fed. Cl. 329 (2019)(noting in a prior SIRVA case that petitioner "apparently consulted with an orthopedist who 'felt [it] unlikely [that] this is all related to flu shot' but who acknowledged that [petitioner] 'certainly could have developed a frozen shoulder if she hasn't moved it x 5 mo' since the flu vaccination.").

For these reasons, I find Dr. Szumski's description of traumatic nerve injury following injection leading to adhesive capsulitis to be persuasive as a general theory of causation. However, petitioner asserts in her petition a cause-in-fact claim of a Shoulder Injury Related to Vaccine Administration or "SIRVA."

SIRVA is a specific concept by which some musculoskeletal injuries temporally associated to vaccination are deemed to have been vaccine caused where they meet certain criteria that rule out other causes. Prior cases in this program have accepted the SIRVA concept as an acceptable medical theory sufficient to satisfy *Althen* prong one based on the Secretary's rulemaking establishing SIRVA as a Table injury and respondent's history of conceding causation in prior, pre-Table SIRVA claims. *See, e.g. Tenneson*, 2018 WL 3083140; *Cooper v. Sec'y of Health & Human Servs.*, No. 16-1387V, 2018 WL 1835179 (Fed. Cl. Spec. Mstr. Jan. 18, 2018); *Schoonover v. Sec'y of Health & Human Servs.*, No. 16-1324V, 2019 WL 1040642 (Fed. Cl. Spec. Mstr. Jan. 30, 2019).

Because a SIRVA is a musculoskeletal rather than neurologic injury, petitioner's SIRVA and traumatic nerve injury theories are mutually exclusive. However, Dr. Szumski's failure to establish the presence of any nerve injury would still leave open the possibility that petitioner could prevail if she can establish under *Althen* prongs two and three that her injury fits within the confines of the SIRVA concept. Accordingly, petitioner has satisfied *Althen* prong one under either of two alternative theories.

b. *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 v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras*, 993 F.2d at 1528. However, medical records and/or statements of a treating physician's views do not *per*

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and the lateral cutaneous nerve of the forearm, which is the lateral antebrachial cutaneous nerve. (Ex. 20, p. 1.) In his supplemental report, Dr. Cohen did not address that point. (Ex. C.)

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").

Dr. Szumski opined that petitioner experienced an immediate post-vaccination injury directly to the lateral subcutaneous nerve. He further opined that this injury gradually led to an adhesive capsulitis. However, the findings of fact discussed in Section IV(b), above, are incompatible with that opinion. There is not preponderant evidence that petitioner experienced injection-related shoulder pain immediately following her vaccination or at any time prior to August 8, 2013. To the extent she did experience shoulder pain during that period, it is better explained by her ongoing and preexisting cervical condition. Moreover, Dr. Szumski's reliance on the suspicion of frozen shoulder by petitioner's physical therapist is suspect and his opinion is unpersuasive overall for failing to adequately address petitioner's preexisting cervical spinal stenosis which the contemporaneous medical records show to explain her condition at and following the time of vaccination. Accordingly, Dr. Szumski's opinion fails to set forth a logical sequence of cause and effect explaining how petitioner's vaccination would have caused her injury.

Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009); (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L.Ed.2d 508 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010)). "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." *Dobrydnev v. Sec'y of Health & Human Servs.*, 566 Fed. Appx. 976, 982-83 (Fed. Cir. 2014) (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp*., 509 U.S. 209, 242 (1993)).

Notably, however, Dr. Szumski is not merely an expert opining in this case, but also a treating physician. As described above, treating physician opinions are ordinarily accorded a degree of deference. This is because, "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.'" *Capizzano*, 440 F.3d at 1326. "In contrast to treating physicians who had observed the patient as the condition unfolded, retained experts [are] limited to a review of the records after the fact. Consequently, treating physicians' opinions are often regard as 'quite probative' with respect to the causation prong under *Althen*." *Nuttall v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 821, 832 (2015), *aff'd* 640 Fed. Appx. 996 (Fed. Cir. 2016) (citing *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009).).

On the other hand, treating physician opinions are not "sacrosanct." *Snyder,* 88 Fed. Cl. at 746 n.67; *Accord* § 300aa-13(b)(1). And, significantly, "[t]he reasoning underlying the finding that opinions of treating physicians should be given particular weight does not apply when, as here, the treating physician only saw the patient after the injury and based his opinion on the same evidence as relied upon by the retained experts." *Nuttall*, 122 Fed. Cl. at 832.

In this case, petitioner did not seek out Dr. Szumski for care of her shoulder until nearly a year after her vaccination. By that point, by Dr. Szumski's own reasoning, her alleged frozen shoulder symptoms had already supplanted the prior direct nerve injury he posits. (Ex. 19, p. 2 (describing petitioner as suffering insidious onset of increased pain and reduced functional use of her shoulder due to frozen shoulder prior to seeking medical care).) Accordingly, Dr. Szumski never actually observed or treated the direct nerve trauma he theorized to have caused petitioner's injury.[30] Additionally, the resulting adhesive capsulitis condition that he describes in his reports and that was purportedly the primary injury present at the time of his physical examination is orthopedic and is therefore outside his area of expertise as a neurologist.

