In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1324V
Filed: January 30, 2019
UNPUBLISHED

LORI SCHOONOVER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Ruling on Entitlement; Causation-In-Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner.
Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

Dorsey, Chief Special Master:

On October 12, 2016, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that she experienced a left shoulder injury following receipt of her October 16, 2013 influenza ("flu") vaccination. Petition at 1. For the reasons described below, the undersigned now finds that petitioner is entitled to compensation for her injury.

[1] The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling 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, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in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).

[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

Along with her petition, petitioner filed medical records marked as Exhibits 1 and 2. ECF No. 1. An initial statement of completion was filed on October 24, 2016. ECF No. 7. Based on the allegations in the petition, the case was assigned to the Special Processing Unit and an initial status conference was held with the staff attorney managing the case on November 22, 2016. ECF Nos. 4-5, 8.

At the initial status conference additional outstanding records were identified. ECF No. 8. On March 9, 2017, petitioner later filed further medical records marked as Exhibits 3 through 7 as well as a workers' compensation file marked as Exhibit 8 and an amended statement of completion. ECF No. 16-17. However, respondent additionally requested further evidence of vaccination which was later filed as Exhibit 9 on May 11, 2017, along with a second amended statement of completion. ECF Nos. 18, 21-22.

On July 12, 2017, respondent indicated that he felt this case was appropriate for informal resolution. ECF No. 26. Despite exchanging several proposals, the parties were unable to resolve the case and filed a joint status report on July 16, 2018, in which petitioner requested that respondent file his Rule 4(c) Report. ECF No. 52. During this period, petitioner filed personnel records marked as Exhibits 10 through 12 and updated medical records marked as Exhibit 13. ECF Nos. 41, 51.

Respondent filed his report on August 31, 2018. ECF No. 54. Respondent recommended against compensation in this case. *Id.* at 1. Specifically, respondent contended that petitioner had not met her burden of establishing a shoulder injury related to vaccine administration ("SIRVA") that was caused-in-fact by her October 16, 2013 vaccination.[3] *Id*. at 6. Respondent stressed, in particular, the view that petitioner had not presented preponderant evidence that her shoulder pain began within 48 hours of her vaccination. *Id*. Respondent requested that the case be dismissed. *Id*. at 7.

Based on a review of respondent's report, the undersigned indicated that the case would proceed to a ruling and ordered the parties to file simultaneous motions for a ruling on the record.[4] ECF No. 55. The parties filed their respective motions on October 25, 2018. ECF Nos. 57, 58. Petitioner argued that the record evidence is sufficient to establish both that her left shoulder pain began within 48 hours of vaccination and that her injury constitutes a SIRVA claim compensable under the Vaccine Act. ECF No. 58 at 11. Respondent argued that his review of petitioner's medical history suggests that petitioner failed to satisfy any of the three prongs to the *Althen* test for determining causation-in-fact in this program and requested a ruling from the undersigned denying compensation.[5] ECF No. 57 at 5-10.

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[3] Although SIRVA was added to the Vaccine Injury table in March of 2017, since this case was filed prior to that date, it does not qualify for any presumption of causation as a Table SIRVA. *See* § 14(c)(4) (indicating that any modification to 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.").

[4] Pursuant to Vaccine Rule 8(d), the undersigned may decide a case on the basis of written submissions without conducting an evidentiary hearing."

[5] Referring to *Althen v. HHS*, 418 F.3d 1274 (Fed. Cir. 2005), discussed further below.

In accordance with the undersigned's order, no responses were filed to either motion. Thus, this case is now ripe for a ruling on entitlement.

II. Factual History

On October 16, 2013, petitioner received a flu vaccination administered intramuscularly in her left deltoid at her place of employment, St. Luke's Hospital of Kansas City. Ex. 9 at 1. Petitioner's medical history does not indicate any relevant history of prior shoulder problems.[6]

On November 5, 2013, petitioner reported to St. Luke's Hospital's Employee Health Services. Ex. 7 at 119. At that time, petitioner reported left shoulder pain which she attributed to her flu vaccination. *Id*. She reported that "[s]he noticed at the time that the site of administration seemed to be much higher than she was used to . . . [and that] [s]he developed some persistent pain at the site of the injection on her left shoulder."[7] *Id*.

