In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1387V
Filed: January 18, 2018
UNPUBLISHED

JODI COOPER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Ruling on Entitlement; Causation-In-Fact; Hepatitis A (Hep A) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Amy Paula Kokot, U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACT AND RULING ON ENTITLEMENT[1]

Dorsey, Chief Special Master:

On October 24, 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 suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of her October 30, 2015 Hepatitis A ("Hep A") vaccination. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. Petitioner now moves for a decision on the written record (1) making a fact finding as to the onset of petitioner's shoulder pain and (2) further finding that petitioner is entitled to compensation. (*See* ECF No. 29.) For the reasons

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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).

described below, the undersigned grants petitioner's motion and finds that petitioner is entitled to compensation.

I. Procedural History

On November 4, 2016, petitioner filed medical records marked as Exhibits 1-9 along with an affidavit marked as Exhibit 10. (ECF No. 7.) Following an initial status conference, additional records were ordered, which were filed as Exhibits 11 and 12 on January 17, 2017. (ECF Nos. 9, 10.)

Initially, the parties engaged in settlement discussions. (ECF No 15.) However, on August 7, 2017, petitioner's counsel advised the undersigned that the parties had reached an impasse. (ECF No. 24.) During a status conference held August 23, 2017, the parties reported that "they have evaluated and valued the case differently and that the most significant issue is respondent's view regarding the period of time from vaccination until petitioner sought treatment of her injury." (ECF No. 25.) The parties further agreed that the record was complete, with the exception of a potential fact hearing. (*Id*.)

Subsequently, the parties agreed to proceed to a ruling on the written record in lieu of a fact hearing and a further status conference was held to establish a briefing schedule. (ECF No. 28.) The parties agreed that petitioner would file a motion for a finding of fact accompanied by any outstanding supplemental evidence petitioner wished to have considered, followed by a combined Rule 4 Report and motion response by respondent, and a reply brief by petitioner. (*Id*.)

Petitioner filed her motion on October 23, 2017, and did not include any accompanying supplemental evidence. (ECF No. 29.) Respondent filed his combined Rule 4 report and motion response on January 2, 2018, and petitioner's reply was filed on January 17, 2018. (ECF Nos. 31, 32.)

Thus, petitioner's motion for a ruling on the written record is now ripe for adjudication.

II. Factual History

On October 30, 2015, petitioner received a Hepatitis A vaccination from her primary care physician which was administered in her left deltoid. (Ex. 1, p. 1; Ex. 2, p. 1.) Petitioner averred that she received the vaccination in preparation for a month long trip to Vietnam beginning November 24, 2015. (Ex. 10, pp. 1-2.)

At the time of her vaccination, petitioner was 51 years old. (Ex. 2, p. 1.) Her prior medical history included prior reports of back pain (*e.g.* Ex. 5, p. 1), headaches (*e.g.* Ex. 5, pp. 4-5), joint pain (*e.g*. Ex. 12, p. 7), and right shoulder pain (*e.g*. Ex. 12, p. 3).[3] Perhaps most notably, more than two years prior to the vaccination at issue in this case,

[3] Petitioner's right shoulder pain began as a sudden pain while exercising (push-ups) in July of 2012. It was diagnosed as a rotator cuff strain. (Ex. 12, p. 3.)

on July 8, 2013, petitioner presented to her chiropractor with a two day history of left shoulder pain radiating down the left arm and into the little finger. (Ex. 5, p. 4.) Petitioner did not relate her shoulder pain to any trauma. (*Id*.) Her chiropractor suggested the pain could be related to her ongoing neck and back problems and performed a full spine adjustment and recommended cryotherapy. (*Id*.) Three days later, petitioner returned to her chiropractor on July 11, 2013, and reported that the shoulder pain had resolved. (*Id*.) Additionally, petitioner reported in her affidavit that she previously slipped and fell on the deck of her boat in August of 2015, but indicated that she did not suffer any injury as a result. (Ex. 10, p. 2.)

Petitioner averred that her October 30 Hep A injection was "excruciating." (Ex. 10, p. 1.) She further indicated that she commented on the pain to the nurse who administered the injection, but was told the pain was normal. (*Id*.) Petitioner felt the vaccination had been given high on the shoulder. (*Id*.) She described aching for three weeks following the vaccination and indicated that she performed massage and minor stretching. (*Id*. at 2.) Petitioner represented that she was very busy during this period, preparing for her upcoming trip to Vietnam and making care arrangements for her 91 year old mother, a dementia patient living in a nursing home. (*Id*.) Petitioner averred that she prioritized these concerns over her own care. (*Id*.)