As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed.Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 Fed. Appx. 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06–522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed.Appx. 765 (Fed. Cir. 2012). As described above, Dr. Szumski's opinions are not persuasive in light of petitioner's contemporaneously recorded medical history.

Alternatively, since I do not find Dr. Szumski's opinion of a direct nerve injury persuasive, it is appropriate to examine whether petitioner can otherwise establish a SIRVA. In prior cases where a SIRVA has been addressed as a cause-in-fact-claim, the Qualifications and Aids to Interpretation ("QAI") governing the Table Injury of SIRVA have been found to be persuasive guidance in establishing whether there is a logical sequence of cause and effect leading to a SIRVA. *Tenneson, Cooper, Schoonover, supra.* Under that standard, petitioner must satisfy the following four criteria to establish the presence of a SIRVA:

[30] As the treating neurologist for petitioner's late husband, Dr. Szumski did know petitioner prior to becoming her physician. (Ex. 18, p. 2.) In fact, Dr. Szumski addressed the circumstances of petitioner's care for her husband extensively. (Ex. 18, p. 2; Ex. 19, p. 2.) However, nothing in his records or his reports suggests that he at any time observed petitioner's shoulder condition or spoke to her about it prior to becoming her treating neurologist on January 29, 2014.

(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; and

(ii) Pain occurs within the specified time-frame [*i.e.* 48 hours]; and

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. §100.3(c)(10); *see also Tenneson, Cooper, Schoonover, supra.*

Again, in light of the above fact findings, petitioner has not satisfied any of these criteria. Specifically, as described in section IV(b) above, petitioner's preexisting cervical condition was noted to encompass her upper extremities bilaterally. This explains the only specific notation of any left shoulder pain following her vaccination as that pain was noted to be radicular. Thus, the first, third, and fourth, SIRVA criteria are not established by preponderant evidence. That is, petitioner had a relevant history of cervical pain and dysfunction affecting her shoulder; she had reduced range of motion in her neck as well as her shoulder; and her cervical spinal stenosis represents an abnormality that explains her symptoms.[31] To the extent petitioner complained in later histories of shoulder pain she related to her vaccinations, I did not find preponderant evidence that such pain actually existed on or prior to August 8, 2013, which is roughly six months from the date of vaccination. Thus, the second SIRVA criterion also is not satisfied.

Accordingly, petitioner has not satisfied *Althen* prong two under either of her proposed theories.

c. *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. 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." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an

[31] As previously noted, in addition to the evidence contained in her medical records, Dr. Cohen also opined that petitioner's cervical condition can explain her symptoms. (Ex. A, p. 2.)

injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 Fed. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Pursuant to Dr. Szumski's theory of direct nerve trauma, there should be an "immediate" onset of pain. (Ex. 18, p. 1; Ex. 19, p 2.) The relevant period of onset for shoulder pain in a typical SIRVA claim is forty-eight hours. *See Tenneson, Cooper, Schoonover, supra*.

In this case, petitioner's February 13, 2013 physical therapy evaluation references the presence left shoulder pain. (Ex. 5, p. 18.) That record was created one day following her vaccination. However, for the reasons discussed in section IV(b) above, I concluded that this reference to left shoulder pain, which was characterized as radicular shoulder pain, is explained by her ongoing and preexisting spinal condition, which was documented to have radiated into her arms, and does not represent a report of vaccine-caused shoulder pain. Notwithstanding petitioner's much later reports of shoulder pain that immediately followed her vaccination, I have found the contemporaneous medical records, which do not support the allegation of immediate onset, to be more credible. Accordingly, there is not preponderant evidence of shoulder pain on or prior to August 8, 2013, about six months after petitioner's vaccination, which is too late to be medically appropriate under any theory proposed by petitioner.

I also note that to the extent Dr. Szumski separately opined that petitioner's months-long insidious onset of adhesive capsulitis occurred within a medically appropriate timeframe (Ex. 18, p. 2), Dr. Szumski never adequately addressed the appropriate timeframe for development of adhesive capsulitis. He stressed that petitioner's pain "eventually" and "gradually" increased and her function gradually decreased "over months," but never actually described the expected time course for the onset of adhesive capsulitis. (Ex. 18, p. 2; Ex. 19, p. 2.) In any event, Dr. Szumski's description of adhesive capsulitis was as a further sequela to the direct nerve injury he posited had an immediate onset. Insofar as petitioner has not demonstrated immediate onset of a direct nerve injury, the timing of the onset of her alleged adhesive capsulitis is irrelevant.

Accordingly, petitioner has not satisfied *Althen* prong 3 under either of her proposed theories.

VI. Conclusion

Petitioner has my sympathy for the pain and suffering she endured during what must have been a very difficult period in her life and I do not doubt her sincerity in bringing this claim. However, for all the reasons discussed above, after weighing the evidence of record within the context of this program, I cannot find by preponderant

evidence that petitioner's injury was caused by her February 12, 2013 influenza vaccination as alleged. Therefore, this case is dismissed.[32]

IT IS SO ORDERED.

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

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