In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-0452V
Filed: March 20, 2018
UNPUBLISHED

LORRAINE SOFIA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Entitlement; Ruling on the Record; Decision Without a Hearing; Causation-In-Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Ronald Craig Homer and Joseph Pepper, Conway, Homer, P.C., Boston, MA, for petitioner.
Adriana Ruth Teitel, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT [1]

Dorsey, Chief Special Master:

On April 11, 2016, Lorraine Sofia ("petitioner" or "Ms. Sofia") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, *et seq*.[2] (the "Vaccine Act" or "Program"), alleging that as a result of receiving an influenza ("flu") vaccination on September 30, 2014, she suffered a shoulder injury related to vaccine administration ("SIRVA"). *See* Petition at 1, 6. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters. For the reasons discussed herein, the undersigned finds that petitioner is entitled to compensation.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Ms. Sofia filed her petition for compensation on April 11, 2016. She alleged that she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") as result of receiving a flu vaccine on September 30, 2014. On April 15, 2016, petitioner filed 27 medical record exhibits and a Statement of Completion. After conducting a review of the records, respondent filed a status report on June 9, 2016 noting that, "[r]espondent has completed her review of the filed medical records and is willing to engage in discussions regarding a litigative risk settlement." Respondent's Status Report dated June 9, 2016, page 1. The parties, therefore, began discussions regarding an informal resolution of petitioner's claim.

Approximately five months later, on November 28, 2016, petitioner filed a status report asking for guidance from the Court in order to facilitate the parties' settlement discussions. In response, the undersigned held a Rule 5 status conference on February 13, 2017, during which the undersigned discussed her preliminary views on the merits of petitioner's claim. These preliminary findings were memorialized in an Order dated February 23, 2017, and which concluded:

> The undersigned makes a preliminary finding that petitioner meets the criteria for SIRVA and that her clinical course is consistent with a SIRVA injury. Petitioner did not have a history of shoulder pain prior to vaccination that would explain her shoulder symptoms after vaccination. The undersigned acknowledges that petitioner had cervical radiculitis which explains the paresthesia in her hands she experienced, but the undersigned finds that the evidence preponderates in favor of this symptom being a distinct condition, separate from her shoulder injury. Order of February 23, 2017, page 2-3.

The parties again resumed settlement discussions. However, on June 16, 2017, petitioner filed a status report informing the Court the parties were at an impasse. A status conference was held before the undersigned on August 10, 2017, to discuss further proceedings and several options were discussed as a means to move this case forward to resolution. On August 18, 2017, the parties filed a joint status report where petitioner indicated her preference for a ruling on the record, while respondent preferred the case be transferred from the SPU to a special master for further proceedings. The parties agreed to defer to the Court's preference as to how to proceed. Thereafter, the undersigned issued an Order on September 14, 2017, stating that, "based on the undersigned's review of the procedural posture of this case and the options discussed during the most recent status conference, the undersigned will issue a ruling on entitlement based on the evidence and briefs submitted by the parties." Order of September 14, 2017, page 1.

On December 20, 2017, the undersigned filed two articles pertaining to causation of vaccine-related shoulder injuries which were filed as court exhibits. These articles are: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E Montalvo,

Vaccination Related Shoulder Dysfunction, 25 Vaccine 585 (2007), filed as Court Exhibit II. (ECF No. 56.)[3] The parties were given until January 19, 2018, to provide any additional evidence regarding entitlement or any response to the court exhibits. (*Id*.) No further filings were made and the undersigned considers the record as to entitlement closed as of January 19, 2018. The matter is now ripe for adjudication.

II. Medical History

Ms. Sofia was born in 1947 and is currently retired, although she frequently spends her time caring for her grandchildren. Petitioner's Exhibit ("Pet. Ex.") 2 at 24; Pet. Ex. 26 at 1. Her medical history is significant for vertigo and disequilibrium in 2012, mild canal stenosis of her cervical spine, and arthritis and joint pain. Pet. Ex. 4; Pet Ex. 5 at 1; Pet. Ex. 6 at 2, 7; Pet. Ex. 19 at 2; Pet. Ex. 21 at 17. On September 30, 2014, she received a flu vaccine to her right arm at Rite Aid Pharmacy. Pet. Ex. 1-3.

