

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-980V

Filed: October 29, 2018

UNPUBLISHED

JEAN GENTILE,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Fact
Ruling – Onset; Ruling on
Entitlement; Causation-In-Fact;
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.

Robert Paul Coleman, III, U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACT AND RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On August 10, 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 left shoulder injury caused by an October 15, 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 ruling on the record (1) making a finding of fact that the onset of petitioner’s shoulder injury was within 48 hours of receiving the flu

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 Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website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

vaccination and (2) that petitioner is entitled to compensation. ECF No. 45 at 8, Petitioner's Motion for Ruling on the Record ("Petitioner's Motion"). For the reasons discussed below, the undersigned grants petitioner's motion and finds that petitioner is entitled to compensation.

I. Procedural History

Following the filing of the August 10, 2016 petition, petitioner submitted medical records on August 19, 2016. Petitioner also filed an affidavit on August 31, 2016 (ECF No. 8) and a statement of completion on September 20, 2016 (ECF No. 9). Subsequently, during the initial status conference held on October 18, 2016, petitioner agreed to file updated medical records. ECF No. 10. Additional records were filed on November 23, 2016 (ECF No. 13), and a statement from petitioner's physician was filed on December 1, 2016, with an amended statement of completion filed on December 8, 2016 (ECF No. 15). Petitioner also filed a corrected affidavit on February 3, 2017. ECF No. 20.

Respondent stated in a status report on March 2, 2017, that he was willing to engage in discussions regarding potential settlement. ECF No. 21. Subsequently, on July 14, 2017, the parties had a status conference to discuss the status of the settlement discussions. ECF No. 32. Petitioner's counsel stated that the parties had reached an agreement with regard to out-of-pocket expenses and medical bills, but not on pain and suffering. *Id.* The staff attorney suggested a Rule 5 Conference, and respondent requested that he be allowed to submit a Rule 4(c) Report.

On August 14, 2017, petitioner filed additional evidence including a personal statement, a personal statement of petitioner's ex-husband, and updated medical records. ECF No. 33. On September 12, 2017, respondent filed Respondent's Rule 4(c) Report ("Respondent's Report") stating that he has concluded this case is not appropriate for compensation, based in part on his conclusion that petitioner did not complain of shoulder pain until more than seven weeks after she received the October 15, 2015 flu vaccination. Respondent's Report at 6. Respondent also noted that petitioner did not mention any shoulder pain during medical visits on October 16, 2015 and October 26, 2015. *Id.*

On October 25, 2017, petitioner filed an affidavit addressing her silence with regard to her shoulder pain during the medical visits described above, and an explanation with regard to her seven-week delay in seeking treatment for any vaccine-related injury. ECF No. 38-1.

During a status conference on December 22, 2017, the parties discussed how they would like to proceed in this case. The parties stated that they would be amendable to a ruling on the record in the alternative to a hearing. ECF No. 41. On May 16, 2018, petitioner filed a Motion for Ruling on the Record ("Petitioner's Motion"), requesting that the undersigned find the onset of petitioner's injury was within 48 hours of receiving the vaccination, and that petitioner is entitled to compensation. ECF No. 45. On that same day, respondent filed a Memorandum Requesting that Petitioner's Claim for Entitlement to Compensation Be Denied ("Respondent's Motion"). ECF No. 44.

II. Factual History

On October 15, 2015, petitioner received a flu shot in her left shoulder. Ex. 3 at 4, Ex. 1 at 2, Ex. 6 at 89. Prior to the flu shot, petitioner's medical history shows no evidence that petitioner suffered previous shoulder injuries or reports of left shoulder pain. Petitioner's records do contain reports of reversible cerebral vasoconstriction syndrome ("RCVS"), a disease characterized by thunderclap headaches. Ex. 5 at 6.

After her flu shot, petitioner visited the emergency room for diarrhea on October 16, 2015. Ex. 7 at 33-36. Petitioner sought medical care again on October 26, 2015, for headaches. Ex. 6 at 5-9. There is no mention of shoulder pain during either visit.

Petitioner first complained of left shoulder pain to a medical professional on December 3, 2015, when she visited Dr. Mark Alexander. Ex. 2 at 2. The medical record states "[p]atient reports that she noticed the pain and it seems like to her that it was following her flu shot that she got about a month ago.... She now complains of pain lifting the arm and pain with dressing." *Id.* Upon examination, petitioner had some tenderness on the lateral aspect of her shoulder, "positive Neer's and Hawkins" but full range of motion. *Id.* An x-ray showed slightly down sloping acromion but was otherwise unremarkable. *Id.* Petitioner was diagnosed with left shoulder impingement and treated with a corticosteroid injection. *Id.* at 2-3.

