### In the United States Court of Federal Claims

### **OFFICE OF SPECIAL MASTERS**

No. 15-1241V Filed: January 10, 2018 UNPUBLISHED

JAMES YOUNG,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Entitlement; Ruling on the Record; Decision Without a Hearing; Causation-In-Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Edward M. Kraus, Law Offices of Chicago Kent, Chicago, IL, for petitioner. Robert Paul Coleman, III, U.S. Department of Justice, Washington, DC, for respondent.

#### **RULING ON ENTITLEMENT <sup>1</sup>**

#### **Dorsey, Chief Special Master:**

On October 23, 2015, James Young ("petitioner" or "Dr. Young") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, et seq.² (the "Vaccine Act" or "Program"), alleging that as a result of receiving an influenza ("flu") vaccination on October 24, 2013, he suffered an injury to his left shoulder, including adhesive capsulitis, which caused him severe pain and significantly limited range of motion.³ Petitioner alleges that his shoulder injury fits the criteria for SIRVA (Shoulder Injury Related to Vaccine Administration). See Petition at

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 Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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

<sup>&</sup>lt;sup>3</sup> Petitioner originally claimed that he received the flu vaccine in November 2013, but after additional investigation by his attorney, petitioner discovered and does not dispute that he received the flu vaccine on October 24, 2013. See Petitioner's Status Report filed 3/9/2016 (ECF No. 16) and Pet. Ex. 12.

1, 4. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters. For the reasons discussed herein, the undersigned finds that petitioner is entitled to compensation.

#### I. <u>Procedural History</u>

Dr. Young filed his petition for compensation on October 23, 2015, alleging that the injuries he received to his left shoulder were caused by an influenza vaccine he received sometimes in November 2013. (ECF No. 1). A vaccination record had not been obtained or filed at this time. From November 4-5, 2015, petitioner filed 11 medical record exhibits and a Statement of Completion. (ECF No. 8-10). On December 28, 2015, the staff attorney managing this case held the initial status conference. On February 11, 2016, respondent filed a status report requesting that petitioner obtain and file the record of vaccination to enable a complete review of the case. (ECF. No. 13). On February 25, 2016, petitioner filed exhibit 12, an immunization record which showed that he actually received the influenza vaccination on October 24, 2013. (ECF No. 15). On August 5, 2016, petitioner filed a status report confirming that all requested records have been filed. (ECF No. 25). On September 6, 2016, respondent filed a status report stating he intended to contest entitlement and requested a deadline be set to file his Rule 4(c) report. (ECF No. 26). An order was entered on September 7, 2016, setting a deadline of November 7, 2016 for respondent to file the Rule 4(c) report. (ECF No. 27).

On November 4, 2016, respondent filed his report pursuant to Vaccine Rule 4(c) stating that compensation was not appropriate in this case because the records "do not provide the requisite evidence to establish that the influenza vaccine in fact caused [petitioner's] injury." Respondent's Report at 1, 4. (ECF No. 28). Specifically, respondent argued that although some of petitioner's treating physicians recorded petitioner's complaint that his shoulder pain followed his flu vaccination, "none of these physicians attribute petitioner's condition to the vaccine." *Id.* at 4. In addition, respondent states that petitioner has not submitted an expert report to support his claim. Finally, respondent notes that "a five month gap between vaccination and medical treatment is anything but a logical sequence of events" and that "such a gap in time is too large to support a finding of vaccine causation." *Id.* at 4-5. Based on the evidence submitted, respondent argued that petitioner cannot satisfy any of the prongs of *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Id.*<sup>4</sup>

On January 4, 2017, with the permission of the parties, the undersigned held a status conference pursuant to Vaccine Rule 5, to present her preliminary findings and conclusions. (ECF No. 29). After summarizing petitioner's medical records, the undersigned found that petitioner received the flu vaccine on October 24, 2013, and that the onset of petitioner's shoulder injury began on the day he received his flu vaccine,

<sup>&</sup>lt;sup>4</sup> Respondent also argued that if petitioner intended to pursue a significant aggravation claim, that claim must also fail because petitioner has not provided evidence of "(4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." Respondent's Report at 6. (ECF No. 28). During a status conference held on January 4, 2017, petitioner confirmed that he was not pursuing a significant aggravation claim. See Rule 5 Order, dated Jan. 5, 2017. (ECF No. 29).