At that time, petitioner was evaluated by Scott Rex Steelman, DO. *Id*. Examination revealed diffuse palpable tenderness of the deltoid as well as point tenderness close to the attachment of the supraspinatus tendon to the humeral head. There was no evidence of reduced range of motion, but evidence of "painful arch" was present. No strength deficits were noted, but Dr. Steelman observed mild symptoms of impingement. *Id*. His assessment indicated that petitioner's injury was "left shoulder tendonitis secondary to flu shot administration" and recorded petitioner's date of vaccination as the date of injury. *Id*. A two-week course of Diclofenac sodium was prescribed and recommended before seeking any further follow up. *Id*.

Subsequently, petitioner sought orthopedic care from Dr. Lowry Jones on December 30, 2013. Ex. 1 at 56-59. Dr. Jones recorded that petitioner "had a flu shot at [St. Luke's Hospital], she felt it was too high. She has had constant pain in the shoulder and arm since. She was placed on Diclofenac without benefit." *Id*. at 56. Physical exam showed tenderness at the lateral acromion and pain with all motion overhead. Although she showed good strength, petitioner had pain with resisted strength evaluation above the shoulder. She demonstrated no significant limitation in motion other than internal rotation, which was attributed primarily to pain. *Id*. at 57. Dr. Jones noted no abnormality upon review of x-ray imaging. *Id*.

Dr. Jones's clinical assessment was subacromial bursitis and possible capsulitis. He did not believe that rotator cuff pathology was likely and postulated that petitioner's flu vaccine "resulted in some type of inflammatory change" in petitioner's shoulder. Ex.

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[6] Respondent agrees that petitioner's prior history is noncontributory. ECF No. 54 at 2.

[7] The next day, a workers' compensation report of injury form was completed on petitioner's behalf indicating an injury of "inflammation" in the upper left arm "due to receiving flu vaccination." Ex. 7 at 121. It lists the date of petitioner's vaccination as the date of injury. *Id*.

1 at 57. An MRI study was recommended, which was later performed on January 6, 2014. Ex. 1 at 57; Ex. 2 at 47.

Petitioner returned to Dr. Jones on January 16, 2014, for a recheck of her shoulder and to review her MRI results. Ex. 1 at 50-51. She complained of "continued constant pain." *Id*. at 50. Dr. Jones interpreted petitioner's MRI as showing "some impingement changes, with a few rotator cuff tendon fibers that appear to be torn," which he suggested "is not significant," and "some degenerative changes" to the labrum. *Id*. Dr. Jones's reported physical exam and assessment remained consistent with the record of her prior December 30, 2013 visit. *Id*. at 50-51. He recommended a Depomedrol injection with a further follow-up in three weeks and consideration of an arthroscopic procedure if there was no improvement. *Id*. at 51.

On January 30, 2014, petitioner returned to the orthopedist for a further follow-up, complaining that she experienced no benefit from her prior Depomedrol injection. Ex. 1 at 46. She reported that "the pain is no different" and that "[t]he injection did not give her significant relief." *Id*. Petitioner indicated that she was ready to proceed to arthroscopy. *Id*. The plan was to proceed with left shoulder arthroscopy with bursectomy and possible acromioplasty and debridement. *Id*. at 47.

On April 2, 2014, petitioner underwent the planned left shoulder arthroscopic procedure. Ex. 1 at 44-45. The procedure included bursectomy with "extensive subacromial debridement" and petitioner's post-operative diagnosis was "left shoulder subacromial bursitis (extensive)."

Shortly after petitioner's surgery, on April 7, 2014, Dr. Jones wrote a letter in support of petitioner's workers' compensation claim. Ex. 7 at 104. He opined:

> Based on the patient's subjective history and other data available to me, I believe the injuries sustained on the referenced date of injury are the prevailing cause for the need for her surgical treatment. She was found to have a very extensive subacromial bursitis. Having the onset directly after injection I believe the bursitis was due to her injection. She did not have any significant rotator cuff pathology, or intra-articular pathology. There was no preexistent disease process present. I do not believe the pre-existing treatments and conditions are a causative factor.

