In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 17-1906V Filed: October 11, 2018 UNPUBLISHED

JEANNE RAFFERTY,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Findings of Fact Regarding Site of Vaccination and Onset of Pain; Denial of Motion to Dismiss; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

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

Linda Sara Renzi, U.S. Department of Justice, Washington, DC, for respondent.

ORDER AND FACT RULING¹

Dorsey, Chief Special Master:

On December 8, 2017, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq., 2 (the "Vaccine Act"). Petitioner alleges that she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") caused in fact by the influenza vaccination she received on October 17, 2016. Petition at 1, ¶¶ 1, 4 (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ The undersigned intends to post this order and ruling on the United States Court of Federal Claims' website. **This means the order and 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 Because this unpublished order and ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims'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).

On April 9, 2018, respondent filed a motion to dismiss petitioner's case, arguing that petitioner has failed to establish she is entitled to compensation because the evidence shows she received the vaccination alleged as causal in her left, rather than right, arm. Respondent's Motion to Dismiss ("Res. Motion") at 1. For the reasons described below, the undersigned finds there is preponderant evidence sufficient to establish petitioner received the vaccination in her right injured arm and denies respondent's motion to dismiss. Additionally, the undersigned finds there is preponderant evidence to establish the onset of petitioner's pain occurred within 48 hours of vaccination.

I. Procedural History

Shortly after filing her petition, petitioner filed her medical records and affidavit. See Exhibits 1-9, filed Dec. 21, 2017 (ECF No. 7); Statement of Completion, filed Dec. 21, 2017 (ECF No. 8). The initial status conference was scheduled for January 24, 2018. The morning of the status conference, petitioner filed documentation regarding the past revisions to her vaccination record and her requests to have the record further edited. See Exhibit 10 (ECF No. 10).

Following the status conference, respondent was ordered to file a status report indicating his tentative position regarding the merits of petitioner's case. See Order, issued Feb. 7, 2018 (ECF No. 11). Instead, respondent filed a motion to dismiss petitioner's case, arguing petitioner has failed to provide sufficient evidence to establish she received the vaccination alleged as causal in her right injured arm. (ECF No. 12). Petitioner filed a response on April 19, 2018, addressing respondent's arguments and asserting petitioner has provided sufficient evidence to establish she is entitled to compensation. (ECF No. 13). She "urge[d] the [undersigned] to issue a decision finding that petitioner received the vaccination in her right arm, and is therefore entitled to vaccine compensation based on [her] review of the record as a whole." *Id.* at 10.3 No reply was filed by respondent.

Respondent's motion to dismiss is now ripe for adjudication.

II. Factual History

A. Medical Records

The medical records from petitioner's primary care provider ("PCP"), Dr. Wah at Carroll Health Group, show that petitioner underwent several surgeries after falling on ice in 2006. See Exhibit 2 at 18 (summary from visit on Aug. 19, 2014). Petitioner continued to suffer chronic back and hip pain and weakness in her lower extremities.⁴

³ The undersigned will treat petitioner's request as a motion for a ruling on the record but declines to rule on entitlement at this time.

⁴ Petitioner was assessed with chronic back pain and leg weakness on August 19, 2014. Exhibit 2 at 19. The record of that visit provides a history of petitioner's surgeries in 2006 and 2008 and complication

However, there is no mention of arm or shoulder pain in the medical records from prior to vaccination.

Petitioner's PCP records also show that she received influenza vaccinations on September 24, 2014, November 2, 2015, and October 17, 2016. See Exhibit 2 at 14, 8, 5 (in order of the date of administration). The record for the first vaccination, on September 24, 2014, does not indicate the arm in which the vaccination was administered. *Id.* at 14. The records for the vaccinations in 2015 and 2016 both indicate petitioner received the vaccinations in her left deltoid. *Id.* at 5, 8. However, the record for the later vaccination,⁵ which is alleged to have caused petitioner's SIRVA, indicates the site of vaccination was initially identified as petitioner's left vastus lateralis (thigh)⁶ and was edited to change the site of administration to petitioner's left deltoid. See Exhibit 2 at 5. A snapshot of this record is as follows:

