

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1664V

Filed: March 30, 2018

UNPUBLISHED

KELLI TENNESON,

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)

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.

Daniel Anthony Principato, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On December 20, 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 6, 2015 influenza (“flu”) 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 finding she is entitled to compensation. (See ECF No. 28.) Respondent conversely moves for a ruling on the record denying compensation to petitioner. (See ECF No. 27.) For the

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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

reasons described below, the undersigned finds that petitioner is entitled to compensation.

I. Procedural History

Between December 23, 2016 and April 13, 2017, petitioner filed medical records and affidavits from six individuals, including herself, in support of her claim. (ECF Nos. 7-8, 10-11, 16.)

On June 19, 2017 respondent filed his Rule 4(c) Report arguing that petitioner failed to establish the onset of her left shoulder symptoms within a medically appropriate time period, 48 hours, and thus failed to establish by preponderant evidence that she developed SIRVA as a result of her October 6, 2015 flu vaccination. (ECF No. 18 at 5-6)

Thereafter, on July 18, 2017 a status conference was convened by the OSM staff attorney managing this claim on behalf of the undersigned to share the undersigned's impressions of the claim having reviewed petitioner's medical records and affidavits, as well as respondent's Rule 4(c) Report. The undersigned issued a follow-up Order indicating as follows:

[T]his claim generally meets the requirements for SIRVA. As an initial matter, petitioner's affidavit together with the records evidence onset within 48 hours of petitioner's vaccination. Accordingly, a fact hearing should not be necessary. Specifically, both petitioner and her husband aver in their affidavits that petitioner suffered pain the day after her October 6, 2015 flu shot. Exs. 6 and 8. Further, at petitioner's March 30, 2016 medical appointment she indicated she had "left arm pain since the flu shot." Ex. 2 at 89.

Additionally, the undersigned notes that petitioner's clinical course is consistent with SIRVA and that petitioner's delay in reporting her injury speaks to the severity and value of her injury. The undersigned does not believe this is a claim that should go to hearing, but rather should be resolved for a reasonable amount. Accordingly, the undersigned encourages petitioner to make a reasonable demand upon respondent.

Order filed July 26, 2017. (ECF No. 19) To address concerns raised by respondent in his Rule 4(c) Report and at the July 18, 2017 status conference petitioner agreed to file a supplemental affidavit. (*Id.*) On August 22, 2017 petitioner filed supplemental affidavits from three witnesses including herself. (ECF No. 21) Respondent filed a status report on October 2, 2017 indicating that he was not willing to engage in settlement discussions and intended to defend this case. (ECF No. 25)

Subsequently, the parties agreed the undersigned should issue a ruling on the written record in lieu of a fact hearing and a briefing schedule was set. Additionally, the undersigned filed the following two medical journal articles as evidence in regard to

SIRVA: 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. 26)

Petitioner and respondent each filed a motion for a ruling on the record on November 20, 2017. (ECF Nos. 27-28) Petitioner filed response to respondent's motion on December 4, 2017 and respondent filed a reply to petitioner's response on December 5, 2017. (ECF Nos. 29-30)

Thus, this matter is ripe for a ruling on petitioner's entitlement to compensation.

II. Factual History³

On October 6, 2015, petitioner received an intramuscular flu vaccination from Kaiser Permanente – Colorado, her primary care provider, which was administered in her left deltoid. (Ex. 1 at 1) At the time of her vaccination, petitioner was 58 years old. (Ex. 1 at 1.) Her prior medical history was significant for low back pain, osteoporosis, and irritable bowel syndrome. (Ex. 2 at 46-48)