In her affidavit, Ms. Sofia states that later the evening of September 30, 2014, she felt her right arm begin to ache. Pet. Ex. 26 at 1. A few days later, the pain was still bothering her and she was unable to sleep because of the throbbing pain. *Id*. at 1-2. Ms. Sofia states that the achiness in her shoulder and general uncomfortableness continued for weeks. *Id.* She took over-the-counter pain relievers, but the medication did not help. *Id.*

On November 17, 2014, Ms. Sofia presented to her primary care physician, Dr. Ira Kurz with Summit Medical Group, for a routine follow-up on her hypothyroidism. Pet. Ex. 2. at 7. During this visit, petitioner complained of marked discomfort to her right shoulder beginning approximately three and one half weeks prior and after her flu vaccination.[4] Pet. Ex. 2 at 10. No treatment was recommended or discussed for her shoulder. *Id.*

On December 10, 2014, Ms. Sofia presented to FirstCare Medical Group – Lindhurst, an urgent care provider, with a chief complaint of "throbbing pain r[ight] humerus after getting her flu vaccine back in late September." Pet. Ex. 17 at 18. The physical exam, performed by Dr. George Ambrosio, noted "mildly reduced active range of motion [("ROM"] with internal rotation," and mild pain with palpation on upper anterior lateral arm. Pet. Ex. 17 at 19. The assessment was "arm pain, right." *Id*. Petitioner was prescribed a muscle relaxant, nabumetone, for the pain and swelling and instructed to follow up with her primary care physician. Pet. Ex. 17 at 18-20.

On January 29, 2015, Ms. Sofia was again evaluated by Dr. Kurz, who noted petitioner's chief complaint as "right arm pain; R[ight] arm pain x 3 months." Pet. Ex. 2 at 1. The history of present illness indicates that Ms. Sofia reported that she had experienced right arm pain "since 09/2014 (since flu vac received) … proximal ½ upper arm/dorsal surface esp. at night … painful to reach & draw covers on herself. No history

[3] These two articles were also filed as petitioner's exhibits 43-44.

[4] The undersigned noted that the physician referenced an incorrect time frame for the onset of Ms. Sofia's symptoms, as petitioner received the flu vaccine almost seven weeks prior to this appointment.

of trauma." *Id*. at 1-2. Under ROS (review of systems) "no muscle aches or weakness" were reported under musculoskeletal, and "history of vague numbness sensation to fingers, at times … no weakness," was listed under neurologic. *Id*. at 2. It was noted that Ms. Sofia's past medical history included "arthritis: cervical & lumbar spine." *Id*. Dr. Kurtz's assessment was "R[ight] upper arm (noted when lying on back) … arthritic penetrating pain with full ROM. Paraesthesias to finger tips prob. From Cervical spine degen. Joint dis." *Id*. at 5. His plan was to refer Ms. Sofia to an orthopedist for further evaluation. *Id*. The specific diagnoses listed for the visit were: 1. Arthralgia of the upper arm; 2. Retinal defect; 3. Hypothyroidism; 4. Chronic low back pain; 5. Hyperglycemia; 6. Paresthesia of hand; 7. Chronic pain syndrome-right; 8. Cervical syndrome. *Id.*

Ms. Sofia next presented to North Jersey Rheumatology Associates ("NJRA") on February 26, 2015 with a chief complaint of "shoulder pain." Pet. Ex. 13 at 7-8. Petitioner reported that she had right shoulder pain since September that started after she received a flu vaccine. She reported it was "painful to sleep on and painful restricted ROM," and also noted "mild pain to the hands at the end of the day. Some numbness to the hands upon waking but resolved shortly after waking." *Id.* at 8. The physical exam, performed by physician assistant ("PA") Hilary Sugar, noted inflammation, limited ROM (range of motion), and tenderness of the right shoulder. *Id.* at 9. The assessment was subacromial bursitis and parasthesias. *Id.* For the bursitis, Ms. Sofia received a steroid injection and was instructed to return in two weeks for a follow-up. *Id.* Regarding the parasthesias, it was noted that petitioner was a "'stomach' sleeper, causing hyperextension at the c-spine resulting in impingement," and she was encouraged to try sleeping on her back. *Id.* at 10.