Petitioner further explained that from November 25, 2015, until December 21, 2015, she and her husband were in Vietnam. (Ex. 10, p. 2.) Petitioner recalled that she had difficulty dressing while she was on her trip and that she had several massages during her trip for pain relief. (*Id*.) Upon her return from Vietnam, petitioner reports that she was informed on December 23, 2015, that her mother had fallen and was acting strangely. Petitioner further explained that her mother was placed in hospice care and died on December 29, 2015. (*Id*.) Petitioner made all the arrangements for transport and cremation. (*Id*.)

Thereafter, petitioner first sought medical treatment for her shoulder pain on January 6, 2016. (Ex. 3, p. 47; Ex. 10, p. 3.) According to her physician's notes, petitioner "complains of left shoulder pain" that "has been present for the last 1-2 months occurring with reaching or extending. She denies any injury, trauma, swelling, bruising, or pain at rest."[4] (Ex. 3, p. 47.) Petitioner also described "near identical" prior episodes of frozen shoulder. The physician noted that in 2012 she had been diagnosed with right shoulder tendinitis.[5] (*Id*.) Upon physical examination, petitioner's shoulder was "tender to palpation over supraspinatus," but impingement tests ("Hawkins") were negative and range of motion was normal for flexion, extension, and rotation. (Ex. 3, p.

[4] Petitioner also complained of palpitations which she reported were not a new symptom, having been occurring for "a few years." (Ex. 3, p. 47.)

[5] This record does not specifically identify the shoulder implicated in the near identical prior episodes of frozen shoulder, but does seem to suggest in the later notation that this refers to petitioner's 2012 right shoulder tendinitis diagnosis. (Ex. 3, p. 47.) Petitioner's earlier shoulder complaints are recorded at Ex. 5, p. 4 (left shoulder, 2013) and Ex. 12, p. 3 (right shoulder, 2012).

48.) X-rays were negative. (*Id*.) Petitioner was diagnosed as having rotator cuff tendinitis and physical therapy was recommended.[6] (*Id*.)

Subsequently, petitioner underwent a physical therapy evaluation on January 19, 2016. (Ex. 3, p. 2.) Petitioner provided a history indicating that her shoulder pain "began in early November but is not sure what caused it. She did have a fall on a boat in August though." (Ex. 3, p. 2.) She reportedly treated previously with ice, heat, arnica, and TENS.[7] (*Id*.) The date of injury onset is listed on petitioner's evaluation as November 1, 2015. (*Id*.) Hawkins/Kennedy testing for impingement was positive and petitioner was assessed as having impingement and tendinitis. (Ex. 3, p. 3.) Decreased scapular strength and stability was also noted. (*Id*.) Petitioner's physical therapy plan included 1-2 visits per week for six weeks. (*Id*.)

On February 1, 2016, at her fourth physical therapy visit, [8] petitioner reported that "her shoulder continues to be painful. She began having pain shortly after she received a vaccination in the shoulder back in November. She felt the injection was too high in her shoulder and has done some online research which showed others with similar problems."[9] (Ex. 3, p. 10.) The therapist further noted that "Jody and I discussed the possibility of shoulder injury due to vaccine administration. I encouraged her to contact her primary care physician to discuss this further." (*Id*.) Petitioner averred in her affidavit that she discovered that vaccinations can cause shoulder injuries while researching the causes of bursitis and tendinitis. (Ex. 10, p. 3.)

Petitioner continued her physical therapy sessions throughout February 2016 without any further discussions being noted regarding the onset of her condition.[10] (Ex. 3, pp. 12-23.) However, during that same period, petitioner also saw her chiropractor

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[6] Respondent stresses that there was no mention of petitioner's Hep A vaccination in the record of this visit. (ECF No. 31, p. 2.) However, petitioner avers that, at the time of her January 6, 2016 assessment she did not understand or realize that her arm could be injured as a result of a vaccination. (*See* Ex. 10, p. 2 ("I didn't realize a routine vaccine could cause so much pain."); Ex. 10, p. 3 (" . . . I saw my doctor on January 6, 2016. I explained how badly my left shoulder hurt, but still didn't realize my arm could be injured as a result of my vaccine.").)