Id.

Petitioner had post-operative follow-up appointments on April 10, April 22, and May 8, 2014. Ex. 1 at 34-41. She was reportedly doing well, but still had pain. *Id*. at 35, 37. On May 8, 2014, she received a second subacromial Depomedrol injection. *Id*. at 35.

On June 9, 2014, petitioner presented for a physical therapy evaluation. Ex. 1 at 29. She reported that "she initially began having shoulder problems immediately after receiving the flu shot in September of last year." *Id*. She was recommended physical therapy one to three times a week for between four to six weeks. *Id*. at 30.

Petitioner returned to Dr. Jones on June 19, 2014. Ex. 1 at 25-27. She reported that her pain was increasing and that physical therapy was painful. *Id*. at 25. Petitioner had good range of motion and Dr. Jones suspected that her pain was related to localized inflammation as there was no indication of remaining adhesive capsulitis. *Id*. at 26. Petitioner returned again on July 3, 2014, complaining of continued and worsening pain. Id. at 22. On July 31, 2014, petitioner reported to Dr. Jones that she still had ongoing pain and also indicated "having whole arm numbness at times." *Id*. at 16-17. At this time Dr. Jones felt that petitioner's clinical exam "demonstrates progressive limitation in abduction and flexion consistent with inflammatory capsulitis." *Id*. at 17. Since prior injections and pain relievers had not worked, further physical therapy was recommended. *Id*. at 18.

On August 28, 2014, petitioner reported reduced range of motion which was confirmed on physical examination. Ex. 1 at 9-11. She was diagnosed with adhesive capsulitis. *Id*. Physical therapy was discontinued as petitioner believed the therapist was worsening her condition. *Id*. at 11.

In October of 2014, still experiencing pain, petitioner sought a second opinion from orthopedist Jeffrey Bradley, M.D. Ex. 2 at 42-46. Dr. Bradley's impression was adhesive capsulitis. He recommended physical therapy, but also ordered an MRI to rule out infection and better visualize the rotator cuff. *Id*. at 45. Petitioner began physical therapy on November 3, 2014. Ex. 6 at 57. An MRI conducted November 7, 2014, found adhesive capsulitis, small articular sided partial thickness supraspinatus tear, mild subacromial bursitis, and generalized synovitis. Ex. 7 at 67.

On November 14, petitioner returned to Dr. Bradley. Ex. 2 at 38-40. Petitioner reported that her pain remained unchanged. She denied any numbness or tingling. *Id*. at 38. Dr. Bradley felt petitioner's November 7, 2014 MRI was significant for confirming her adhesive capsulitis and felt the supraspinatus tear was "not of significance." *Id*. at 39. Based on petitioner's lack of progress, Dr. Bradley recommended a second arthroscopic surgery and evaluation. *Id*. at 40.

On December 4, 2014, petitioner underwent left shoulder manipulation under general anesthesia with arthroscopic debridement, capsular release, and synovectomy. Ex. 7 at 56. Her post-operative diagnosis was left shoulder adhesive capsulitis. *Id*. Subsequently, petitioner continued with physical therapy and pain management, but her symptoms did not resolve.

On October 22, 2015, petitioner presented to Dr. James Stuckmeyer for an independent medical evaluation related to her workers' compensation claim. Ex. 8 at 204-211. Dr. Stuckmeyer concluded that:

> [I]t would be the opinion of this examiner within a reasonable degree of medical certainty that as a direct, proximate, and prevailing factor of the accident occurring on October 16, 2013, that Ms. Schoonover as a result of a flu shot developed symptoms of significant left shoulder pain with treatment culminating in two separate operative procedures and multiple steroid injections. I would concur with Dr. Jones and Dr. Bradley that as a

> result of the injection, the patient developed a significant inflammatory response leading to marked adhesive capsulitis.

Ex. 8 at 210.