Influenza Vaccine

Health Maintenance:Influenza vaccine X: 0.5 mL: Intramuscular: SGUGLIOTTA: Left Deltoid: 5S349: 05/2017:: GSK; Syringe: Not VFC eligible:: 08/07/2015: 10/17/16

«PLINK:http://www.cdc.gov/vaccines/hcp/vis/vis-statements/flu.pdf»

v

Diagnosis Code

Need for prophylactic vaccination and inoculation against influenza : ICD9 = V04.81 / ICD10 = Z23 / SNOMED = 1411000119106

Procedure Code

INFLUENZA VACCINE QUADRIVALENT 3 YRS PLUS IM: 90688

edited note as it stated patient given vaccine in Left vastus lateralis - vaccine was in fact given in the left deltoid.

The patient was seen at FMA Westminster (02I) FMA Westminster (02I)

SIGNED BY Shannon M Gugliotta, MA (070)

10/17/2016 04:06PM

REVISED BY Ernesto M Mendoza, M.D. (EMM) # REVISED BY Shannon M Gugliotta, MA (070)

10/17/2016 04:33PM 12/20/2016 10:44AM

REVISED BY Shannon M Gugliotta, MA (070)

12/20/2016 11:23AM

during a procedure in 2010. *Id.* at 18. On September 24, 2014, petitioner complained of left hip pain. *Id.* at 15. Her continued back pain was also mentioned in that record. *Id.* An x-ray of petitioner's left hip, the results of which were normal, was performed on October 6, 2014. *Id.* at 30. On November 20, 2015, it was noted that petitioner had slightly less strength in her lower right extremities. *Id.* at 11. Her back pain was evaluated on June 22, 2016, and petitioner was instructed to continue her current pain medication. *Id.* at 6-7.

⁵ In addition to the record contained in the medical records from petitioner's PCP (Exhibit 2 at 5), the vaccination record was also filed as Exhibit 1. When citing this record, the undersigned will refer to the copy filed as part of the medical records from petitioner's PCP, Exhibit 2 at 5.

⁶ Vastus lateralis is the largest muscle in the quadriceps group, located on the side of the thigh. https://www.healthline.com/human-body-maps/vastus-lateralis-muscle (last visited on Aug. 31, 2018).

Id. (record of influenza vaccination administered on October 17, 2016).

It is not clear whether this revision (from left thigh to left deltoid) was made the day of vaccination, October 17, 2016, or later on December 20, 2016. The record indicates it was signed by the person who administered the vaccine, Shannon Gugliotta, on October 17, 2016, revised by Dr. Mendoza that same day, and revised at two different times by Ms. Gugliotta on December 20, 2016. Exhibit 2 at 5. In contrast, the records of vaccination from 2014 and 2015 indicate, on the date of vaccination, they were signed by the person administering the vaccination and co-signed by petitioner's PCP, Dr. Wah. *Id.* at 8, 14. A snapshot of this portion of the influenza vaccination administered on September 24, 2014 is as follows:

SIGNED BY Tashia J Paden, Medical Ass (264) 09/24/2014 01:54PM # CO-SIGNED BY John C Wah, M.D., M.D. (JCW) 09/24/2014 04:08PM

Id. at 14.

On December 1, 2016, petitioner returned to her PCP, complaining of right arm pain. Seen at this visit by Dr. Hirpara, D.O., she reported pain which had been "present since she received her Flu vaccine 5 weeks ago." Exhibit 2 at 3. Petitioner identified the injection site which Dr. Hirpara noted was "tender to touch." *Id.* Describing her pain as extending to her elbow, petitioner reported that lifting her arm was "very painful." *Id.* While examining petitioner, Dr. Hirpara observed minimal swelling, erythema, and tenderness. Exhibit 2 at 4. He ordered an MRI and indicated that, depending on the results of the MRI, he would refer petitioner to an orthopedist. *Id.*

MRIs of petitioner's right humerus and shoulder were performed on December 6, 2016. Exhibit 4 at 1-2. The MRI of her right shoulder showed "[b]ursal sided, partial tearing of the distal supraspinatus tendon with a background of mild tendinosis," "[m]ild tendinosis of the distal infraspinatus tendon," and mild osteoarthritis in the acromioclavicular (AC) and glenohumeral joints. *Id.* at 2.

