

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 17-114V

Filed: August 3, 2018

PUBLISHED

TIFFANY COOPER,

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)

*Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for petitioner.  
Robert Paul Coleman, III, U.S. Department of Justice, Washington, DC, for respondent.*

### **FINDING OF FACT AND RULING ON ENTITLEMENT**<sup>1</sup>

**Dorsey**, Chief Special Master:

On January 26, 2017, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury as a result of her November 17, 2015 influenza (“flu”) vaccination. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

Petitioner has now moved for a ruling on the written record finding that her shoulder injury and its sequela were the result of her vaccination. For the reasons described below, the undersigned finds that petitioner’s alleged shoulder injury is

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 Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims’ website,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

<sup>2</sup> 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).

consistent with a shoulder injury related to vaccine administration (“SIRVA”) and further that petitioner is entitled to compensation for her SIRVA.

## **I. Procedural History**

Initially, petitioner filed medical records marked as Exhibits 1 through 5 on January 31, 2017. (ECF No. 6.) Following an initial status conference, additional medical records marked as Exhibits 6 and 7 were filed on April 19, 2017, and an affidavit by petitioner marked as Exhibit 8 was filed on May 1, 2017. (ECF Nos. 11, 13.) Further medical records marked as Exhibit 9 were filed on July 13, 2017. (ECF No. 17.)

On September 8, 2017, respondent filed his Rule 4 report recommending against compensation in this case. (ECF No. 20.) The primary issue raised by respondent is that any claim that petitioner’s injury is consistent with a SIRVA is undermined by the fact that she waited more than six months before seeking any treatment. (*Id.* at 6.) Respondent further argued that any medical opinion by petitioner’s doctor favoring vaccine causation should carry little weight because it is based only on petitioner’s representation that her pain began immediately after vaccination. (*Id.* at 6-7.) Respondent also argued that petitioner’s affidavit describing the circumstances leading to her delay in treatment is inadequate or not credible. (*Id.* at 7-8.)

The undersigned provided petitioner an opportunity to file additional evidence responsive to the issues raised by respondent. (ECF No. 21.) Additional witness affidavits marked as Exhibits 10 through 13 were filed on February 9, 2018, along with an amended statement of completion. (ECF Nos. 27-28.)

Thereafter, a status conference was held with the staff attorney managing this case. (ECF No. 29.) Respondent’s counsel confirmed that respondent’s position had not changed following petitioner’s submission of further evidence. (*Id.*) At that time, petitioner indicated that she was amenable to a ruling on the written record and respondent did not object. (*Id.*) However, the undersigned instructed petitioner to file additional evidence authenticating certain photographs filed in the case and addressing petitioner’s statement that she had consulted her school’s nurse regarding her shoulder pain. (*Id.*) The parties agreed to a briefing schedule to be set following petitioner’s filing of a further amended statement of completion. (*Id.*)

Additional affidavits responsive to the undersigned’s order and marked as Exhibits 14 and 15 were filed on April 30, 2018, along with an amended statement of completion. (ECF Nos. 31-32.)

Petitioner filed a motion for a fact ruling on the written record on June 4, 2018. (ECF No. 34.) Petitioner requested “a finding of fact that petitioner’s shoulder injury occurred immediately following the vaccination on November 17, 2015, with ongoing pain and decreased range of motion [and] that Ms. Cooper’s ongoing sequelae, specifically frozen shoulder and partial supraspinatus tear was a result of the vaccination . . .” (*Id.* at 5.)

Respondent filed his response on July 18, 2018. (ECF No. 35.) Respondent requested that “the Court find that the evidence is insufficient to support petitioner’s assertion that her shoulder condition occurred immediately following vaccination and deny petitioner’s claim for entitlement to compensation.” (*Id.* at 1.) Respondent requested that the case be dismissed. (*Id.* at 11.)

Petitioner was provided the opportunity to file a reply, but did not do so. Thus, this case is now ripe for a fact ruling resolving the onset of petitioner’s shoulder injury.

## **II. Factual History**

Petitioner, an elementary school teacher, received a flu vaccine on November 17, 2015. Ex. 1, p. 1; Ex. 8. She received her vaccination at her school through the Long County Health Department. Ex. 15. Petitioner filed a record from the Georgia Registry of Immunization Transactions and Services (“GRITS”) as evidence of the fact of her vaccination.