Petitioner, a recently retired director of a preschool, provided testimony in her affidavits that the vaccine was administered "very high up on my left arm." (Ex. 6 at 1; Ex. 14 at 1.) Petitioner explained that the "next day, I woke up with extreme pain in my shoulder. The pain started in the exact area where the shot was given and by the end of the evening I was having sharp pains all the way down my left arm. I thought the pain would go away eventually, so I tried to wait it out." (Ex. 6 at 1-2; Ex. 14 at 1.) Petitioner further testified that she is not someone "who easily goes to the doctor, so despite my ongoing pain as time progressed, I did not immediately seek care for my symptoms." (Ex. 14 at 1; Ex. 6 at 2). Petitioner further explained that she was busy watching her granddaughter and "had never heard of the flu vaccine causing this type of sustained pain, so I continued to tough it out." (Ex. 6 at 2; Ex. 14 at 1). Petitioner's husband, Michael Tenneson, likewise testified by affidavit that the day after she received her flu vaccine petitioner told him that "where she received the flu shot, really hurt. She also told me that she could not lift her left arm above her shoulder without being in pain." (Ex. 8 at 1) Mr. Tenneson testified that he told petitioner it was "probably normal to feel pain the day after receiving a flu shot." (*Id.*)

On December 17, 2015, primary care records indicate that petitioner called her primary care provider requesting "a form faxed to her employer, please asap" indicating that "she has been seen in the last year and is in good health." (Ex. 2 at 78) Petitioner averred in her affidavit that this phone call related to a form that was required by the State of Colorado in order for her to serve as a Substitute Director at the preschool from where she recently retired. (Ex. 14 at 2) Petitioner testified that the form was a one

³ While the undersigned has reviewed and considered all of the filed evidence in this claim, this factual history is condensed for brevity.

page document indicating she had no communicable diseases that her doctor had seen her within the year, and that she was able to work with children. (*Id.*) Petitioner stated the form was based on a physical examination which took place prior to her October 6, 2015 flu vaccination. Petitioner did not undergo a physical examination on December 17, 2015. Petitioner explained that at that time she requested the form be completed “my shoulder was painful, but because I did not know that the flu vaccine could cause such a sustained injury, I continued to have the mindset it would get better with time.” (Ex. 14 at 2) As the pain continued, petitioner testified in her affidavit that she made an appointment in January of 2016 to see her primary care provider. (*Id.* at 3) The appointment was scheduled for March 30, 2016.⁴ (*Id.*)

On January 22, 2016, petitioner’s medical records reflect that she placed a phone call to Kaiser, her primary care provider, regarding a possible UTI. (Ex. 2 at 80) That same day petitioner presented to the emergency room (“ER”), at which time the following symptoms were recorded: right flank/abdominal pain, low back pain, blood in urine, discomfort with urination, pain and vomiting. (Ex. 3 at 1) The level of petitioner’s symptoms were documented by the ER as “severe.” (*Id.*) The physical exam section of petitioner’s ER record includes an “extremities” section with the following descriptions checked: “non-tender,” “nml ROM,” and “no pedal edema.” (*Id.* at 2) Ultimately, petitioner was found to be suffering an acute urinary tract infection and kidney stones. (*Id.* at 3-8) Petitioner explained in her affidavit that she was enroute to a trip to the mountains with her family on January 22, 2016 when she started to experience “excruciating back pain” and that by the time they reached their destination she was “in horrible pain, and could not stop urinating and vomiting.” (Ex. 14 at 3) Petitioner indicated due to her severe symptoms her husband and son took her to the ER where she spent several hours, but was only seen by a doctor for two to three minutes. (*Id.* at 3-4) Petitioner testified that no examination of her upper extremities was conducted while she was at the ER, to include that no examination of her left shoulder for tenderness or range of motion. (*Id.* at 4)⁵ Petitioner testified that only her back and abdomen were touched. (*Id.*) Petitioner explained subsequent to her visit she spoke to the billing department in regard to her visit and after describing her experience at the ER they reduced the cost billed to her and apologized for the care she received. (*Id.*) The affidavits of petitioner’s son and husband, both who stayed with her in the ER examination room, are consistent with petitioner’s recollection of January 22, 2016. (Exs. 15-16)

Thereafter, the medical records reflect that petitioner placed phone calls to Kaiser on January 25 and 26, 2016 in follow-up to her ER visit due to concerns about

⁴ The undersigned notes petitioner’s affidavit contains a typographical error indicating that the appointment was scheduled for March 31, 2016.