Dr. Stuckmeyer found petitioner to have sustained a 40% permanent partial disability to her left shoulder. Ex. 8 at 210. Subsequently, petitioner's unresolved adhesive capsulitis remained on her "Active Problem List" during some further medical appointments (October 25, 2016, and January 6, 2017), though no further evaluation was discussed.[8] Ex. 3 30-38. Petitioner later developed lower back and leg pain, though nothing in the records suggests this was related to her prior shoulder condition. Ex. 13 at 27-28, 37.

III. Ruling on Entitlement

As noted above, the undersigned finds that this case is ripe for adjudication on the question of petitioner's entitlement to compensation for her alleged shoulder injury or SIRVA. For the reasons described below, the undersigned finds that petitioner is entitled to compensation.

a. Legal Standard

In this case, because petitioner's claim predates the inclusion of SIRVA on the Vaccine Injury Table, petitioner must prove her claim by showing that her 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. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). 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 or even the predominant 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. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Under the leading *Althen* test, petitioner must satisfy three elements. The *Althen* court explained this "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

[8] In his Rule 4(c) Report, respondent notes that respondent sought updated medical records from petitioner on March 26, 2018, but that petitioner indicated on May 16, 2018, that petitioner sought no further treatment. ECF No. 54 at 6, n. 3.

> 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.

b. Analysis

The undersigned finds that petitioner satisfies the three prongs of *Althen* as follows:

i. *Althen* Prong 1

Under *Althen* Prong One, there must be preponderant evidence of a medical theory causally connecting petitioner's vaccination to her injury. In satisfaction of *Althen* Prong One, the undersigned takes judicial notice of the fact that respondent has added SIRVA to the Vaccine Injury Table for the influenza vaccine. *See* 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); *see also Doe 21 v. HHS*, 88 Fed. Cl. 178 (2009), ***rev'd on other grounds***, 527 Fed. Appx. 875 (Fed. Cir. 2013)(holding that recognition of a link between vaccine and injury on the Vaccine Injury Table supports petitioner's burden under *Althen* Prong One.).

Significantly, petitioner's diagnoses in this case were bursitis and adhesive capsulitis, both of which were explicitly cited by the Secretary as diagnoses causally related to vaccine injection. 80 Fed. Reg. 45132. Additionally, multiple physicians opined that petitioner's shoulder condition was vaccine-caused. *E.g.,* Ex. 7 at 119 (Scott Steelman, DO, assessing "left shoulder tendonitis secondary to flu shot administration."); Ex. 7 at 104 (Dr. Jones opining that "I believed the bursitis was due to her injection."); and Ex. 8 at 210 (Dr. Stuckmeyer stating that "as a result of the injection, the patient developed a significant inflammatory response leading to marked adhesive capsulitis.").

In any event, although respondent stresses petitioner's burden to establish all *Althen* prongs by preponderant evidence, he has not disputed that the influenza vaccine can cause SIRVA. In that regard, it is worth noting that there is a well-established track

record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program. *See, e.g., Loeding v. HHS*, No. 15-740V, 2015 WL 7253760 (Fed. Cl. Spec. Mstr. Oct. 15, 2015)(noting that "respondent 'has concluded that petitioner's injury is consistent with SIRVA; that a preponderance of evidence establishes that her SIRVA was caused in fact by the flu vaccination she received on October 14, 2014; and that no other causes for petitioner's SIRVA were identified."); *see also Johnson v. HHS*, No. 16-165V, 2016 WL 3092002 (Fed. Cl. Spec. Mstr. Apr. 13, 2016)(awarding compensation for a SIRVA caused-in-fact by the influenza vaccine); *Koenig v. HHS*, No. 16-1496V, 2017 WL 6206391 (Fed. Cl. Spec. Mstr. Apr. 13, 2017)(same).

ii. *Althen* Prong 2

Under *Althen* Prong Two, petitioner must demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury. Although petitioner's claim does not constitute a Table Injury, the undersigned finds the QAI criteria for SIRVA to be persuasive regarding the factors necessary to demonstrate a logical sequence of cause and effect. The criteria under the QAI 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).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA).

In light of the factual history described above, the undersigned finds that all four of the criteria listed in the QAI for SIRVA are satisfied by preponderant evidence.