The GRITS record does not indicate the site of administration. *Id.* However, petitioner has additionally filed an affidavit by Katie Golden, the school’s nurse, averring that petitioner received her vaccination in her left arm.<sup>3</sup> Ex. 15. In addition, petitioner has filed photographs taken by her daughter, Sophie Cooper, approximately ten days after the vaccination. Ex. 8, pp.3-4; Ex. 14. The photographs show petitioner’s left shoulder and have a red circle marking the location of petitioner’s injection. Ex. 8, pp. 3-4. Sophie Cooper avers that she placed the red circles on the photographs to show the injection site. Ex. 14.

In her affidavit, petitioner averred that when she received her November 2015 flu vaccination she felt immediate, severe pain at the injection site and that she had limited range of motion of her left shoulder within 24 hours. Ex. 8, p. 1. Petitioner has also filed affidavits from her school principal, her mother, and her husband. Exs. 10-12. Each of these witnesses avers that petitioner experienced immediate pain following her vaccination. *Id.*

Most significantly, petitioner also filed an affidavit by a coworker, Teri Martin. Ex. 13. Ms. Martin indicates that she was with petitioner when the vaccination was administered. *Id.*, p. 1. Ms. Martin avers that she observed petitioner receive her vaccination and that the nurse was standing over her while administering the injection. *Id.* Ms. Martin further indicates that petitioner commented immediately that her arm was in severe pain. *Id.* Ms. Martin observed that the bandage over petitioner’s injection site was higher on her shoulder than the other teachers who had also been vaccinated at

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<sup>3</sup> There is no evidence to suggest that Ms. Golden was directly involved in the administration of petitioner’s vaccination; however, as described below, petitioner conferred with Ms. Golden in her capacity as the school nurse about her vaccination and shoulder injury less than one month after the vaccination.

that time. *Id.* Ms. Martin recalls that petitioner continued to complain about her shoulder pain for days and weeks. *Id.*, pp. 1-2.

Petitioner first sought treatment of her shoulder pain from the school's nurse. She complained to the school nurse in early December of 2015 that she had trouble lifting her left arm and had pain with movement. Ex. 8, 15. The nurse recommended that Ms. Cooper contact the Long County Health Department. *Id.* Ms. Cooper reports that a nurse from the health department told her to take ibuprofen and use a hot compress. Ex. 8, p. 1. There is no record of either of these encounters filed in the record of this case.

Petitioner avers that she followed the nurse's advice and used a hot compress and ibuprofen with no relief. Ex. 8, p. 1. Despite this, she indicates that she did not seek medical care until the end of the school year, because she wanted to be present for her students. *Id.* She did not indicate that absences were forbidden, but that as a matter of professional responsibility they are "frowned upon and highly discouraged." *Id.* Petitioner's principal, Ms. Wells, has provided an affidavit which confirms she was aware of petitioner's difficulties with her shoulder and also that it was a "critical period in the academic year." Ex. 10. Ms. Wells indicated that she asked Ms. Cooper why she waited to see the doctor and was told that Ms. Cooper hoped her condition would improve. *Id.* Petitioner's mother also indicates that "Tiffany never complains about anything and does not go to the doctor unless necessary." Ex. 11.

Following her vaccination, petitioner's next medical appointment was on April 5, 2016. Ex. 9. She was seen by her OBGYN for a yearly gynecologic evaluation and there was no mention of her shoulder pain.<sup>4</sup> *Id.* There was no notation of any abnormality on physical exam; however, the record does not indicate that any musculoskeletal exam was performed. *Id.*

Petitioner did not return to any physician until May 23, 2016, when she first sought orthopedic care for her left shoulder. At that time, petitioner was seen by orthopedist James Wilson, Jr., M.D. Ex. 4, p. 4. Petitioner reported that she had been experiencing six months of left shoulder pain and stiffness since receiving a flu shot in November of 2015. *Id.* Petitioner showed Dr. Wilson the photographs taken by her daughter and Dr. Wilson agreed that the injection site was elevated and right below the acromion. *Id.*

On physical exam, Dr. Wilson recorded a stiff shoulder with forward flexion about 50 to 60 degrees actively and passively and less on abduction. He estimated external rotation of about 10 degrees. Ex. 4, p. 4. Dr. Wilson diagnoses petitioner as having adhesive capsulitis (or frozen shoulder) and attributed it to petitioner's flu vaccination, noting that "it would appear to me that this for all intent and purpose is the causative factor that set off this adhesive capsulitis." Based on the photograph provided by petitioner, Dr. Wilson believed that the vaccine "probably was given into the subacromial

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<sup>4</sup> Petitioner does not have a primary care physician. Ex. 6, p. 3.

space if not into the joint itself.” *Id.* Dr. Wilson recommended physical therapy and an x-ray.<sup>5</sup> *Id.*

Petitioner began physical therapy on June 8, 2016. Ex. 3, p. 2. She reported seven months of left shoulder pain and decreased range of motion beginning the day after a flu vaccination. *Id.* Petitioner reported no pain at rest, but severe pain (10/10) when performing quick movements. It was noted that her pain and limitations caused difficulty with her activities of daily life. *Id.* Petitioner continued physical therapy through July 27, 2016. Ex. 3, p. 13.