October 24, 2013. *Id.* at 2. The undersigned also found that petitioner's injury would qualify as a SIRVA injury and encouraged the parties to informally resolve this matter taking into account her preliminary findings in the case. *Id.* 

Over the next seven months, the parties attempted to informally resolve this case. On July 27, 2017, petitioner filed a status report stating that the parties were unable to reach an agreement on damages. (ECF No. 43).

On August 23, 2017, a status conference was conducted by the staff attorney managing this case. (ECF No. 44). After discussion, the parties agreed to file simultaneous motions for ruling on the record. *Id.* On September 29, 2017 and October 2, 2017, petitioner and respondent filed motions requesting a ruling on the record, respectively. (ECF No. 45, 46).

On November 9, 2017, the undersigned filed two articles pertaining to causation of vaccine-related shoulder injuries which were filed as court exhibits. These articles are: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I (see also Pet. Ex. 11), and M. Bodor and E Montalvo, Vaccination Related Shoulder Dysfunction, 25 Vaccine 585 (2007), filed as Court Exhibit II. (ECF No. 47.) The parties were given until December 11, 2017, to provide any additional evidence regarding entitlement or any response to the court exhibits. (*Id.*) No further filings were made and the undersigned considers the record as to entitlement closed as of December 11, 2017. (ECF No. 47.) The matter is now ripe for adjudication.

#### II. <u>Medical History</u>

On October 24, 2013, at age 50, petitioner received an influenza ("flu") vaccine at Shands Healthcare Occupational Health Services at the University of Florida. Pet. Ex. 12 at 1.<sup>5</sup> Dr. Young is employed as a physician at the University of Florida Shands Hospital in Gainesville, Florida, and was so at the time of vaccination. Pet. Ex. 3 at 1; Pet Ex. 9 at 1. Dr. Young's medical history included Hodgkin's Lymphoma in remission after chemotherapy, retinitis, and a fall on his left shoulder three years prior to the October 24, 2013 vaccination. See Pet. Ex. 2 at 1; Pet. Ex. 6 at 4; Pet. Ex. 3 at 1.

On March 24, 2014, nearly five months after the flu vaccination, Dr. Young was evaluated by nurse Martha Greishaw at the University of Florida Student Health Care Center for complaints of a painful upper left arm, which petitioner stated began after receiving a flu vaccination, four months prior. Pet. Ex. 3 at 1. Petitioner reported to nurse Greishaw that "[h]is arm was sore the day of the injection and the pain has never resolved." *Id.* Dr. Young also informed nurse Greishaw that he had been taking ibuprofen, Naproxen and even a Medrol Dose Pak to treat his symptoms without any improvement. *Id.* Petitioner reported that his pain at the time was 10/10, was constant and interfering with his daily functions. *Id.* He explained that he was now unable to lift

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<sup>&</sup>lt;sup>5</sup> See infra footnote 3.

his arm past a certain point and had pain when donning his shirt. *Id.* He was no longer able to use his left arm to reach his back. *Id.* Dr. Young reported that he had no previous issues with his upper extremities although he did fall on his left shoulder three years prior. *Id.* That injury was self-limited and resolved. *Id.* Dr. Young stated that the fall did not affect his shoulder strength or function. *Id.* On examination, nurse Greishaw noted that there was some asymmetry of Dr. Young's left shoulder, i.e., the left shoulder was slightly lower than the right. Pet. Ex. 3 at 2. She also noted some atrophy of his left deltoid as well as a "palpable firm tender 2 cm area deep in midline proximal lateral deltoid." *Id.* There was some mild point tenderness over the left shoulder with abduction limited to 45 degrees with pain. *Id.* The diagnosis was pain in the shoulder joint. *Id.* After consultation with Dr. Clugston in Sport's Medicine, an MRI of Dr. Young's left shoulder was ordered to evaluate for a bursa injury. *Id.* 