-

⁷ D.O. stands for Doctorate of Osteopathic Medicine. Unless a particular degree is specified the first time an individual is referenced, it is assumed any individual with the title of "Dr." has earned a Doctor of Medicine (M.D.). Doctors who have earned a D.O. may have received different training but have similar privileges and responsibilities as doctors with an M.D.

⁸ Erythema is "redness of the skin produced by congestion of the capillaries." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 643 (32nd ed. 2012).

On December 14, 2016, petitioner saw an orthopedist at the Carroll Health Group, Dr. Rollo. Exhibit 6⁹ at 5-7. At that visit, she reported two months of right shoulder/arm pain with onset after receiving the influenza vaccination. *Id.* at 5. Describing her pain as worse when attempting to lift objects, petitioner denied any numbness or tingling. *Id.* Dr. Rollo reported that he observed "no swelling, deformity, or atrophy," tenderness at her biceps tendon upon palpitation, and an active range of motion ("ROM") but with pain. *Id.* at 6. Noting bursal sided partial tearing of the supraspinatus¹⁰ and arthritic changes, Dr. Rollo described the changes as "degenerative in nature changes and not related to the injection." *Id.* at 6-7. He prescribed medication to include a prednisone taper and physical therapy ("PT") to begin a few days later. *Id.* at 7. Petitioner began formal PT at Wellspan Rehabilitation on December 28, 2016. *See* Exhibit 7 at 71-72 (intake form).¹¹

Petitioner followed up with Dr. Rollo on January 11, 2017, again describing right shoulder pain which began after she received the influenza vaccination in her right shoulder. Exhibit 6 at 2. Petitioner reported that her pain improved by 50% while on steroids but returned when the medication was completed. Dr. Rollo observed that petitioner's ROM was further limited, to 80 degrees. Acknowledging that he "initially did not believe the needles were long enough to cause any mechanical damage to the underlying RTC [(rotator cuff)]," Dr. Rollo indicated that, after further research, he could not "confirm or deny the injection as a cause of [petitioner's] discomfort." *Id.* Having become aware of studies showing infiltration of the bursa is possible in thin women, Dr. Rollo admitted he was "uncertain of the potential side effects of the vaccine itself." *Id.* He prescribed a daily dose of prednisone and continued PT. *Id.* at 3. Instructing petitioner to return in one month for a re-evaluation, he added that a steroid injection should be considered if petitioner continued to experience pain. *Id.*

On February 7, 2017, petitioner sought a second opinion from Dr. Bischoff at Wellspan Hanover Orthopaedics. See Exhibit 7 at 56 (discharge record from PT indicating petitioner's visit to Dr. Bischoff was for a second opinion). At the initial visit to Dr. Bischoff, petitioner provided a detailed history. See Exhibit 3 at 10. She again described significant right shoulder pain, extending to her elbow, and beginning after she received the influenza vaccination on October 17, 2016. Indicating that "the injection was given high, . . . [petitioner] point[ed] to the region just underneath her

_

⁹ These records show that, in 2014, petitioner was treated by another orthopedist at the Carroll Health Group, Dr. Blue, for pain in her left thigh. See Exhibit 6 at 8-14.

¹⁰ Dr. Rollo did not specify whether he was referring to the supraspinatus tendon or muscle. Given the results of the MRI, showing partial tearing of the tendon, it can be inferred that Dr. Rollo was referring to the supraspinatus tendon. See Exhibit 4 at 2 (results of MRI).