Petitioner began physical therapy on December 7, 2015, complaining of left shoulder pain "which started about 5 weeks ago when she got a flu shot." Ex. 3 at 3. At that time, petitioner's range of motion in her left shoulder was limited, and her strength was slightly reduced. *Id.* at 4. The physical therapist's assessment included left shoulder pain with hypomobile thoracic spine, AC joint, and impaired rotator cuff muscle function. *Id.* at 5. Petitioner attended a second physical therapy session on December 14, 2015. Ex. 10 at 16. Petitioner reported that she had been doing exercises at home, and recently suffered a fall that did not impact her left shoulder. She also mentioned some neck tightness and pain "that has been there for years." *Id.* at 16.

On December 17, 2015, petitioner was evaluated for headaches. Ex. 8 at 1. Petitioner reported a "lifelong history of headache problems beginning with severe migraines, but 3 years ago she had reversible cerebral vasoconstriction which began with a thunderclap headache." *Id.* Petitioner also reported she had a similar thunderclap headache the first week in October. Ex. 6 at 85, Ex. 8 at 1. Petitioner described the headache as "horrible (comfort level 0/10) and the effects linger for a couple of weeks." Ex. 8 at 1. There is no record of any shoulder pain, musculoskeletal problems, or pain in her extremities, however there is no indication that an examination of these areas occurred.

Petitioner was seen for a follow-up appointment for diarrhea on February 18, 2015. Ex. 13 at 97-98. There is no mention of shoulder pain during this visit.

Petitioner next attended a physical therapy session on February 22, 2016. Ex. 3 at 10-12; Ex. 10 at 19. She reported continued left shoulder pain, and that "[g]etting

dressed remains the most painful”, as well as continued pain reaching overhead and bearing weight through the arm. Ex. 10 at 19.

Petitioner saw Dr. Alexander for a follow-up for her left shoulder pain on February 24, 2016. Ex. 10 at 4. Petitioner stated that the pain developed the day after she had a flu shot, and she continued to complain of left shoulder pain with some throbbing at night. *Id.* Petitioner was seen again on February 26, 2016, and diagnosed with “left shoulder pain and stiffness secondary to adhesive capsulitis.” *Id.* at 6. Petitioner also reported that she felt her left shoulder pain was directly related to receiving a flu vaccination. Ex. 10 at 5-6. An MRI on February 26, 2016 showed supraspinatus and infraspinous tendinopathy, thin foci of interstitial tearing, but no full-thickness rotator cuff tendon tear. *Id.* at 7-8. It also showed signs of adhesive capsulitis. *Id.* at 8. A cortisone injection was administered on April 5, 2016. Ex. 10 at 9.

Petitioner attended 15 additional physical therapy sessions between February 29, 2016, and May 9, 2016. Ex. 10 at 22-68. On May 9, 2019, petitioner was discharged from physical therapy. At that time, she reported that her shoulder felt good, but there was still some “mild achiness and waking up due to pain...” Ex. 10 at 69.

Petitioner received another injection to treat pain in her left shoulder on July 14, 2017. Ex. 18 at 1. On March 15, 2018, she reported “[c]hronic left shoulder pain after influenza vaccine.” Ex. 20 at 3.

In support of her petition, petitioner submitted two affidavits (Exs. 15, 19), a signed personal statement (Ex. 16), a letter from her treating physician, Dr. Alexander (Ex. 14), and a signed letter from her ex-husband, Vincent M. Gentile (Ex. 17).

In petitioner’s affidavit, she stated she received a flu shot on October 15, 2016. The following day, she “woke up to a very sore, stiff arm and shoulder.” Ex. 15 at 1. Petitioner assumed “it was just a reaction to the shot” and that she “just kept thinking and hoping that [her] arm would get better, but it didn’t.” *Id.* Petitioner also explained that she did not seek treatment sooner because she “kept thinking that it was a bad reaction but that it would only last a few days. Those days turned into weeks with the pain increasing as well as self-medication of various combinations of Tylenol, Ibuprofen, Aleve and ice packs.” *Id.* at 3. Petitioner also stated that she delayed in seeking treatment because of her profession as a teacher. *Id.* According to petitioner,

At the time of my shot, I had a classroom of students with very high needs including severe autism, behavior disorders, special education students, a non-verbal student and a student who was both visually and hearing impaired. Often students with these types of extreme needs do not do well when there is a substitute, not only for that day, but a break in routine can upset special needs students for several days. So, while it is possible for me to take a day off during a normal work week, it would always be as a last resort. When serving in this caretaker role, I put the needs of my students before my own.