On July 11, 2016, petitioner returned to Dr. Wilson. Ex. 4, p. 3. He noted that she was still stiff and that her frozen shoulder was “significantly frozen.” *Id.* Dr. Wilson ordered an MRI to rule out any other problems. That MRI study, conducted on July 15, 2016, showed a longitudinal partial tear of the supraspinatus insertion, though the majority of the supraspinatus was intact. Ex. 2, p. 2. It also showed a moderate subchondral bone contusion and a small glenohumeral joint effusion. *Id.* Following the MRI, Dr. Wilson maintained his assessment of frozen shoulder, noting that the MRI “does show the listed problems with a little bit of impingement spur, a little bone marrow edema on the superior humeral head just medial to the rotator cuff tendon” and no rotator cuff tear or avascular necrosis. Ex. 4, p. 2. Dr. Wilson recommended continued physical therapy and noted that petitioner would return for further follow up, and possible arthroscopy, when her teaching scheduled permits. *Id.*

Petitioner returned to Dr. Wilson on February 20, 2017. Ex. 6, p. 7. Petitioner reported that her pain had resolved but that she still had stiffness. Dr. Wilson recorded that “forward flexion is 100, abduction is 90, external rotation is 34, internal rotation is 10 on the left shoulder.” *Id.* He maintained his assessment of left shoulder adhesive capsulitis “apparently related to a flu vaccination” and recommended manipulation with arthroscopic capsular release. *Id.*

No further records have been filed, though later dated affidavits suggest that petitioner remained symptomatic with no indication that she pursued the recommended shoulder surgery. Ex. 8; Ex. 12.

### **III. Party Contentions**

In her motion, petitioner stresses that pursuant to Vaccine Rule 8 the undersigned has the authority to make a finding of fact without a hearing based on the record evidence. (ECF No. 34, p. 1.) Petitioner contends that the factual record – including both medical records and witness affidavits as described above – demonstrates that petitioner experienced a SIRVA which occurred immediately following her November 17, 2015 influenza vaccination. (ECF No. 34, pp. 1, 5.) Petitioner further contends that there is no evidence for an alternative cause for petitioner’s injury, noting that her treating physicians ruled out any structural or traumatic etiology. (ECF No. 34, p. 5.)

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<sup>5</sup> That x-ray showed no abnormality. Ex. 5, p. 4.

Respondent contends, however, that petitioner has not provided preponderant evidence that onset of her injury occurred within 48 hours of her flu vaccination, noting that petitioner did not seek treatment until approximately six months after receiving the vaccine. (ECF No. 35, p. 8.) Respondent also stresses that petitioner presented for a gynecological exam during the intervening period without referencing her shoulder pain. (*Id.*)

Respondent argues that petitioner's stated reason for delaying treatment is not credible. Respondent notes that notwithstanding her assertion that absences are frowned upon and that she felt it is "imperative" that she be present for her students, petitioner was able to attend the April 5, 2016 gynecological appointment. (ECF No. 35, p. 8.) Respondent also stresses that petitioner's affidavit did not address petitioner's ability to secure an appointment outside of school hours. (*Id.*) Respondent further argues that petitioner's claim of immediate onset is uncorroborated because there are no contemporaneous medical records and all of the fact witness affidavits filed in this case are dated two or more years after the vaccination in question. (ECF No. 35, p. 9.)

Finally, respondent argues that Dr. Wilson's causation opinion should carry little weight. Respondent argues that Dr. Wilson "did not see petitioner until more than six months after vaccination, and the basis for this conclusion rests entirely upon petitioner's representation to him that her left arm pain developed immediately post-vaccination. See ex. 4 at 4. However, because the medical and scientific basis underlying any attribution of causation must be thoroughly examined, Dr. Wilson's opinions hold little-to-no weight as a physician's conclusions 'are only as good as the reasons and evidence that support them.'" (ECF No. 35, p. 9. (quoting *Davis v. HHS*, 20 Cl. Ct. 168, 173 (1990).) In that regard, respondent is critical of Dr. Wilson's reliance on petitioner's photographs of her injection site, arguing that the photographs are undated and unverified and inadequate to determine the details of petitioner's injection. (ECF No. 35, pp. 9-10.)