⁵ However, petitioner did aver that she noted to the CT scan technician at the ER that she could not raise both of her arms overhead because she had very minimal range of motion as a result of her flu vaccine in October. (Ex. 14 at 5) He indicated she should let a doctor know what occurred and she told him she had a physical scheduled for March. (*Id.*)

leaving town in a few weeks. (Ex. 2 at 84-85) Petitioner described her kidney stone, and “[d]enied pain, blood in her urine and fever.” (*Id.* at 84) Deja Vandeloo, MD, noted that pain medication was “not really need(ed) right now unless absolutely has to” and that petitioner indicated she was feeling better. (*Id.* at 85) Dr. Vandeloo stated urology indicated the stone should pass and to follow-up in two weeks if it does not. (*Id.*)

Subsequently, petitioner first received medical treatment for her shoulder pain on March 30, 2016. (Ex. 2 at 89) Petitioner testified in her affidavit this was the first time she had seen her primary care doctor, Dr. Vandeloo, since prior to her flu shot. (Ex. 14 at 6) According to Dr. Vandeloo’s record, petitioner reported she experienced

left arm pain since flu shot 10/15, pain all the way down arm. Can barely move arm now. Just hasn't gotten better. Wakes her up at night. Does watch her grand-baby and can lift her but hard time getting seat belt, etc. No other trauma. No prior shoulder problems. Wondering if they hit a nerve or something as they gave the flu shot kind of high up she thinks.

(Ex. 2 at 89) Dr. Vandeloo’s musculoskeletal examination of petitioner found “limited ROM left shoulder—can only abduct/extend to approx 80-90 degrees and can only get a few more degrees passively.” (*Id.* at 90) Dr. Vandeloo diagnosed petitioner with adhesive capsulitis of the left shoulder. (*Id.* at 91) Dr. Vandeloo followed up with the “shot line who said [petitioner’s shoulder injury] was not due to vaccine by they can’t comment on administration.” (*Id.*) An orthopedist was also consulted who “also felt unlikely this is all related to flu shot.” (*Id.*) However, the orthopedist did note that petitioner “certainly could have developed a frozen shoulder if she hasn’t moved it [for] 5 mo[nths] [since the flu vaccination].” (*Id.* at 97) Dr. Vandeloo ordered a left shoulder xray and referred petitioner to physical therapy and an orthopedist. (*Id.* at 91) Petitioner’s orthopedist referral notes as follows:

Kelli Tenneson is a 58 year old female. Please see this patient and send me a copy of your note including your opinion and recommendations for the following left shoulder problem: frozen shoulder--pt has had pain ever since flu shot 10/15 w/ no injury. Worsening ROM over last 5 months. No trauma.

(*Id.* at 89)

Petitioner followed up with physical therapist, Robert Webers, on April 13, 2016. (*Id.* at 99) Mr. Webers recorded the following history: “Pt got a flu shot in Oct. 2015, and since then she has had pain as above [right lateral humerus pain].” (*Id.*) Mr. Webers performed an exam and found petitioner’s range of motion to be limited. (*Id.*) Mr. Webers found that petitioner presented with signs and symptoms consistent with adhesive capsulitis and recommended treatment every 10 days for four weeks with a goal to increase petitioner’s range of motion. (*Id.*)

Subsequently, petitioner was evaluated by orthopedist, Tracy Frombach, DO, on April 27, 2016. Dr. Frombach recorded the following history,

patient is a 58-year-old female who in October received her flu shot. The patient states that the day following her flu shot she had significant pain in the left shoulder and had limited range of motion. The patient states that she is unable to lift her arms above her head, but her strength close to the body and lower than the shoulder is adequate.

(*Id.* at 109) Dr. Frombach's exam found petitioner suffered limited range of motion and mild tenderness through petitioner's mid deltoid. (*Id.* at 110) Dr. Frombach assessed petitioner's injury as follows: "1. Adhesive capsulitis of the left shoulder following a flu injection in October 2015. 2. Left rotator cuff syndrome." (*Id.*) Dr. Frombach administered a left subacromial injection to treat petitioner's left shoulder and recommended petitioner strictly adhere to her home exercise program through physical therapy. (*Id.* at 110-111) Thereafter, petitioner continued to follow-up with Dr. Frombach through October 2016 at which time Dr. Frombach noted in her history that "[t]his started in October of 2015 and is resolving" and found specifically that petitioner's "[l]eft adhesive capsulitis [was] almost completely resolved." (Ex. 4 at 44-45) Petitioner continued to pursue physical therapy through at least March of 2017. (Ex. 13 at 33)