Id. at 4.

In her second affidavit, petitioner explains that she did not mention the shoulder pain during the October 16, 2015 emergency room visit because she “assumed it was just a bad reaction to the injection from one day previous and that it would get better in a few days.” Ex. 19 at 1. Further, her “main concern at the time of [that] appointment was severe diarrhea and dehydration.” *Id.* Petitioner further explained that on October 26, 2015, she saw her doctor due to a “thunderclap, also referred to as a lone acute severe headache.” *Id.* Petitioner states that her shoulder was very painful and stiff, but her “overwhelming concern and fear during [that] visit was [her] headaches, which is why the shoulder pain was not raised as an issue....” *Id.* at 1-2.

Petitioner’s physician, Dr. Alexander, also submitted a signed letter. Ex. 14. Dr. Alexander stated that he first saw petitioner on December 3, 2015, for “left shoulder pain that started after she had a flu shot about a month prior.” Ex. 14 at 1. Dr. Alexander also stated that there was no preexisting shoulder condition prior to this injection, that petitioner reported her shoulder pain started soon after the flu shot in the fall of 2015, and that he believes the pain and adhesive capsulitis was likely due to the flu vaccination. *Id.*

Mr. Vincent M. Gentile, petitioner’s ex-husband, also submitted a signed letter dated August 25, 2016. Ex. 17. Mr. Gentile stated that petitioner received a flu vaccination on October 15, 2015. The following day, “she reported to me that her shoulder was very sore and she was awakened throughout the night with pain.” Mr. Gentile also stated the pain continued to get worse “even after seeing an orthopedic doctor and going to physical therapy,” and that petitioner continued to have pain in her shoulder and sleepless nights for many months. *Id.*

III. Parties’ Contentions

Respondent requests that entitlement to compensation be denied in this case. Respondent correctly notes that petitioner’s claim was filed prior to the inclusion of a SIRVA on the Vaccine Injury Table.³ However, respondent states that even if this claim

³ 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

was filed on or after March 17, 2017, it would not qualify as a Table claim due to the timing and onset of petitioner's injury. Motion at 6 n.3. Specifically, respondent argues petitioner's contemporaneous records do not establish that her injury manifested within 48 hours of vaccination. Respondent's Motion at 6-8. Respondent stresses that petitioner waited until December 3, 2015, seven weeks after her flu vaccination, to seek medical treatment. According to respondent, this delay "is particularly surprising given her statement in her affidavit that she knew something was wrong with her shoulder in the hours after receiving the vaccination...." *Id.* at 7.

Respondent further suggests that the evidence offered to establish onset of petitioner's injury is lacking. Specifically, respondent argues that Mr. Gentile's letter was authored approximately ten months after petitioner received the vaccine, is not in the form of a sworn affidavit, and offers no explanation as to how he remembered the specific dates that he mentioned. Respondent's Motion at 7. Respondent also argues that Dr. Alexander's letter and opinion is of little weight because it is not objective, contemporaneous evidence. *Id.* Respondent argues that Dr. Alexander did not see petitioner until more than seven weeks after the vaccination, and the basis for his conclusions rests "entirely upon petitioner's representation to him that her left arm pain developed shortly post-vaccination." *Id.* Respondent asserts that the absence of any objective contemporaneous evidence that petitioner suffered left shoulder pain within 48 hours of the vaccination is fatal to her claim. *Id.* at 7-8. Respondent requested that petitioner's petition be dismissed. *Id.* at 8.