Ms. Sofia returned to NJRA on March 12, 2015, and was again seen by Ms. Sugar. Pet. Ex. 13 at 4. Ms. Sofia reported that her shoulder was "somewhat better" since the last visit and injection, but she still had some "tightness and cracking" and pain at night. *Id.* The physical exam was unchanged from the last visit. *Id.* at 5. The assessment was "shoulder pain," which was noted to be "improved after IAI [intra-articular injection] but not completely." *Id.* at 6. Petitioner was referred to physical therapy ("PT"). *Id.* Petitioner also underwent an x-ray of her right shoulder on March 12, 2015. Pet. Ex. 10 at 1. It revealed "mild degenerative changes of the AC joint characterized by joint space narrowing, subchondral sclerosis and small marginal spurs." *Id.* "Mild degenerative spurring of the inferior glenoid rim," was also observed. *Id.*

On April 8, 2015, Ms. Sofia had her initial PT evaluation. Pet. Ex. 14 at 1. In the history of injury, petitioner reported that she had a flu shot on September 30, 2014, and had experienced shoulder pain since. *Id*. She rated her a pain at 8/10. *Id*. She had reduced ROM, decreased strength of 2+/5 in most planes of motion, and positive impingement testing. *Id.* at 2. During her final PT session, it was documented that petitioner's strength had improved to 4/5 in most planes while her ROM remained relatively unchanged. *Id.* at 31-32. At the time of her discharge from physical therapy on May 29, 2015, Ms. Sofia was still experiencing some discomfort in her shoulder.

She had pain with abduction and adduction, internal and external rotation, with slight relief from her symptoms post PT session. *Id*. Her prognosis by the PA was fair. *Id*.

On June 10, 2015, Ms. Sofia saw orthopedic surgeon, Dr. Ronald E. Gennace, with a chief complaint of "pain in the neck." Pet. Ex. 16 at 1. However, under HPI (history of present illness), petitioner also described her shoulder pain, which she reported had been ongoing for four months. *Id.* She conveyed that after her flu shot she "immediately developed a superficial reaction," and "[o]ver the ensuing weeks the pain became more severe." *Id.* Petitioner also noted that she had received a steroid injection, which "did not give her much relief." *Id.* On exam, Dr. Gennace observed full range of motion of the right shoulder and no weakness against resisted elevation. *Id.* Dr. Gennace described petitioner's cervical spine x-ray as showing "degenerative disc disease with displaced nonunion C5-C6." *Id.* Petitioner received a diagnosis of "cervical radiculitis." *Id.*

Ms. Sofia returned to Summit on November 2, 2015, and was evaluated by Dr. Seth Jawetz, who noted that petitioner's shoulder pain had not yet been adequately addressed. Pet. Ex. 24 at 1-4. In the ROS, it is noted that petitioner had arthralgias/joint pain under musculoskeletal and the physical exam revealed pain with posterior extension and elevation of shoulder. *Id.* at 4-5. The visit assessment included "chronic R[ight] shoulder syndrome (prob. Impingement)," and the diagnostic codes included arthralgia of the upper arm, cervical syndrome, arthritis of shoulder region joint, and pain in right arm. *Id.* at 5. Dr. Jawetz did not believe petitioner's shoulder pain was related to her prior flu vaccination. *Id.* at 7 (noting that vaccination was "unrelated event in this examiner's opinion"). Petitioner was scheduled to return in January to be evaluated by Dr. Kurz. *Id*. at 1.

Also on November 10, 2015, Ms. Sofia is evaluated by Dr. Oscar Vazquez at Active Orthopedics & Sports Medicine, an orthopedic physician, who noted that petitioner's shoulder pain began after she was administered a flu shot. Pet. Ex. 23 at 5-6. Ms. Sofia indicated that she had gotten minimal relief from physical therapy, anti-inflammatories, cortisone injection and topical patches, and continued to have pain and limitations. *Id.* Dr. Vazquez assessed her as having impingement of the right shoulder and rotator cuff tendonitis, for which he administered a corticosteroid injection and gave a prescription/referral for a MRI. *Id.* at 6-7.