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

Upon the undersigned's review, nothing in petitioner's prior medical history suggests any relevant history of pain, inflammation or dysfunction of petitioner's left shoulder. Moreover, respondent conceded that petitioner's "past medical history was noncontributory." ECF No. 54 at 2.

2. Pain occurs within the specified time-frame

The question of when petitioner's shoulder pain first manifested is the primary basis for respondent's recommendation against compensation in this case. In his Rule 4(c) Report, respondent argues that:

> The current record does not establish by preponderant evidence that petitioner's left shoulder pain began within forty-eight hours of vaccination.[9] When petitioner first reported her shoulder pain to Employee Health nearly three weeks after her vaccination, she did not specify when she developed pain. She only stated that her symptoms had improved since the week before. While petitioner consistently generally relates her symptoms to receiving the flu vaccine, there [are] insufficient records substantiating that the onset of her pain occurred within the requisite forty-eight hour timeframe.

ECF No. 54 at 6 (citations omitted).

The undersigned is not persuaded by this argument. Medical records generally "warrant consideration as trustworthy evidence." *Cucuras v.HHS,* 993 F.2d 1525, 1528 (Fed. Cir. 1993). Based on the undersigned's review of the medical records in this case, the undersigned finds preponderant evidence that the onset of petitioner's shoulder pain was immediate.

Petitioner's medical records reflect that she consistently and repeatedly linked her shoulder pain to her vaccination in an explicit fashion throughout the course of her treatment. Moreover, in several instances she explicitly stated that the pain was "immediate" or occurred "since" the time of the vaccination. Dr. Jones recorded that petitioner "had a flu shot at [St. Luke's Hospital], she felt it was too high. She has had constant pain in the shoulder and arm since. She was placed on Diclofenac without benefit." Ex. 1 at 56. Additionally, when she first reported for physical therapy, petitioner reported that "she initially began having shoulder problems immediately after receiving the flu shot in September of last year." Ex. 1 at 29.

Given the record as a whole, the fact that the first of her physicians (Dr. Steelman) did not specifically record the time of onset is of no moment. Despite failing to record the exact onset of petitioner's shoulder pain, Dr. Steelman nonetheless assessed petitioner's shoulder pain at that visit as being "secondary to flu shot administration." Ex. 7 at 119.

In weighing medical records, "it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. HHS*, 23 Cl.Ct. 726,

[9] Forty-eight hours is the period for onset included in the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(B).

733 (1991), *aff'd,* 968 F.2d 1226 (Fed. Cir. 1992). Notably, respondent cites no notation anywhere in petitioner's medical records that is inconsistent with an immediate onset of shoulder pain or in any way suggestive of onset outside of the appropriate timeframe.

Respondent's argument concedes that petitioner's injury was attributed to her vaccination, but nonetheless argues that the medical record entries are too vague with regard to the timing of onset to be credited as evidence regarding onset. The undersigned has previously observed in prior SIRVA cases, however, that histories of present illness reported by patients may include imprecise or generalized recollections of onset that should not be overanalyzed where they are consistent with the appropriate timeframe. *Cooper v. HHS*, No. 16-1387V, 2018 WL 1835179, n.13 (Fed. Cl. Spec. Mstr. Jan. 18, 2018). This is particularly so in a case such as the instant case where petitioner's physician felt the history provided by petitioner was sufficient for him to attribute her condition to the vaccination.

In that regard, the undersigned notes that respondent's argument is inconsistent with the Vaccine Act insofar as the statute instructs – at least with regard to Table injuries – that the special master may find the time period for the first symptom or manifestation of onset required for a Table injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset . . . occured within the time period described in the Vaccine Injury Table." *Id.*

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

The undersigned finds no evidence that petitioner's pain and reduced range of motion extended beyond her left shoulder. Nor does respondent suggest that any such evidence exists. Although petitioner later suffered from lower back and leg pain, nothing in the records suggests that this was related to her shoulder condition.

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)

The undersigned also finds no evidence of any condition or abnormality that would otherwise explain her symptoms. Although petitioner reported numbness "at times" at one orthopedic appointment (Ex. 1 at 16-17), no clinical significance was ascribed to the report and no neurological follow up testing was ordered. When later seeking a second orthopedic opinion, petitioner denied any numbness or tingling. Ex. 2 at 38. Respondent has not suggested that any other condition is present that could explain petitioner's shoulder condition.