III. Party Contentions

In sum,⁶ petitioner argues she has satisfied the criteria, as detailed by Vaccine Injury Table's Qualifications and Aids to Interpretation ("QAI"), to establish a Table claim for SIRVA. (ECF No. 28 at 16-20) Alternatively, petitioner argues that she has met the burden for establishing entitlement to compensation in an "Off-Table" claim by demonstrating the *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) criteria to establish petitioner more likely than not suffered a SIRVA. (*Id.* at 24-26)

Respondent argues that petitioner's contemporaneous records do not establish that her injury manifested within a medically appropriate time frame. (ECF No. 27 at 6.) Respondent argues that petitioner's contemporaneous records indicate that petitioner's shoulder pain began approximately three to six months subsequent to her October 6, 2015 vaccination. (*Id.* at 7) Respondent asserts that the literature submitted by the court establishes that most SIRVA injuries begin within two days, and all occur within four days of vaccination. (*Id.* at 6) Accordingly, respondent argues petitioner's claim should be denied. (*Id.* at 7-10)

IV. Finding of Fact

The first issue to be addressed is when the onset of petitioner's shoulder injury occurred. 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

⁶ The undersigned has fully reviewed and considered the parties' briefing in this matter, however for the purpose of brevity does not summarize and/or address each argument put forward.

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 6, 2015 flu vaccination.

As described above, petitioner’s medical records demonstrate that petitioner repeatedly and consistently placed the onset of her condition within 48 hours of her vaccination. Respondent argues that there is no corroborating evidence that petitioner experienced the onset of symptoms during the six months after the vaccination and before seeking treatment for her injury. (ECF No. 27 at 9) However, respondent unreasonably dismisses petitioner’s contemporaneous treatment records since the records were not created contemporaneously with the onset of petitioner’s shoulder pain. (ECF No. 30 at 1-2) The fact that petitioner delayed seeking treatment for her shoulder symptoms does not negate the value of her treatment records or render this evidence not credible, although it may speak to the severity of her injury.⁷ The undersigned does not find petitioner’s delay in treatment of nearly six months to be dispositive regarding the question given the facts and circumstances of this case.

Three different health care providers documented consistently as to onset. The first time petitioner sought medical treatment for her injury from her primary care provider, Dr. Vandeloo on March 30, 2016, she placed the onset of her pain as since her October 2015 flu shot. (Ex. 2 at 89) Her subsequent physical therapy evaluation by physical therapist, Robert Webers on April 13, 2016 noted that “[patient] got a flu shot in Oct. 2015, and since then she has had pain.” (*Id.* at 99) Petitioner again linked her shoulder pain to her October 6, 2015 flu vaccination at her April 27, 2016 evaluation by orthopedist, Dr. Frombach. Dr. Frombach noted “patient is a 58-year-old female who in October received her flu shot. The patient states that the day following her flu shot she had significant pain in the left shoulder and had limited range of motion.” (*Id.* at 109)

Additionally, the undersigned finds petitioner’s affidavits 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, cogent and corroborates the statements she made to her health care providers. Moreover, in the undersigned’s experience, petitioner’s affidavits and medical records together reflect a pattern of treatment consistent with and similar to many other SIRVA claims.⁸ Likewise, petitioner’s affidavits are consistent with the affidavits filed from petitioner’s family members.

⁷ The undersigned further rejects respondent’s argument that her finding of onset in these circumstances opens up the Vaccine Program to fraud and abuse. (ECF No. 27 at fn 6; ECF No. 30 at 1-2) The undersigned has carefully reviewed all evidence filed in this matter and finds no evidence of fraud.