In light of these arguments, respondent requests that petitioner's claim be dismissed. (ECF No. 35, p. 11.)

#### **IV. Findings of Fact**

There is no dispute that petitioner had a left shoulder injury. Nor is there any dispute that petitioner's injury is limited to her left shoulder. The question at issue is whether petitioner's left shoulder injury as reflected in the medical records was vaccine-caused. In order to reach that question on this record, the undersigned will resolve three factual issues: (1) the location of petitioner's alleged injury-causing vaccination; (2) whether petitioner experienced immediate pain following that vaccination; and (3) whether any alternative explanation exists for petitioner's shoulder pain.

### **A. Injection Site**

The undersigned finds that petitioner's November 17, 2015 influenza vaccine was administered in her left shoulder. As described above, the injection site is not included in petitioner's vaccination record as filed in this case. Ex. 1. However, petitioner has filed additional evidence supporting her contention that the injection was administered into her left shoulder. First, petitioner has sworn that this is so. Ex. 8. Additionally, petitioner's statement is corroborated by a statement from the school nurse, who indicated that petitioner was given an injection by the Long County Health Department in her left arm. Ex. 15. Petitioner's sworn statement is still further corroborated by photographs taken days after the injection. Ex. 8, pp. 3-4. These photographs were contemporaneously marked by petitioner's daughter to show the site of injection. Ex. 14. Although respondent disputes the authenticity of the photographs based on the fact that they are not dated, respondent has not addressed the affidavit by Sophie Cooper authenticating the photographs and averring as to the date that they were taken. Moreover, the undersigned takes note of the fact that petitioner's orthopedist documented the fact that petitioner showed him photographs of her injection site the first time she saw him for her shoulder injury, lending further credibility to Sophie Cooper's affidavit. Ex. 4, p. 4. Additionally, petitioner explicitly and consistently linked her left shoulder injury to her vaccination when presenting to multiple medical providers. See, e.g. Ex. 4, p. 4; Ex. 3, p. 13.

### **B. Whether petitioner experienced immediate pain**

The undersigned finds based upon the record as a whole that there is preponderant evidence that petitioner experienced pain immediately following her vaccination and reduced range of motion within 24 hours. This is sworn to by petitioner (Ex. 8), but is also supported by significant corroborating evidence.

First, petitioner's contemporaneous medical records indicate that when she first sought formal care for her shoulder injury, she reported that her pain began in November of 2015 when she was given the flu shot. Ex. 4, p. 4. At that time, petitioner presented her orthopedist photographs demonstrating that her injection was unusually high. *Id.* This underscores the fact that at the time of her first orthopedic appointment, petitioner firmly linked the onset of her pain to her vaccination. Her orthopedist further noted that "[s]he has had no injury that set this off, by her report, other than the flu shot." *Id.* Additionally, petitioner repeated similar reports to her physical therapist. Ex. 3, p. 2. At that time, she specifically identified her reduced range of motion as beginning "the day after a flu vaccination." *Id.*

Medical records generally "warrant consideration as trustworthy evidence." *Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed.Cir.1993). 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.") To the extent respondent argues in effect that

these medical records are not credible because they are not contemporaneous to the onset of petitioner's injury, the undersigned is not persuaded.

As the undersigned has previously noted, a delay of several months before seeking treatment does not necessarily defeat a SIRVA claim. *See, e.g. Cooper v HHS*, 16-1387V, 2018 WL 1835179, \*6 (Fed. Cl. Spec. Mstr. Jan. 18, 2018) (holding that "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.") Although these records are about six months removed from the onset of petitioner's injury, they represent the first time she was formally evaluated by a medical professional for her injury and her injury was still ongoing at that time with active treatment continuing for several months after. They are therefore contemporaneous *treatment* records and are entitled to significant weight as they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528. As the Federal Circuit has previously noted, treatment records are considered trustworthy at least in part because "[w]ith proper treatment hanging in the balance, accuracy has an extra premium." *Id.* This remains true regardless of whether there is some delay in seeking treatment.