[7] TENS is an acronym for transcutaneous electrical nerve stimulation. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd Ed.), p. 1882.

[8] Petitioner's first physical therapy session occurred January 19, 2016, her second on January 22, 2016, and her third on January 27, 2016. (Ex. 3, pp. 4-9.) None of the session notes for these visits contain any notations regarding onset of petitioner's injury.

[9] This record is somewhat ambiguous in stating that "she began having pain shortly after she received a vaccination in the shoulder back in November." One might interpret this language as misplacing the date of vaccination, however, the undersigned interprets this notation as being silent as to the date of vaccination and indicating that the pain began "back in November." This remains consistent with petitioner's other reports of pain starting at the beginning of November.

[10] The record of petitioner's February 23, 2016 session repeats the same history of onset included in her initial evaluation, but does not appear to be a new or separate report from petitioner regarding onset. (Ex. 3, p. 20.)

and an acupuncturist. In both instances, petitioner reported that she was experiencing shoulder pain that she linked to her vaccination.[11] (Ex. 5, p. 22; Ex. 4, p. 1.) Petitioner's health history questionnaire from the acupuncturist lists the onset of her shoulder pain as the "1st week of Nov." (Ex. 4, p. 1.) Additionally, the acupuncturist's notes of the same date indicate that petitioner's left shoulder pain "started after getting 2nd Hep A shot in upper arm Oct. 2015. Pain and stiffness increased over next 2-3 mos." (Ex. 4, p. 5.)

On February 23, 2016, petitioner's physical therapist noted that after eight sessions, petitioner's shoulder pain was increasing while her range of motion decreased. (Ex. 3, p. 21.) An orthopedic consultation was recommended. (*Id*.)

On March 11, 2016, petitioner was evaluated by an orthopedist. (Ex. 7, p. 1.) The history taken by the orthopedist stated that petitioner:

> has been having left shoulder restricted mobility and problems since she had a hepatitis A vaccine for travel back on October 30, 2015. She said when the shot was administered, it was very painful for several days afterwards, and then she began to have increasing pain in the shoulder to the point where it gradually became worse where she had difficulty moving the shoulder. She now has a lot of trouble staying asleep because of the discomfort in the shoulder. She has tried Advil. She has done physical therapy and continues with physical therapy, but none of this has really helped her condition. She is most frustrated by the restricted mobility of the shoulder in addition to the nighttime pain. Other than this injection, she has had no prior injury to the shoulder. Pain is described as deep in the shoulder, sometimes radiating to the upper arm. She has not noted distal grip weakness. There has been no numbness, paresthesias, tingling, or neck pain.

(Ex. 7, p. 1.)

On physical examination, the orthopedist found no visible swelling or atrophy of the shoulder but noted slight palpatory pain over the anterolateral subacromial bursa. "Global limitations" were noted in range of motion, including having only 80 degrees of forward flexion, 70 degrees of abduction, and 20 degrees of external rotation. (Ex. 7, p. 2.) Impingement signs were noted to be difficult to assess, but increased pain was noted on the Hawkins test. (*Id.*) Additionally, the orthopedist confirmed that petitioner's prior January 6, 2015 x-rays were negative and additionally ordered diagnostic ultrasound, which was also negative for any shoulder abnormalities. (*Id*.) The orthopedist's diagnostic impression was that "Jodi's symptoms appear consistent with

[11] Petitioner also presented to her chiropractor with "increased pain in both sides of the cervicothoracic area" as well as increased neck pain potentially due to her shoulder exercises. (Ex. 5, p. 22.) The chiropractor believed that "there may be a connection in the lack of improvement in her shoulder with PT and her upper back and neck issues." (*Id*.)

left adhesive capsulitis. I suspect given her history, this may have been aggravated initially by the injection into the subacromial bursa with her hepatitis vaccine that may have triggered this." (Ex. 7, p. 2.)

In the several months following her orthopedic evaluation, petitioner had further appointments with her chiropractor (Ex. 9, p. 9), a massage therapist (Ex. 6), and physical therapist (Ex. 3, p. 36). She also established care with a new primary care physician on March 21, 2016. (Ex. 8, p. 7.) Her intake history included "frozen shoulder on left since last October." (*Id*.) Petitioner declined a second orthopedic evaluation. (Ex. 8, p. 8.) On April 20, 2016, petitioner returned to her primary care physician. (Ex. 8, p. 3.) At that time it was noted that petitioner had ended her physical therapy sessions, but that she still had "quite limited" range of motion. (*Id*.)