On March 28, 2014, petitioner underwent an MRI of his left shoulder. Pet. Ex. 3 at 11. The findings were consistent with adhesive capsulitis and mild subscapularis tendinosis. *Id.* 

On April 1, 2014, nurse Greishaw reviewed the results of the March 28, 2014 MRI noting that there was no atrophy of the rotator cuff and the deltoid muscle was normal. Pet. Ex. 3 at 3. She noted, however, that there was mild subscapularis tendinosis and adhesive capsulitis. *Id.* After a review with Dr. Clugston, Dr. Young was given an orthopedic referral. *Id.* 

On April 15, 2014, petitioner was seen at the University of Florida, Department of Orthopedics (Division of Sports Medicine), for a chief complaint of left shoulder pain. Pet. Ex. 2 at 1. He was evaluated by Dr. Stephen Ikard who noted that petitioner's left shoulder pain "started in November 2013 around the time he got his flu shot." *Id.* Dr. Ikard noted that the pain was deep in the joint, in the posterior and lateral left shoulder. *Id.* Petitioner reported shoulder pain with overhead motion and during sleep. It was also noted that petitioner had taken a steroid dose pak "with no help." *Id.* On physical examination, petitioner had limited range of motion and pain. *Id.* a 3. Petitioner was assessed with left shoulder pain and left shoulder adhesive capsulitis. *Id.* He was referred for a steroid injection and a shoulder x-ray and instructed to follow up in four weeks. *Id.* at 4.

Also on April 15, 2014, petitioner was seen by Dr. Bryan Prine, an orthopedist, who was to administer the steroid injection. Pet. Ex. 3 at 5. In the medical history, it was noted that petitioner "has been in pain since last fall" and that he was restricted in his range of motion. *Id.* Dr. Prine administered the steroid injection and Dr. Young was instructed to follow up in four weeks. Pet. Ex. 3 at 8-10.

An x-ray of petitioner's left shoulder was conducted on April 17, 2014. Pet. Ex. 2 at 5. The results were unremarkable. *Id*.

Petitioner began attending physical therapy at Shands University of Florida on April 15, 2014. Pet. Ex. 4. Dr. Young noted in the medical questionnaire that he

believed his shoulder pain and adhesive capsulitis began after a flu shot. *Id.* at 24. Petitioner attended physical therapy for seven of the planned 12 weeks and was discharged on June 27, 2014, because he was moving back to Atlanta, Georgia. Pet. Ex. 4 at 1.

On June 24, 2014, petitioner presented for a follow-up visit with a physician's assistant, Jessica Lauren, at the University of Florida, Department of Orthopedics (Division of Sports Medicine). Pet. Ex. 13 at 4. Petitioner stated that he was feeling "100% better" and noted significant improvements in his range of motion, although he continued to complain of some minor posterior shoulder pain and tightness. *Id.* On physical examination, petitioner still had positive results for the cross arm and impingement tests, but his shoulder symptoms had otherwise improved. *Id.* at 7. The diagnosis was adhesive capsulitis of the left shoulder. Petitioner was instructed to continue with physical therapy, his home exercise program, but he was permitted to slowly return to activities as tolerated. *Id.* 

In October 2014, Dr. Young elected to get the intranasal FluMist instead of the flu shot. Petition at 4; Pet. Ex. 8 at 3. Petitioner alleges that immediately after receiving the FluMist, he began experiencing new inflammation of his right shoulder and lost range of motion. Petition at 4; Pet. Ex. 8 at 2. In addition, he alleges that his left shoulder injury was aggravated, and he experienced renewed pain and lost range of motion in his left shoulder again. *Id.* 

As of February 2017, Dr. Young reported pain with his right shoulder and right knee and was attending physical therapy. Pet. Ex. 14 at 1-5. There is no mention of any issues with his left shoulder.

#### III. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if he has received a vaccine covered by the Program and "sustained, or had significantly aggravated, any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the "Table"). § 11(c)(1)(A) and (C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination.<sup>6</sup> § 14(a). If the petitioner establishes that he suffered such a "Table Injury," causation is presumed. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1146–47 (Fed.Cir.1992).