5. Substantiation by medical records or by medical opinion

Moreover, separate and apart from the specific requirements of the QAI, as noted above, multiple of petitioner's treating physicians opined that petitioner's shoulder condition was vaccine-caused. *E.g.*, Ex. 7 at 119,104; Ex. 8 at 210. "[T]reating 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 v. HHS,* 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280).

Respondent argues that these physician opinions should be discounted or rejected altogether, because "all of these notations appear to be based on a temporal association between the vaccination and the claimed injury, which is legally insufficient." ECF No. 57 at 8. The undersigned disagrees. Although petitioner's report of immediate onset was likely significant to these physicians, each physician also based their assessments on a physical examination. Drs. Jones and Bradley also each maintained their opinions after review of MRI imaging and operative findings. Moreover, as noted above, petitioner's specific diagnoses – bursitis and adhesive capsulitis – were explicitly cited in respondent's proposed rulemaking as constituting SIRVA when respondent added the condition to the Vaccine Injury Table. Thus, it is not accurate to say that these physicians' opinions were based on a temporal association alone.[10]

Thus, for all of the above reasons, the undersigned finds that petitioner has satisfied *Althen* Prong Two.

iii. *Althen* Prong 3

Under *Althen* Prong Three, there must be a proximate temporal relationship between vaccination and injury. In this case, both parties agree that the relevant, medically accepted, timeframe for onset of a SIRVA injury is within 48 hours of vaccination.[11] ECF No. 58 at 9; ECF No. 54, at 6. Thus, in light of the above finding

[10] Though mindful of the distinction between Table and Cause-in-Fact burdens of proof, the undersigned also notes that no particular diagnosis or finding is required for a condition to constitute a SIRVA. Respondent proposed SIRVA as a Table injury on the basis of prior literature that found a temporal relationship between vaccination and a number of different shoulder conditions. 80 Fed. Reg. 45132 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052). As defined in the QAI, and as conceded on a causation-in-fact basis across hundreds of prior cases, SIRVA is effectively established by a temporal association between vaccination and onset of shoulder pain along with the absence of any other explanation. Thus, particularly where, as here, petitioner's actual medical diagnoses of bursitis and adhesive capsulitis have been specifically identified by respondent as associated with post-vaccination pain and consistent with SIRVA, it is not at all clear what additional factors respondent believes should have been considered by these treating physicians.

[11] In his motion for a ruling on the record, respondent stressed that "[w]hat constitutes an 'appropriate' temporal association is a question of fact that varies with the particular theory of causation advanced, and is not the respondent's burden to establish." ECF No. 57, p. 9 (citing *Pafford* v. *HHS*, 451 F.3d 1352, 1358 (Fed. Cir. 2010)). Respondent further indicated that "[i]n this case, no theory has been advanced and the onset of petitioner's left shoulder pain is unclear." *Id*. Nonetheless, respondent cited approvingly

that petitioner's shoulder pain began immediately after her October 16, 2013 flu vaccination, petitioner has necessarily satisfied *Althen* Prong Three.

iv. Factors Unrelated to Vaccination

Respondent has not asserted, nor would the undersigned find, that there is any evidence to support respondent's burden of establishing an alternative cause for petitioner's injury unrelated to vaccination.

II. Conclusion

Thus, for all the foregoing reasons, **the undersigned finds that petitioner is entitled to compensation.** Accordingly**,** the undersigned **DENIES** respondent's motion for a ruling on the record denying compensation (ECF No. 57) and **GRANTS** petitioner's motion for a ruling on the record finding that petitioner is entitled to compensation (ECF No. 58).

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

to the 48 hour timeframe applicable to Table SIRVA claims and asserted that "[t]he current record does not establish by preponderant evidence that petitioner's left shoulder pain began within forty-eight hours of vaccination." ECF No. 57 at 9, n. 3. In his prior Rule 4(c) Report, respondent explicitly relied on the 48 hour time period when discussing his prior recommendations for compensation in previous causation-in-fact SIRVA claims. ECF No. 54 at 6.