Although petitioner acknowledges that this petition was filed prior to the inclusion of a SIRVA on the Vaccine Injury Table, petitioner's motion nonetheless urges that petitioner meets all the specified criteria for a SIRVA as set forth in the Qualifications and Aids to Interpretation for a SIRVA ("QAI"). Petitioner's Motion at 5. Petitioner notes that respondent "tacitly acknowledges that petitioner meets three of the four criteria for showing a Table SIRVA injury" and that the "only issue raised by respondent ... is whether petitioner's onset of the injury occurred within 48 hours [of the vaccination]." *Id.* at 5. 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 six separate notations in the medical records which she asserts support her contention, and "multiple affidavits/statements in the record". *Id.* at 6. Petitioner also urges that her sworn statement regarding her delay in seeking treatment be credited. *Id.* at 6-7. Based on those arguments, petitioner requests that the undersigned find onset of petitioner's

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).

shoulder injury was within 48 hours of her receiving the October 15, 2015 flu vaccination, and that petitioner is entitled to vaccine compensation.

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 15, 2015 flu 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. The first time petitioner sought medical treatment for her injury on December 3, 2016, she placed the onset of her pain as following her flu shot "about a month ago..." Ex. 2 at 2-3. Her subsequent physical therapy evaluation on December 7, 2015 placed onset at "when she got a flu shot." Ex. 3 at 3. Petitioner further linked the onset of her injury to her vaccination in an explicit fashion on February 24, 2016, when she stated her left shoulder pain developed the day after she had a flu shot, and on February 26, 2016, when petitioner stated she felt the left shoulder pain was directly related to receiving a flu vaccination. Ex. 10 at 4-6. Moreover, all of petitioner's subsequent reports regarding onset remained consistent with her initial recollection.⁴

Respondent implicitly argues that the above-described medical records do not constitute *contemporaneous* records, noting that petitioner did not seek treatment for left shoulder pain until December 3, 2015, even though she stated in her affidavit that she knew something was wrong hours after receiving the vaccine. Respondent's Motion at 7. Although respondent raises a reasonable point in the abstract, the undersigned does not find this argument persuasive given the specific facts of this case.

⁴ The undersigned recognizes that many of these records are imprecise regarding onset (e.g. "about a month ago," or "5 weeks ago"). However, petitioner's vaccination having occurred on October 15, the reported timeframe reflected by the record as a whole does encompass the 48 hour post-vaccination period. Additionally, it is significant that when petitioner began physical therapy she stated her pain began "when she got a flu shot." Ex. 3 at 3. This allows that petitioner's treating practitioners understood at the time that her earliest reports, general as they may be, reflected onset as beginning soon after she received the flu vaccination.

Medical records generally “warrant consideration as trustworthy evidence.” *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, greater weight is typically given to contemporaneous records. *Vergara v. Sec’y of Health & Human Servs.*, 08-882V, 2014 WL 2795491,*4 (Fed. Cl. Spec. Mstr. May 15, 2014) (“Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.”). In this case, the undersigned does not accept respondent’s premise that the records in this case constitute later histories rather than contemporaneous records.

The weight afforded to contemporaneous records is due to the fact that they “contain information supplied to or 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 seeking treatment of seven weeks 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 first treatment record regarding her shoulder injury. Moreover, none of her subsequent medical records contain any notation inconsistent with her placement of her injury beginning directly after her flu vaccination.

As respondent notes, there are intervening medical visits where petitioner failed to complain of shoulder pain. Respondent’s Motion at 6-7. Specifically, petitioner did not mention shoulder pain when at an emergency department visit on October 16, 2015, or a medical visit on October 26, 2015. *Id.* The medical records, when reviewed in conjunction with petitioner’s affidavits, provide a plausible and credible explanation for why her shoulder pain was not mentioned in either the October 16 or October 26 visits. The reasons petitioner sought care at those times were for specific and acute medical concerns, unrelated to petitioner’s shoulder. Petitioner’s emergency room visit on October 16 was for severe diarrhea. Ex. 7 at 33-36. Petitioner stated in her affidavit that she did not mention her shoulder pain because she assumed it was a bad reaction to the vaccine, and her main concern at that time was severe diarrhea and dehydration. Ex. 19 at 1. The October 26, 2015 visit was also for an unrelated concern: thunderclap headaches. Ex. 6 at 5-9. Petitioner’s medical history shows she suffered from RCVS, a disease characterized by extremely painful headaches. Ex. 5 at 6. Petitioner explained in her affidavit that, while her shoulder was still very painful and stiff, the “overwhelming concern and fear during [that] visit was [her] headaches....” Ex. 19 at 1-2.