Ms. Sofia presented to the Metropolitan Pain Institute ("MPI") on March 23, 2016. Pet. Ex. 29 at 1. She reported having "persistent and progressing neck to hand and hip to back pain that does periodically radiate." *Id.* Petitioner indicated it had been ongoing for more than six months, and that she had tried physical therapy and NSAIDS. *Id.* The ROS did not include any specific reports of shoulder pain. *Id.*at 2. Based on petitioner's subjective complaints and physical exam, she was assessed with sacroillitis, spinal stenosis, and other intervertebral disc degeneration. *Id.* at 2-3. Additionally, a diagnoses of cervical disc disorder with radiculopathy was included. *Id.* at 3.

On March 30, 2016, Ms. Sofia underwent an MRI of her cervical spine. Pet. Ex. 30 at 2. The clinical history on the report references "left upper extremity

radiculopathy." *Id.* There was multilevel neuroforaminal narrowing, and a small central disc herniation was observed at C6-7. *Id.* at 2-3. Petitioner underwent an MRI of her lumbar spine on April 4, 2016. *Id.* at 4. The MRI was read as showing "disc degeneration at T11-12, disc bulging at L1-2 and L2-3, disc degeneration with broad disc protrusion more to left at L3-4 and L4-5, and central disc protrusion with facet joint DJD [degenerative joint disease] and L5 anterolisthesis noted upon evaluation on the L5-S1 level."

On September 16, 2016, Ms. Sofia returned to Dr. Vazquez. Pet. Ex. 35 at 1. Dr. Vasquez noted that petitioner's right shoulder pain improved after a cortisone injection and as a result, petitioner decided not to undergo the MRI on her shoulder as he prescribed. *Id*. However, petitioner conveyed that her "shoulder ha[d] begun to bother her again." *Id.* On exam, there was no reduced range of motion, though pain was reported during impingement testing. *Id.* at 2. Additionally, tenderness was observed on petitioner's left elbow. *Id.* The assessment included impingement of the right shoulder, right rotator cuff tendonitis, and disorder of the tendon of the left elbow. *Id*. Dr. Vazquez administered another corticosteroid injection and prescribed petitioner an anti-inflammatory for her impingement. *Id.* He also prescribed a topical cream for left elbow tendonitis. *Id.* at 3.

Ms. Sofia followed up with Dr. Vazquez on March 7, 2017. Pet. Ex. 39 at 1. She reported that she continued to experience shoulder pain, and noted that the cortisone injection gave her about three months of relief. *Id.* Her exam was unchanged from the September 16, 2016 visit. Ms. Sofia received another cortisone injection at the visit, and was instructed to return as needed. *Id.*

III. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if she has received a vaccine covered by the Program and "sustained, or had significantly aggravated, any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the "Table"). § 11(c)(1)(A) and (C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination.[5] § 14(a). If the petitioner establishes that she suffered such a "Table Injury," causation is presumed. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1146–47 (Fed.Cir.1992).

If, however, the petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, the petitioner must prove that the

[5] The Vaccine Act authorizes the Secretary of the Department of Health and Human Services to "promulgate regulations" to periodically modify the Vaccine Injury Table. § 14(c). The updates are contained in the Code of Federal Regulations (C.F.R.), as cited above.

claimed vaccine caused the alleged injury to receive compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner is said to assert a "non-Table" or "off-Table" claim, and must prove her claim by preponderant evidence. § 13(a)(1)(A). A special master is prohibited from making "such a finding "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 13(a)(1). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant*, 956 F.2d at 1148). Additionally, "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently restated these requirements in its *Althen* decision. *Althen* requires a petitioner

> 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 a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. All three prongs of *Althen* must be satisfied. *Id.*

Section 11(c)(1) also contains requirements concerning the type of vaccination received and the geographic location where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. *See* § 11(c)(1)(A),(B),(D) and (E). With regard to duration, whether a Table or non-Table claim, the petitioner must establish she

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 11(c)(1)(D).

IV. Analysis - Althen Prongs

i. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. *See Pafford v. Sec'y of Health & Human Servs.*, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. *See, e.g.*, *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (reputable); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

1. SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). *See* Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

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). *Id.; see also* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

a. The elements of petitioner's SIRVA claim

The undersigned's findings and conclusions are as follows:

1. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed Ms. Sofia's medical history prior to her influenza vaccination. The medical records demonstrate that Ms. Sofia did not have a history of pain, inflammation or dysfunction of the affected (right) shoulder prior to vaccination. Thus, petitioner has satisfied this criterion.