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<sup>&</sup>lt;sup>6</sup> The Vaccine Act authorizes the Secretary of the Department of Health and Human Services to "promulgate regulations" to periodically modify the Vaccine Injury Table. § 14(c). The updates are contained in the Code of Federal Regulations (C.F.R.), as cited above.

If, however, the petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, the petitioner must prove that the claimed vaccine caused the alleged injury to receive compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner is said to assert a "non-Table" or "off-Table" claim, and must prove his claim by preponderant evidence. § 13(a)(1)(A). A special master is prohibited from making "such a finding "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 13(a)(1). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that petitioner "must show 'a medical theory causally connecting the vaccination and the injury" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant*, 956 F.2d at 1148). Additionally, "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Id.* The Federal Circuit subsequently restated these requirements in its *Althen* decision. *Althen* requires a petitioner

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 a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. All three prongs of *Althen* must be satisfied. *Id.* 

Section 11(c)(1) also contains requirements concerning the type of vaccination received and the geographic location where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. See § 11(c)(1)(A),(B),(D) and (E). With regard to duration, whether a Table or non-Table claim, the petitioner must establish she

(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 11(c)(1)(D).

#### IV. Analysis - Althen Prongs

## i. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. *See Pafford v. Sec'y of Health & Human Servs.*, 2004 WL 1717359, at \*4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. *See*, *e.g.*, *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (reputable); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

#### 1. SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria 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). *Id.; 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).

#### a. The elements of petitioner's SIRVA claim

The undersigned's findings and conclusions are as follows:

## <u>a.</u> Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed Dr. Young's medical history prior to his influenza vaccination. Other than a fall on his left shoulder three years prior, petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccination. The prior fall injury was self-limited and resolved. There is no indication in the record that there was any lingering issues with petitioner's left shoulder and thus, petitioner satisfies this criterion.

#### b. Onset occurred within the specified time frame.

One significant issue identified by respondent is that the medical records do not document any complaints from petitioner about his shoulder until nearly five months post-vaccination. The undersigned finds that the onset of petitioner's pain in his left shoulder began on October 24, 2013, the day of his flu vaccination. The undersigned bases her finding on several medical records. First, a note from a treating nurse, Martha Greishaw, dated March 24, 2014, states that petitioner "reports that he developed pain in left upper arm after receiving injection 4 months ago at Shands Hospital. His arm was sore *the day of injection and the pain has never resolved.*" Pet. Ex. 3 at 1 (emphasis added). This medical record is the most contemporaneous and reliable medical record close in time to the date of petitioner's flu vaccination.

On April 15, 2014, petitioner was evaluated by Dr. Stephen Ikard who noted that petitioner's left shoulder pain "started in November 2013 around the time he got his flu shot." Pet. Ex. 2 at 1. Although it was later confirmed that petitioner received his flu shot on October 24, 2013, his reporting that his shoulder pain started at the time he received his flu shot provides additional evidence that the onset of his shoulder injury began within 24 hours of his flu vaccination. Also on April 15, 2014, petitioner reported to Dr. Prine that he had suffered pain in his shoulder "since last fall" and that he was restricted in his range of motion.

When petitioner filled out his medical questionnaire for his physical therapy, he reported that his shoulder pain and adhesive capsulitis began after the flu shot. Pet. Ex. 4 at 24. In his affidavit, petitioner recalled that "[s]oon after receiving the flu shot, I noticed my left arm becoming progressively painful and limited in its use. Colleagues began to notice me wince when I moved my left arm." Pet. Ex. 8 at 1. Petitioner explained that after a couple of months, he was no longer using his left arm because of the severe pain. His range of motion became increasingly limited, and as a result of nonuse, he developed left arm weakness. *Id.* Reviewing the record as a whole, the undersigned find that there is a preponderance of the evidence showing that the onset of petitioner's pain began within 24 hour of his October 24, 2013 flu shot.

The undersigned also credits that statements in the medical records that petitioner essentially self-treated his left shoulder (with nonsteroidal anti-inflammatory agents (NSAIDS) and Medrol Dose Pak) from the date of vaccination until March 24, 2014, when he first sought formal medical treatment. See Pet. Ex. 3 at 1-2; Pet. Ex. 2 at 1. Petitioner was a critical care anesthesia fellow at the time he received his flu vaccine, presumably with a busy schedule, and the undersigned finds that such circumstances support petitioner's statements that he self-treated for some time before seeking formal treatment for his left shoulder injury.