¹¹ On her intake form, petitioner listed "flu shot administration" as the cause of her injury and dated the injury as occurring on October 17, 2016. See Exhibit 7 at 71. Petitioner included information about her earlier neck and back injury on the intake form. *Id.*

acromion laterally" which she stated occasionally felt swollen. *Id.* Although that area of her right shoulder "ached significantly for the next 2 weeks" following vaccination, petitioner recounted that she did not seek medical care earlier due to the death of a friend. *Id.*

Dr. Biscoff reported, "[o]n examination of [petitioner's] right shoulder, once again, she points just inferior to the lateral ledge of the acromion as to where the injection was given." Exhibit 3 at 10. While indicating he could not "appreciate any significant swelling about the shoulder, [and] [t]here is no erthythema or warmth," Dr. Bischoff did observe "mild tenderness to the palpitation about the shoulder girth itself," adding that it was non-specific. *Id.* He also reviewed the MRI of petitioner's right shoulder, noting that her "rotator cuff tendons appear to be intact, [t]here may be some evidence of a tendinopathy, . . . "mild effusion within the soft tissues, [and] some subacromial spurring and AC joint arthritis." *Id.* He opined that the cause of petitioner's right shoulder pain was the influenza vaccination she received, adding that, although rare, SIRVA is "described in the literature." *Id.* He discussed options such as a steroid injection or arthroscopic surgery, prescribed an additional tapering dose of prednisone, and instructed petitioner to stop PT. *Id.*; see also Exhibit 7 at 56 (describing petitioner's discharge from PT upon the recommendation of Dr. Bischoff, after attending eight sessions).

On March 1, 2017, petitioner visited Dr. Bischoff for a pre-operative physical, having "elected to proceed with the right shoulder arthroscopy." Exhibit 3 at 8. In the record from that visit, it is noted that petitioner "once again describe[d] the pain as being instantaneous at the time of the injection and it has not improved with time." *Id.* Dr. Bischoff described the planned surgery as "arthroscopic irrigation and debridement of the subacromial space," possibly including an acromioplasty.¹² Exhibit 3 at 8.

Arthroscopic surgery on petitioner's right shoulder was performed by Dr. Bischoff on March 15, 2017. Exhibit 3 at 13-14; see also Exhibit 5 (records from Hanover Hospital where the surgery was performed). According to Dr. Bischoff's records, general anesthesia was administered. Exhibit 3 at 13. Dr. Bischoff then created several portals but elected not to enter the joint itself to avoid introducing any irritants. He observed the bursa to be enlarged¹³ and hyperemic.¹⁴ Exhibit 3 at 13. Performing a bursectomy, Dr. Bischoff used a shaver to debride the bursa, undersurface of the

¹² Acromioplasty is the "surgical removal of an anterior spur of the acromion to relieve mechanical compression of the rotator cuff during movement of the glenohumeral joint." DORLAND'S at 20.

¹³ Dr. Bischoff noted that petitioner had "an abundant amount of hypertrophic bursa." Exhibit 3 at 13. Hypertrophic is the adjective form of hypertrophy, "the enlargement or overgrowth of an organ or part due to an increase in size of its constituent cells." DORLAND'S at 898.

¹⁴ Hyperemic is the adjectival form of hyperemia, "an increase of blood in a part." DORLAND'S at 888.

acromion, and coracoacromial ligament. *Id.* at 13-14. An acromioplasty was not performed, but Dr. Bischoff debrided further in the subdeltoid interval. *Id.* at 14. He observed no evidence of a rotator cuff tear. *Id.*

Petitioner returned to Wellspan Rehabilitation for her post-surgery PT on March 17, 2017. See Exhibit 7 at 50-51 (plan of care from Dr. Bischoff), 52-53 (initial evaluation by physical therapist). She had post-surgical visits with Dr. Bischoff on March 21, 24, April 25, June 6, and August 21, 2017. Exhibit 3 at 2-7, 16-17. At all visits, petitioner was described as healing well, still experiencing some post-surgical pain, and participating in PT. *Id.* Throughout the medical records from Dr. Bischoff and Wellspan Rehabilitation, petitioner's injured arm/shoulder is identified as her right arm/shoulder. Petitioner was discharged from PT on May 30, 2017, having participated in 21 sessions. Exhibit 7 at 21. At her last visit, on August 21, 2017, Dr. Bischoff noted that petitioner was improving and "making good progress." Exhibit 3 at 17. He instructed her to continue her home exercise program and to return "on an as needed basis." *Id.*

On September 20, 2017, petitioner visited Wellspan Family Medicine to establish new patient care. See Exhibit 8 at 2. Her recent shoulder surgery was included in petitioner's history, but no ongoing symptoms were noted. *Id.* at 2-5.