2. Onset occurred within the specified time frame.

Respondent argues in his responsive motion for ruling on the record, for the first time, that there "is a lack of sufficient evidence to place the onset of her shoulder pain either within 48 hours of vaccination as required for a SIRVA table claim, or the more generous timeframe of four days as was reported in one of the case reports in the Atanasoff et al article." Respondent's Response at 10. Respondent further argues that "[b]ecause petitioner did not visit a medical provider until approximately six weeks after vaccination and first sought care for shoulder pain ten weeks after vaccination, there is only petitioner's subjective reporting of onset to medical providers." Respondent's response at 10-11. Respondent states that petitioner's affidavit is "silent regarding why, if the pain had been ongoing for six weeks, she did not overtly complain about the pain and seek treatment for it at her November 17, 2014 appointment with Dr. Kurz." *Id.* at 11. Finally, respondent argues that petitioner's subsequent description of her injury to orthopedist surgeon, Dr. Gennace, states it was first a superficial problem, with pain occurring over the ensuing weeks. *Id*. at 11. The undersigned finds these arguments to be unpersuasive.

First, the undersigned notes that Ms. Sofia did complain to Dr. Kurz of her shoulder pain during the November 17, 2014 appointment. Pet. Ex. 2. at 7. During this visit, Dr. Kurz specifically noted that Ms. Sofia complained of "marked discomfort to her R[ight] arm where influenza vacc[ination] administered 3 w[eeks] ago." Pet. Ex. 2 at 10. This statement is directly contrary to respondent' assertion that Ms. Sofia "did not overtly complain about the pain." The undersigned also previously noted, and notes again, that Dr. Kurz clearly referenced an incorrect time frame for the onset of Ms. Sofia's symptoms, as she received the flu vaccine almost seven weeks prior to this appointment. Although no treatment or further discussion for her shoulder appeared in the notes from this visit, this omission does not automatically lead to an implication that Ms. Sofia did not complain of shoulder pain or seek treatment of her pain. *Id.* Ms. Sofia's affidavit does state in her affidavit that she complained of the pain to her husband and explains that she attempted to treat her shoulder pain with over the counter pain relievers before she sought formal medical treatment at urgent care. To the undersigned, Ms. Sofia's actions and explanations in these specific circumstances are reasonable and the testimony in her affidavit is credible.

Based upon the evidence set forth in the medical records and affidavits, the undersigned makes finds that onset was within 48 hours of the September 30, 2014 flu vaccination, and therefore, is within the Vaccine Table specified time frame of ≤48 hours. § 13(a)(1)(A) (preponderant standard). *See e.g.,* Pet. Ex. 2 at 1(petitioner reported that she had experienced right arm pain "since 09/2014 (since flu vac received)"; Pet. Ex. 2 at 104 ("marked discomfort to [right] arm where influenza vacc[ination] administered[.]"); Pet. Ex. at 18 ("[Patient] [complains of] throbbing pain [right] humerus immediately after getting her flu vaccine back in late September. . ..[Right] arm pain that started after she received the flu shot[.]"); Pet. Ex. 26 at 1("The flu vaccine was injected into my right arm. Later that evening, my arm started to ache.").

3. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

As discussed above, Ms. Sofia received the flu vaccination to her right shoulder and all of her reports of pain, the objective examinations of reduced range of motion, impingement and bursitis, and all of the treatments she received due to these complaints have been limited to her right shoulder. *See e.g.,* Pet. Ex. 26 at 1 (petitioner's affidavit where she describes the pain to the her right shoulder in the days and weeks following her flu vaccination); Pet. Ex. 2 at 10 (at a physician visit, petitioner reports marked discomfort to her right shoulder beginning approximately three and one half weeks prior and after her flu vaccination); Pet. Ex. 17 at 18 (on December 10, 2014, petitioner presents to urgent chare with a chief complaint of "throbbing pain r[ight] humerus after getting her flu vaccine back in late September'; Pet. Ex. 13 at 5-6 (on March 12, 2015, Physician's Assistant Hilary Sugar noted that petitioner's "shoulder joints are abnormal, inflammation on the right. Limited ROM on the right. Tenderness on the right . . . . Bursitis of shoulder, right[,] Shoulder impingement[.]"; Pet. Ex. 24 at 3; (on November 2, 2015, Dr. Ira Kurz, noted, "Chronic [right] Shoulder Syndrome (prob[ably] impingement)"; Pet. Ex. 35 at 2 (on November 10, 2015, Dr. Oscar Vazquez noted that petitioner was suffering from, "Impingement of the right shoulder [and] Right rotator cuff tendonitis…)".