Based upon the evidence set forth in the medical records and affidavits, the undersigned makes finds that onset was within 24 hours of the October 24, 2013 flu vaccination, and therefore, is within the specified time frame of  $\leq$ 48 hours.

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

The medical records demonstrate that petitioner reported to nurse Martha Greishaw on March 24, 2014, that the pain to his left shoulder began the day of his vaccination and progressively worsened. Pet. Ex. 3 at 1. Prior to that time, Dr. Young self-treated by taking over-the-counter medications as well as a Medrol Dose Pak. The pain and limited range of motion affected his daily activities. Pet. Ex. 8 at 2. By the time Dr. Young had his initial visit with nurse Greishaw, he was unable to lift his arm and experienced pain when putting on his shirt. Pet. Ex. 3 at 1. Petitioner reported to nurse Greishaw that his left shoulder pain was constant and interfering with his daily functions. *Id.* Upon physical examination, Nurse Greishaw noted that there was some asymmetry on petitioner's left shoulder which was slightly lower than the right, that there was some atrophy noted on his left deltoid and a "palpable firm tender 2 cm are deep in midline proximal lateral deltoid." Pet. Ex. 3 at 2. It is also noted that petitioner's abduction was limited to 45 degrees with pain, and that he had pain and limited internal and external rotation of the left shoulder. *Id.* 

Petitioner underwent an MRI on March 28, 2014. Pet. Ex. 3 at 11. The MRI showed mild subscapular tendinosis consistent with adhesive capsulitis. *Id.* On April 1, 2014, nurse Greishaw also reviewed petitioner's MRI findings with a physician, Dr. Clugstone, and petitioner was referred to an orthopedic physician. *Id.* at 3.

On April 15, 2014, petitioner was examined by Dr. Bryan Prine of the Orthopaedic and Sports Medicine Institute. Dr. Young reported that he had been in pain since the vaccination and was restricted in his range of motion. Pet. Ex. 3 at 5. He rated his pain as 5 out of 10 at best, but 10 out of 10 at worst. *Id.* Dr. Young complained that his pain was worse with motion and better with rest. *Id.* He was diagnosed with adhesive capsulitis of the left shoulder. *Id.* at 7. In this undersigned's view and experience, the past medical history, physical examination and MRI findings are consistent with what is typically seen in SIRVA cases.

For the above reasons, the undersigned finds that petitioner experienced pain and decreased range of motion which are limited to the shoulder in which he received the vaccine.

<u>d.</u> 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).

There is no evidence in the record that demonstrates any type of condition or abnormality that would explain petitioner's symptoms.

## ii. <u>Logical sequence of cause and effect showing the vaccine was the reason for the injury</u>

Guided by the criteria for evaluating a Table SIRVA injury, the undersigned finds that petitioner has shown, by a preponderance of the evidence, a logical sequence of cause and effect showing that his October 24, 2013 flu vaccine was the reason for his shoulder injury. The SIRVA criteria provides a perfectly logical sequence of cause and effect including (1) no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (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). The undersigned has found, *infra*, that petitioner has satisfied all these requirements and thus has satisfied *Althen* prong two.

# iii. <u>Proximate temporal relationship between vaccination and injury</u>

"The proximate temporal relationship prong [under *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. *See Langland v. Sec'y of Health & Human Servs.*, 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner's shoulder injury must begin within 48 hour or less of the vaccination. The

undersigned has found that the onset of petitioner's shoulder injury began within 24 hours of the vaccination, and thus, petitioner has satisfied Althen prong two.

#### V. <u>Conclusion</u>

A cause-in-fact injury is established when petitioner demonstrates by a preponderance of the evidence: (1) he received a vaccine set forth on the Vaccine Injury Table; (2) he received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must establish each of three factors announced by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs*. by preponderant evidence: (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 proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

In light of all of the above, and in view of the submitted evidence, including the medical records and the parties' respective motions, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master