B. Petitioner's Affidavit and Other Documents

In her affidavit, which was signed and notarized on December 15, 2017, petitioner addresses the onset of her injury, the difficulties it has caused her, and her attempts to amend the vaccination record to reflect vaccine administration in her right, rather than left, arm. See Exhibit 9. She provided documents which describe her efforts to amend the vaccination record and the responses she received. See Exhibit 10.

Regarding onset, petitioner alleges that she "immediately experienced severe pain in [her] shoulder which was different than any other vaccine [she] had previously received." Exhibit 9 at ¶ 1. Indicating she had her three-year-old son with her, petitioner maintains she did not say anything about her pain because she did not want to frighten her son and "assumed it would feel fine in a short time." *Id.* Petitioner reports being unable to open the car door with her right arm after leaving the clinic. Petitioner indicates, rather than subsiding, her "shoulder and arm pain worsened to the point that [she] could no longer lift a cup of tea to my mouth with my right hand." *Id.*

Petitioner describes the effects of her right shoulder injury over the subsequent year. See Exhibit 9 at ¶¶ 2-4, 6. A mother of twin three-year-old sons, one of whom has autism, petitioner contends she was unable to care for her sons or herself and was forced to rely on her husband, mother, sister-in-law, and neighbor for help. *Id.* at ¶¶ 2-4.

Petitioner describes difficulty brushing her teeth, dressing, and washing her hair. *Id.* at ¶ 4. In addition to the physical difficulties she experienced, petitioner claims she and her family suffered emotionally. *Id.* She credits the second orthopedist she saw, Dr. Bischoff, for "the improvement and relief [she has experienced] thus far." *Id.* at ¶ 6.

In her affidavit, petitioner claims her ordeal has been complicated by "the fact that [her] vaccine record is not correct." Exhibit 9 at \P 5. She indicates she was not aware the record originally indicated she received the vaccination in her left thigh. Further, she did not know that the record was revised to reflect administration in her left deltoid until January 2017, after she contacted her PCP, in early December 2016, regarding her shoulder injury. She indicates she requested the record be further revised to indicate administration was in her right deltoid and "was told nothing could be done." *Id.*

In early April 2017, petitioner received a letter from Sandra Haines, the H.I.M. Coordinator at Carroll Health Group, with a form petitioner could submit to request her record be amended. Exhibit 9 at ¶ 5; see Exhibit 10 at 2 (copy of the letter dated March 30, 2017), at 3 (copy of partially completed form). Petitioner indicates she returned the completed form in May 2017, after her shoulder surgery. Exhibit 9 at ¶ 5. It appears the form was marked as denied on July 3, 2017, and returned to petitioner, along with a second letter from Sandra Haines. See Exhibit 10 at 5 (copy of letter), at 10 (copy of completed form, signed by petitioner on May 29, 2017, with July 3, 2017 denial). In the letter, also dated July 3, 2017, Ms. Haines informed petitioner that her request had been denied but that she could submit a rebuttal in a "statement of disagreement" which would be included in her medical records and released, along with the medical records, in response to any request authorized by petitioner. Exhibit 10 at 5.

Petitioner has provided an unsigned copy of her statement, dated August 14, 2017. See Exhibit 10 at 6-8. In the statement, she notes that her vaccination record was revised twice in December 2017, and describes her attempts to amend the record to reflect what she alleges is the correct information regarding the site of vaccination. *Id.* at 6. She provides further information regarding the vaccination, recounting that her vaccination "was given extremely high in [her] right shoulder" (*id.* at 7) and was administered close enough to a red mole she has on her right arm/shoulder that the mole was covered by the bandage placed over the injection site (*id.* at 7-8).