III. Party Contentions

Although petitioner acknowledges that this petition was filed prior to the inclusion of SIRVA on the Vaccine Injury Table, petitioner's motion nonetheless urges that the Qualifications and Aids to Interpretation ("QAI") for SIRVA should be considered instructive regarding the criteria for determining whether a SIRVA exists.[12] (ECF No. 29, p. 6.) Petitioner asserts that the medical records and affidavit filed in this case establish that petitioner's symptoms began within 48 hours of her alleged injury-causing vaccination as required by the QAI. (*Id*.) Petitioner cites eight separate notations in the medical records which she asserts support her contention and urges the undersigned to evaluate the record of the case as a whole, discounting instances of erroneous vaccination dates or records that are silent as to onset. (*Id*. at 7.) Petitioner also urges

[12] Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). *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). 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); *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).

that her extensive, sworn statement regarding her delay in seeking treatment be credited. (*Id*. at 7-8.)

In his response, respondent counters that petitioner's contemporaneous records do not establish that her injury manifested within 48 hours of vaccination. (ECF No. 31, p. 6.) Respondent stresses that petitioner waited more than two months to seek medical treatment, and that this delay casts doubt on both the development of her injury and the accuracy of her recollections. (*Id*.) Respondent further stresses that petitioner did not link her vaccination with her injury until she conducted online research, having initially linked it to her slip and fall on her boat, and did not report the link to her treating providers until February of 2016. (*Id*. at pp. 6-7.)

Respondent further suggests that the physician statements in petitioner's medical records purporting to link the vaccination and her injury stem from petitioner's own reports and do not constitute reliable medical opinions. (*Id*. at 7.) Respondent argues that "it must be determined whether any of these statements actually represents physicians' medical conclusions, as opposed to mere speculation or recitation of assertions made by petitioner." (*Id*.) Respondent asserts that, when viewing the record as a whole, the claim that petitioner's symptoms began within 48 hours or the claim that there is a causal relationship between petitioner's injury and her vaccination "amount to no more than 'the claims of petitioner alone'" and therefore cannot form the basis for an award of compensation. (*Id*. (citing §300aa-13(a)(1).) Respondent requested that petitioner's petition be dismissed. (*Id*. at 8.)

In her reply, petitioner reiterates her argument that her affidavit should be viewed as credible and further stresses that respondent does not directly challenge any of the factual statements made by petitioner. (ECF No. 32, pp. 1-2.) Additionally, petitioner challenges respondent's view that the histories petitioner provided to her physicians should be given less weight or viewed as less credible, contending in particular that petitioner's use of online research was a reasonable means to inform the history she provided her doctors. (*Id*., pp. 3-4.)

IV. Finding of Fact

The first issue to be addressed is the parties' dispute over whether the onset of petitioner's condition was within 48 hours of the vaccination implicated by petitioner's claim. Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). In light of all of the above record evidence and for the reasons described below, the undersigned finds that there is preponderant evidence that the onset of petitioner's alleged shoulder pain occurred within 48 hours of petitioner's October 30, 2015 Hep A vaccination.

As described above, petitioner's contemporaneous medical records demonstrate that petitioner repeatedly and consistently placed the onset of her condition within 48 hours of her vaccination, even during the period where she has suggested that she did not herself understand the connection between her vaccination and injury. The first time petitioner sought medical treatment for her injury on January 6, 2016, she placed the onset of her pain as being up to two months prior, which would place onset in early November. (Ex. 3, p. 47.) Her subsequent physical therapy evaluation just two weeks later placed onset at November 1, 2015, *i.e*. specifically within 48 hours of October 30, 2015. (Ex. 3, p. 2.) Petitioner further linked the onset in her injury to her vaccination in an explicit fashion in subsequent medical visits during the course of her treatment. (*E.g*. Ex. 3, p. 10.; Ex. 5, p. 22; Ex. 4, p. 5; Ex. 7, p. 1.) Moreover, all of petitioner's subsequent reports regarding onset remained consistent with her initial recollection.[13]

Respondent implicitly argues that the above-described medical records do not constitute *contemporaneous* records, noting that these records are "well outside of a medically appropriate interval to ascribe causation to the vaccine, and the months-long gap casts doubt upon both the development of left shoulder pain shortly after petitioner's vaccination and the accuracy of her recollection." (ECF No. 31, p. 6.) Although respondent raises a reasonable point in the abstract, the undersigned does not find this argument persuasive given the specific facts of this case.