In any event, these medical records are not the sole evidence bearing on the onset of petitioner's injury. In this case, petitioner has secured an affidavit from an eye witness who was with her at the time of her injection. That witness, Teri Martin, indicated that she observed that petitioner's vaccination was awkwardly administered, that petitioner complained of severe pain immediately thereafter, and that she observed this pain continuing over time. Ex. 13. Other witnesses have similarly averred that petitioner's pain began following her vaccination and continued during the months that she delayed formal treatment. Exs. 10-12. Although respondent argues that these affidavits should generally be discounted based on the fact that they were drafted two years after the events at issue, respondent has not raised any specific issue calling into question the veracity or accuracy of these recollections. Moreover, the undersigned finds that they are cogent and consistent with the contemporaneous medical records *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); *Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight.").

Additionally, petitioner has provided an affidavit from her school nurse, who verifies that petitioner sought medical advice from her regarding her shoulder injury approximately one month after her injurious vaccination. Ex. 15. Crediting this affidavit, it is not accurate to say that petitioner delayed in seeking *any* treatment for six months. This also diminishes the significance of the fact that petitioner saw her OBGYN in April of 2016 without mentioning her shoulder pain. An intervening medical appointment without mention of the ongoing shoulder injury could cast doubt on petitioner's claim. In this context, however, this is of little concern. The evidence shows that petitioner had already sought medical advice regarding her shoulder from the school nurse and health



department prior to the OBGYN appointment and was hoping the pain would resolve on its own. Exs. 8, 11, 15. Moreover, the appointment was not with a primary care physician, but with a specialist unrelated to orthopedics or any other relevant specialty, and there is no evidence to suggest any musculoskeletal exam was conducted.

To the extent explanation for the delay in seeking orthopedic treatment is helpful, petitioner cites her work obligations as an explanation for her delay. Ex. 8. The undersigned is not persuaded by respondent's argument that petitioner has not satisfactorily demonstrated that she was prevented by her work from pursuing treatment. Petitioner has not averred that she was prevented from seeking treatment. Nor would the record support such a claim. Rather, she only indicated that she prioritized her work duties over her self-care. In the undersigned's experience, such prioritization is not unusual among individuals experiencing SIRVA. See, e.g. *Cooper*, 2018 WL 1835179, \*2 (noting that petitioner described a delay in seeking treatment due to an extended trip to Vietnam and care for her ailing mother); *Marino v. HHS*, 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); *Almanzar v. HHS*, No. 16-340V, 2017 WL 8220616, at \*3 (Fed. Cl. Spec. Mstr. Dec. 21, 2017) (noting delay in treatment due to difficulty scheduling appointments and snow storms); *Knauss v. HHS*, 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018) (noting three month delay in seeking treatment without a specified reason). That petitioner appeared for a gynecological exam in the intervening period is not discrediting. There is no evidence in the record that the exam interfered with her work duties. As respondent notes, the record is silent as to the availability of appointments outside of work hours.<sup>6</sup> Moreover, petitioner's subsequent records noted that she considered the academic year in considering if and when to undergo arthroscopy. Ex. 4, p. 2.

### **C. Alternate Explanation for Shoulder Pain**

Upon complete review of the record, the undersigned finds no basis for concluding that there is any explanation for petitioner's shoulder pain other than her November 17, 2015 influenza vaccination. Prior to vaccination, petitioner was a generally healthy individual and there is no evidence that she had any relevant pre-

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<sup>6</sup> Respondent's argument on this point is speculative. Respondent suggests, in effect, that the OBGYN appointment shows that it was possible for petitioner to balance her work schedule and medical appointments. This argument assumes either that petitioner's OBGYN appointment resulted in an excused absence from work or that the OBGYN's scheduling practices both allowed for after-work appointments and are representative of other medical offices available to petitioner, such as Dr. Wilson's office. Nothing in the record supports either assumption. Respondent's reference to other unspecified providers, such as urgent care clinics, that may have been available is also speculative. Nothing in the record speaks to what providers were available to petitioner or what limiting factors impacted her selection of an orthopedist. In any event, the undersigned does not find that it is incumbent upon petitioner to demonstrate that her delay in treatment resulted from completely insurmountable obstacles.

existing health concerns.<sup>7</sup> Moreover, petitioner's contemporaneous orthopedic treatment records are clear in stating that she reported no other injury, had no risk factors for a fracture, and her orthopedist checked for scars or bruising. Ex. 4, p. 4. Following that exam, the orthopedist concluded that the vaccine was the cause of petitioner's frozen shoulder. *Id.* A subsequent MRI study did not reveal any findings interpreted as inconsistent with the orthopedists initial assessment. Ex. 4, p. 2; Ex. 6, p. 7.