For the above reasons, the undersigned finds that Ms. Sofia experienced pain and reduced range of motion limited to the shoulder in which she received the vaccine.

4. 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).

Prior to her September 30, 2014 flu vaccination, and as respondent notes in his brief, Ms. Sofia did have a medical history which included possible cervical radiculopathy and general arthritis. Pet. Ex. 6 at 8. Ms. Sofia underwent a cervical spine MRI on April 26, 2012, which was interpreted as showing "severe left C4-5 facet degenerative change", "congenital fusion of the left C2-3 facet", and "mild canal stenosis of C2-3, C3-4, C5-6, and C6-7." *Id.* at 8. The intake forms completed by Ms. Sofia in 2012-2014 reflect the presence of arthritis and joint pain. *See, e.g.* Pet. Ex. 5 at 1; Pet.

Ex. 19 at 2; Pet. Ex. 21 at 17. However, respondent's responsive motion does not discuss how or why petitioner's cervical spine issues or general arthritis may have explained petitioner's right shoulder symptoms following her flu vaccination.

A review of the records demonstrate that petitioner's issues with her cervical spine appear to affect mostly her left arm, elbow and hand. There is not preponderant evidence in the record to show that it affected or in any way contributed to her right shoulder symptoms. A diagnosis of cervical spine radiculopathy does not explain the specific circumstances of this case where Ms. Sofia experienced an abrupt onset of right shoulder pain within 48 hours of her September 30, 2014 flu vaccination, nor does it explain the objective decrease in the range of motion of her right shoulder after vaccination that was not present previously. *See e.g.* Pet. Ex. 14 at 2 (results of range of motion testing showing decreased range of motion in right shoulder versus left shoulder); *see also* Pet. Ex. 13 at 8 ("Painful to sleep on and painful restricted [range of motion]"); Pet. Ex. 13, p. 5 ("The shoulder joints are abnormal, inflammation on the right. Limited [range of motion on the right. Tenderness on the right").

Therefore, the undersigned finds that petitioner's cervical spine issues are a separate condition from her right shoulder injury associated with the flu vaccination, and that there are no conditions or abnormalities present that would explain petitioner's right shoulder symptoms.

i. <u>Logical sequence of cause and effect showing the vaccine was the reason for the injury</u>

Guided by the criteria for evaluating a Table SIRVA injury, the undersigned finds that Ms. Sofia has shown, by a preponderance of the evidence, a logical sequence of cause and effect showing that her September 30, 2014 flu vaccine was the reason for her shoulder injury. The SIRVA criteria provides a perfectly logical sequence of cause and effect including (1) 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). The undersigned has found, *infra*, that petitioner has satisfied all these requirements and thus has satisfied *Althen* prong two.

Moreover, based on the undersigned's knowledge and experience reviewing a large number of SIRVA claims, petitioner's clinical course is consistent with SIRVA. The undersigned further bases this finding on the previously filed articles, Court Exhibit I (B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010)) and Court Exhibit II (M. Bodor and E Montalvo, Vaccination Related Shoulder Dysfunction, 25 Vaccine 585 (2007)).

ii. Proximate temporal relationship between vaccination and injury

"The proximate temporal relationship prong [under *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. *See Langland v. Sec'y of Health & Human Servs.,* 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner's shoulder injury must begin within 48 hour or less of the vaccination. The undersigned has found that the onset of petitioner's shoulder injury began within 48 hours of the vaccination, and thus, petitioner has satisfied Althen prong two.

V. Conclusion

A cause-in-fact injury is established when petitioner demonstrates by a preponderance of the evidence: (1) she received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must establish each of three factors announced by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.* 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 proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

In light of all of the above, and in view of the submitted evidence, including the medical records and the parties' respective motions, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master