Medical records generally "warrant consideration as trustworthy evidence." *Cucuras v.HHS,* 993 F.2d 1525, 1528 (Fed.Cir.1993). However, greater weight is typically given to contemporaneous records. *Vergara v. HHS*, 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.") In this case, the undersigned does not accept respondent's premise that the records in this case constitute later histories rather than contemporaneous records.

As respondent notes in his motion response, the weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or

[13] The undersigned recognizes that many of these records are imprecise regarding onset (e.g. "1-2 months," "1st week of November," or "early November"); however, it would be a mistake to overanalyze these notations in search of a precise onset date when they were clearly provided as generalizations (*e.g*. it would not be accurate to assume that petitioner's reference to "1-2 months" made on January 6 and clearly intended as an approximation necessarily meant November 6 and not a day earlier). It is sufficient that, petitioner's vaccination having occurred on October 30, the reported timeframe of early November reflected by the record as a whole does encompass the 48 hour post-vaccination period. Additionally, it is significant that when petitioner's physical therapist selected a date certain for onset based on petitioner's report, she selected November 1, 2015, which is within 48 hours of the vaccination. (Ex. 3, p. 2.) This allows that petitioner's treating practitioners understood at the time that her earliest reports, general as they may be, reflected onset at the beginning of November rather than some later point in November.

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by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." *Cucuras*, 993 F.2d at 1528. That is exactly the context in which the above-described medical records discussed the onset of petitioner's shoulder pain. Thus, the undersigned does not find a delay in treatment of several months to be dispositive in and of itself regarding the question of onset in a SIRVA case such as this. Petitioner's recollection that her injury began during the period immediately following her vaccination is evidenced from her very first treatment record regarding her shoulder injury. Moreover, none of her subsequent medical records contain any notation inconsistent with her initial placement of her injury in early November.[14] Additionally, there are no records reflecting intervening medical visits where petitioner failed to note her shoulder pain. That is, petitioner's recollection of onset was clearly documented (initially and many times subsequently) in the context of diagnosis and treatment "with proper treatment hanging in the balance." Thus, contrary to respondent's assertion, petitioner's claim is corroborated by contemporaneous treatment records.

Additionally, the undersigned finds petitioner's sworn statement explaining her pattern of treatment and reports to her physicians as reasonable and credible. *See, e.g. Stevens v. HHS*, 90-221V, 1990 WL 608693, *3 (Cl. Ct. Spec. Mstr. 1990)(noting that clear cogent, and consistent testimony can overcome missing or contradictory medical records). Petitioner's account is detailed, concrete, and describes verifiable facts bearing on petitioner's delay in seeking treatment. Moreover, in the undersigned's experience, petitioner's sworn statement and medical records together reflect a pattern of treatment consistent with and similar to many other SIRVA claims.

Also significant is that petitioner's account is fully consistent with her contemporaneous medical records. 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, 733 (Fed. Cl. 1991)(*aff'd* 968 F.2d 1226 (Fed. Cir. 1992)); *cf. Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight."). In this case, the undersigned is persuaded that petitioner's much more detailed sworn statement is in harmony with the contemporaneous records and provides additional

[14] Petitioner's first physical therapy evaluation on January 19, 2016, does include a reference to a fall on a boat in August; however, this reference immediately follows her report that the injury began in "early November" and expands on petitioner's explanation that she does not know what caused her injury. (Ex. 3, p. 2.) Thus, the undersigned does not interpret petitioner's reference to the August slip and fall as a statement regarding onset. Petitioner has averred that she did not understand until later that her vaccination was capable of causing her injury. (Ex. 10, pp. 2-3.) Additionally, petitioner reported at her January 6, 2016 medical visit that her shoulder pain was not related to any injury or trauma. (Ex. 3, p. 47.)

credible statements regarding her condition that are absent or omitted from the medical records, rather than contradicted by the medical records.

Thus, petitioner's contemporaneous reports to her physicians and her much more detailed statements in her sworn affidavit corroborate one another. The undersigned finds that petitioner's sworn statements and medical records work in tandem to provide preponderant evidence that her shoulder pain began within 48 hours of her October 30, 2015 Hep A vaccination.

V. Ruling on Entitlement

In light of the above finding of fact, the undersigned further finds that this case is ripe for adjudication on the question of petitioner's entitlement to compensation for her alleged 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 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 Hepatitis A 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 (July 30, 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.)