⁸ The undersigned disagrees with respondent’s characterization of petitioner’s affidavit as internally inconsistent. (ECF No. 27 at 9-10) The undersigned finds that petitioner’s lack of awareness that a flu

Respondent argues petitioner's earlier visit to the ER on January 22, 2016, and follow-up phone calls to Kaiser, establish that petitioner's shoulder pain approximately began three to six months subsequent to her October 6, 2015 flu vaccination. (ECF No. 27 at 7-9) In particular, respondent relies upon checkmarks next to "non-tender," "nml ROM," and "no pedal edema" under the "extremities" portion of the physical exam section of petitioner's ER record (Ex. 3 at 2) as evidence that the onset of petitioner's injury did not commence until three to six months after the flu vaccine. (*Id.*) Given the context of these records the undersigned disagrees with respondent's assertion. The undersigned notes that petitioner was seen at the ER on January 22, 2016 for a UTI and kidney stones which are extremely painful conditions for which petitioner was seeking urgent medical attention. Additionally, in the undersigned's experience thorough physical examinations are not conducted in the ER setting for issues beyond or unrelated to the reason for the visit. The undersigned notes this is in contrast to a general or physical examination conducted by a primary care physician or orthopedist. The undersigned finds that petitioner's subsequent phone calls to Kaiser on January 25 and 26, 2016 are clearly in follow-up to petitioner's emergency room visit for her UTI and kidney stones, and the description of lack of pain relates accordingly to those issues, as opposed to a lack of pain in her left shoulder. Additionally, petitioner, her husband, and son in their testimony by affidavit offer consistent, cogent, and reasonable descriptions of the events leading to petitioner's ER visit and the ER visit itself. (See Ex. 14-16)

The undersigned finds that the affidavits submitted by and on behalf of petitioner and the medical records work in tandem to provide preponderant evidence that petitioner's shoulder pain began within 48 hours of her October 6, 2015 flu 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,⁹ 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

vaccination can cause a sustained injury is not inconsistent with petitioner still believing or attributing her left shoulder pain to her flu shot in the left shoulder.

⁹ 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 (codified at 42 CFR Part 100.3(c)); 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).

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 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)¹⁰; 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 it is petitioner's burden to establish all *Althen* prongs by preponderant evidence, respondent has not disputed that the flu 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:

Shoulder Injury Related to Vaccine Administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

¹⁰ Codified at 42 CFR Part 100.3(c).

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR Part 100.3(c)(10) (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.

Based on petitioner's medical records and affidavit, prior to petitioner's flu vaccination October 6, 2015 she had no history of pain, or other signs or symptoms in her left shoulder consistent with SIRVA. The undersigned further notes that respondent has not alleged that petitioner had any symptoms of SIRVA prior to her October 6, 2015 flu vaccine.

Additionally, petitioner's post-vaccination medical records reveal no other proffered explanation for her injury and her diagnostic evaluations are significant for findings consistent with a SIRVA injury, including limited range of motion (*Id.* at 90-91, 99, 110) and a diagnosis of adhesive capsulitis (*Id.* at 90-91, 99, 110).

As discussed above, based upon petitioner's medical records and affidavits, the undersigned finds petitioner's onset of her shoulder injury is within the specified time frame of ≤ 48 hours. The undersigned finds petitioner offers a reasonable and persuasive explanation in her affidavits for her delay in reporting her shoulder injury, and finds persuasive petitioner's reports to both Drs. Vandelloo and Frombach, as well as physical therapist, Mr. Webers regarding the onset of her shoulder pain. The undersigned further finds that petitioner offers a reasonable and cogent explanation of the limited nature of her examination at the ER on January 22, 2016 and the nature of her follow-up phone calls with Kaiser.

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. Respondent asserts that the relevant, medically accepted, timeframe for onset of a SIRVA injury based upon the literature submitted by the undersigned is within 4 days of vaccination. (ECF No. 27 at 6) Thus, in light of the above finding of fact that petitioner's shoulder pain began within 48 hours of her October 6, 2015 flu vaccination, petitioner has satisfied *Althen* Prong Three.

iv. Factors Unrelated to Vaccination

Respondent has not asserted, nor has the undersigned identified any factor unrelated to petitioner's vaccination which would meet respondent's burden of establishing an alternative cause for petitioner's injury unrelated to vaccination.

VI. Conclusion

Thus, for all the foregoing reasons, the undersigned finds petitioner's has established by preponderant evidence that her October 6, 2015 flu vaccination was the cause-in-fact of her SIRVA. Accordingly, the undersigned DENIES respondent's request for a ruling denying compensation (ECF No. 27 at 10) and GRANTS petitioner's motion for a finding that petitioner is entitled to compensation for SIRVA (ECF No. 28 at 26).

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master