## **V. Ruling on Entitlement**

In light of the above findings of fact, the undersigned further finds that this case is ripe for adjudication on the question of whether petitioner is entitled to compensation for her alleged SIRVA. For the reasons described below, the undersigned finds that Ms. Cooper 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 his 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

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<sup>7</sup> Petitioner did not have a primary care physician. Her only regular medical care was through her OBGYN. There are no indications in the OBGYN records of any shoulder or musculoskeletal issues. Ex. 7.

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 notice of the fact that respondent has added SIRVA to the Vaccine Injury Table for influenza vaccines intended for intramuscular administration in the upper arm.<sup>8</sup> See 42 C.F.R. § 100.3; 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 a medical theory, he has not disputed that the influenza vaccine can cause SIRVA. In that regard, it is worth noting that there is a well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program. See, e.g. *Loeding v. HHS*, No. 15-740V, 2015 WL 7253760 (Fed. Cl. Spec. Mstr. Oct. 15, 2015)(noting that “respondent ‘has concluded that petitioner’s injury is consistent with SIRVA; that a preponderance of evidence establishes that her SIRVA was caused in fact by the flu vaccination she received on October 14, 2014; and that no other causes for petitioner’s SIRVA were identified.”); see also *Johnson v. HHS*, No. 16-165V, 2016 WL 3092002 (Fed. Cl. Spec. Mstr. April 13, 2016)(awarding compensation for a SIRVA

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<sup>8</sup> Although petitioner’s vaccine record is silent as to the route of administration, the record does indicate that the vaccine petitioner received was a Fluarix-PF, which the undersigned understands to be formulated for intramuscular use. Significantly, respondent has raised no issue as to the route of administration in this case.

caused-in-fact by the influenza vaccine); *Koenig v. HHS*, No. 16-1496V, 2017 WL6206391 (Fed. Cl. Spec. Mstr. April 13, 2017)(same); *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 Qualifications and Aids to Interpretation ("QAI") criteria for SIRVA to be persuasive regarding the factors necessary to demonstrate a logical sequence of cause and effect.<sup>9</sup> 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).

42 C.F.R. § 100.3(c)(10) (Qualifications and Aids to Interpretation for SIRVA).

In light of the factual history and findings 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 November 17, 2017 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 claim is supported by the medical opinion of her orthopedist. Ex. 4, p. 4. Following a physical examination, Dr. Wilson concluded that petitioner was experiencing adhesive capsulitis caused by her flu vaccine. *Id.*

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<sup>9</sup> Of note, although respondent does not explicitly endorse the use of the QAI to guide a determination as to causation-in-fact, he does cite the 48 hour requirement from the Vaccine Injury Table as a necessary component of establishing *Althen* prongs 2 and 3. (ECF No. 35, p. 10.)

Respondent argues that Dr. Wilson's opinion should be discounted, because he did not see petitioner until more than six months after vaccination and the basis of his opinion is petitioner's representation to him that her left arm pain developed immediately post-vaccination. In that regard, respondent stresses that a physician's conclusions "are only as good as the reasons and evidence that support them." (ECF No. 35, p. 9 (quoting *Davis v. HHS*, 20 Cl. Ct. 168, 173 (1990).))

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 immediately after her vaccination is credible and supported by corroborating evidence. Thus, the undersigned does not find that petitioner's physician's reliance on that history was misplaced or suspect. Moreover, the orthopedist's records reflect a physical evaluation, including the ruling out of alternate traumas or injuries. Additionally, the orthopedist subsequently ordered and reviewed MRI studies without changing his assessment of petitioner's injury and its cause. Ex. 6, p. 7 (characterizing petitioner's injury as apparently vaccine-related subsequent to interpretation of petitioner's MRI). Significantly, respondent raises no other concern about this orthopedist's opinion, such as challenging his qualifications or clinical skills.

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 supported by medical opinion 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, respondent agrees that the relevant, medically accepted, timeframe for onset of a SIRVA injury is within 48 hours of vaccination. (ECF No. 35, p. 10.) Thus, in light of the above finding of fact that petitioner's shoulder pain began immediately, with reduced range of motion within 24 hours, petitioner has necessarily satisfied *Althen* Prong Three.

### **iv. Factors Unrelated to Vaccination**

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

## **VI. Conclusion**

In light of all of the above, 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 within 24 hours.

Thus, in view of the evidence of record, the undersigned finds that petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Nora Beth Dorsey  
Nora Beth Dorsey  
Chief Special Master