In any event, although respondent stresses petitioner's burden to establish all *Althen* prongs by preponderant evidence, he has not disputed that the Hep A 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. April 13, 2016)(awarding compensation for a SIRVA caused-in-fact by the influenza vaccine); *Koenig v. HHS*, No. 16-1496V, 2017 WL6206391 (Fed. Cl. Spec. Mstr. April 13, 2017)(same). Moreover, respondent has conceded causation in many prior Hep A-caused SIRVA cases in particular. *See, e.g. Telonidis v. HHS*, No. 15-450V, 2015 WL 5724746 (Fed. Cl. Spec. Mstr. Sept. 2, 2015); *Salas v. HHS*, No. 16-739V, 2016 WL 8459834 (Fed. Cl. Spec. Mstr. Nov. 7, 2016).

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. Although petitioner did seek treatment for left shoulder pain in 2013, the records show that the pain resolved within five days. (Ex. 5, p. 4.) Moreover, no follow up diagnostics were performed at that time to reveal any shoulder dysfunction and ultrasound and x-rays conducted post-vaccination did not reveal any potentially pre-existing condition or abnormality to explain petitioner's symptoms. (Ex. 7, p. 2.) Nor, for that matter, has respondent asserted that petitioner's 2012 report of left shoulder pain could explain her post-vaccination condition.

Additionally, petitioner's post-vaccination medical records reveal no other proffered explanation for her injury and her diagnostic evaluations are significant for multiple findings on physical examination consistent with a SIRVA injury, including tenderness to palpation over the supraspinatus (Ex. 3, p. 48) and positive impingements on Hawkins/Kennedy tests (Ex. 3, p. 3). Further, following his evaluation, petitioner's orthopedist concluded that "Jodi's symptoms appear consistent with left adhesive capsulitis. I suspect given her history, this may have been aggravated initially by the injection into the subacromial bursa with her hepatitis vaccine that may have triggered this." (Ex. 7, p. 2.)

Respondent argues that the physician statements contained in the medical records should be discounted, because they likely constitute either "mere speculation or a recitation of assertions made by petitioner." (ECF No. 31, p. 7.) In that regard, respondent stresses that a physician's conclusions "are only as good as the reasons and evidence that support them," and argues that the claim of a causal relationship based on petitioner's report of onset within 48 hours "amount to no more than 'the claims of petitioner alone.'"

Given the finding of fact above, the undersigned is not persuaded by respondent's argument. As noted above, petitioner's assertion that her injury began within 48 hours of her vaccination is credible and supported by contemporaneous records. Thus, the undersigned does not find that petitioner's physicians' reliance on that history was misplaced or suspect. Moreover, the orthopedist's records reflect a full physical evaluation, including diagnostic ultrasound to rule out shoulder irregularities. Therefore, it is not accurate to characterize his medical opinion has "mere speculation." Respondent has not raised any other challenge to the credibility of petitioner's treating physicians.

For all these reasons, the undersigned finds that petitioner has presented preponderant evidence pursuant to *Althen* Prong Two of a logical sequence of cause and effect showing that her injury was vaccine-caused.

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. (ECF No. 29, p. 7; ECF No. 31, pp. 7-8.) Thus, in light of the above finding of fact that petitioner's shoulder pain began within 48 hours of her October 30, 2015 Hep A vaccination, petitioner has necessarily satisfied *Althen* Prong Three.

iv. Factors Unrelated to Vaccination

Although petitioner's medical records include a reference to prior left shoulder pain in 2012 (Ex. 5, p. 4) as well as a report of a slip and fall on a boat made in the context of assessing the cause of petitioner's shoulder injury (Ex. 3, p. 2), respondent has not asserted, nor would the undersigned find, that these isolated notations in the medical records are sufficient to carry respondent's burden of establishing an alternative cause for petitioner's injury unrelated to vaccination.[15]

VI. Conclusion

Thus, for all the foregoing reasons, the undersigned DENIES respondent's request that this case be dismissed (ECF No. 31, p. 8) and GRANTS petitioner's motion for a finding that petitioner is entitled to compensation (ECF No. 29, p. 1).

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[15] Respondent does assert that petitioner's reference to the slip and fall on her boat should cast doubt on the accuracy of her recollection (ECF No. 31, p. 7), but this is addressed above. In particular, *see* fn. 14, *supra*.