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. Sec’y of Health & Human Servs.*, 90-221V, 1990 WL 608693, *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that clear cogent, and consistent testimony can overcome missing or contradictory medical records). Petitioner indicates that she

delayed seeking treatment because she hoped her injury would resolve itself, and that she “kept thinking it was a bad reaction but that it would only last a few days.” Ex. 15 at 3; Ex. 19 at 1. Petitioner also indicated that she delayed seeking treatment because of her work obligations. Ex. 15 at 4. In the undersigned’s experience, such prioritization is not unusual among individuals experiencing a SIRVA. See, e.g. *Cooper v. Sec’y of Health & Human Servs.*, 16-1387V, 2018 WL 1835179, *2 (Fed. Cl. Spec. Mstr. Jan. 18, 2018) (noting that petitioner described a delay in seeking treatment due to an extended trip to Vietnam and care for her ailing mother); *Marino v. Sec’y of Health & Human Servs.*, 16-622V, 2018 WL 2224736, at *2 (Fed. Cl. Spec. Mstr. Mar. 26, 2018) (noting a delay in seeking treatment due to a busy work schedule and difficulty making appointments). Moreover, in the undersigned’s experience, petitioner’s sworn statement and medical records together reflect a pattern of treatment consistent with, and similar to, 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. Sec’y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam* 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 statements are in harmony with the contemporaneous records and provides additional 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 affidavits 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 15, 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, 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. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). 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. Sec’y of Health & Human Servs.*, 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 court also indicated that, in finding causation, a 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 One

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 flu 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. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 178 (2009), *rev'd on other grounds sub nom., Paterek v. Sec'y of Health & Human Servs.*, 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 flu vaccine can cause a 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. Sec'y of Health & Human Servs.*, 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. Sec'y of Health & Human Servs.*, 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. Sec'y of Health & Human Servs.*, No. 16-1496V, 2017 WL6206391 (Fed. Cl. Spec. Mstr. Apr. 13, 2017) (same); *Telonidis v. Sec'y of Health & Human Servs.*, No. 15-450V, 2015 WL 5724746 (Fed. Cl. Spec. Mstr. Sept. 2, 2015); *Salas v. Sec'y of Health & Human Servs.*, No. 16-739V, 2016 WL 8459834 (Fed. Cl. Spec. Mstr. Nov. 7, 2016).

ii. *Althen* Prong Two

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. As

noted above, the undersigned finds no history of pain, inflammation or dysfunction of petitioner's left shoulder prior to her October 15, 2015 vaccination. Additionally, the undersigned found that petitioner experienced pain and reduced range of motion within 48 hours of receipt of her vaccination. There has been no suggestion that petitioner experienced pain and reduced range of motion other than in the impacted shoulder. Nor would the record of the case support such a contention. Further, the undersigned found no evidence of any other condition or abnormality that would explain petitioner's 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 on the lateral aspect of her shoulder and positive impingement tests. Ex. 2 at 2. Further, petitioner was also diagnosed with left shoulder pain "secondary to adhesive capsulitis." Ex. 10 at 4, 8. Moreover, Dr. Alexander stated in a signed letter that petitioner's shoulder pain and adhesive capsulitis was likely due to the flu vaccination. Ex. 14 at 1.

Respondent argues that the Dr. Alexander's statements contained in his signed letter should be discounted, because "he did not see petitioner until more than seven weeks after vaccination, and the basis for this conclusion rests entirely upon petitioner's representation to him" Respondent's Motion at 7. In that regard, respondent stresses that a physician's conclusions "are only as good as the reasons and evidence that support them." *Id.* Respondent argues that the absence of contemporaneous evidence that petitioner suffered from left shoulder pain in the time between the administration of the vaccination and her visit with Dr. Alexander is fatal to petitioner's claim.

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 records reflect a full physical evaluation, including diagnostic MRI, which showed results consistent with a SIRVA.

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 Three

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. Respondent's Motion at 6 n.3; Petitioner's Motion at 5. Thus, in light of the above finding of fact that petitioner's shoulder pain began within 48 hours of her

October 15, 2015 flu vaccination, petitioner has necessarily satisfied *Althen* Prong Three.

iv. Factors Unrelated to Vaccination

Respondent has not asserted, and the undersigned does not find, that there is any evidence in the record to support 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 GRANTS petitioner's motion and DENIES respondent's competing request that petitioner's claim be dismissed. The undersigned finds that there is preponderant evidence that petitioner suffered a left shoulder injury consistent with a SIRVA and that petitioner's SIRVA first manifested with immediate pain and reduced range of motion with 24 hours.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master