In a letter dated November 15, 2017, Ms. Haines acknowledged petitioner's statement had been received and that it, as well as the other written documents pertaining to petitioner's request, would be included in any subsequent authorized release of her medical records. Exhibit 10 at 9.

III. Party Contentions

In his motion to dismiss, respondent argues that "[b]ecause the current record is insufficient to establish that petitioner received a vaccination in her right arm, petitioner cannot meet her burden to establish SIRVA injury under the Vaccine Act." Res. Motion at 3. Respondent bases his argument on the vaccination record and conclusion of the administrator that this record was accurate. *Id.* at 1 (citing the vaccination record, Exhibit 1), 3 (citing language in the denial of petitioner's request for correction, Exhibit 10 at 10). Respondent dismisses the information contained in contemporaneously created medical records as "based solely on the histories provided by petitioner." *Id.* at 3. He also dismisses the information in petitioner's affidavit and documentation regarding her attempts to change the site of vaccination.

"Petitioner asserts that the overwhelming evidence in the record is that she received the October 17, 2016 flu vaccination in her right arm." Petitioner's Response to Res. Motion ("Pet. Response"), filed Apr. 19, 2018, at 2 (ECF No. 13). Arguing that "[t]he medical records are replete with references that petitioner's shoulder pain was associated with the flu vaccination she received in her right arm on October 17, 2016," petitioner maintains that "[t]he single record relied upon by respondent is clearly in error and stands in sharp contrast with the vast majority of other medical records in this case." *Id.*

Petitioner counters respondent's criticism of the information contained in histories provided by petitioner by asserting that, like other information in contemporaneously created medical records, these histories are entitled to greater weight. Pet. Response at 6. She argues that by questioning these histories, respondent is assuming that petitioner was either mistaken or dishonest when she provided them. *Id.* at 7-8. Moreover, petitioner notes that some information comes not from medical histories but from physical examinations performed by petitioner's treating physicians. *Id.* Stressing that special masters are not bound by any particular medical record in vaccine cases, petitioner argues that the vaccination record, already edited on at least one occasion, is not reliable and should be given little weight. *Id.* at 9-10 (citing § 13(b)).

Petitioner maintains that, once the question of the site of administration is resolved, "this is a straightforward Table case." Pet. Response at 1. She asks that the undersigned deny respondent's motion and urges her "to issue a decision finding that petitioner received the vaccination in her right arm, and is therefore entitled to vaccine compensation based on the [undersigned's] review of the record as a whole." *Id.* at 10.

IV. Findings of Fact

A. Legal Standard

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(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).

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed.Cir.1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). As the Federal Circuit has noted, it is appropriate for a special master to give greater weight to evidence contained in medical records created closer in time to the vaccination, even if the information is provided as part of a medical history. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). The Circuit Court explained that

Medical records, in general, warrant consideration as trustworthy evidence. The records 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. These records are also generally contemporaneous to the medical events.

ld.

Additionally, when determining the impact of the evidence presented, the special master should consider factors such as the reliability and consistency of the evidence. *Burns*, 3 F.3d at 416. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent. If a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 74931, at *4 (Fed. Cl. Spec. Mstr. Apr. 25, 1991), *aff'd*, 23 Cl. Ct. 726 (1991), *aff'd per curium*, 968 F.2d 1226 (Fed.Cir.1992).

B. Site of Vaccination

There is consistent evidence throughout the medical records sufficient to establish petitioner received the influenza vaccination in her right arm. When seeking treatment for her right arm/shoulder pain, petitioner regularly attributed her condition to the influenza vaccination she received in her injured right arm. Not once does petitioner indicate that she received the vaccination in her left arm.

On December 1, 2016, petitioner was examined by Dr. Hirpara, a physician in the same practice as her PCP, Dr. Wahl, at the Carroll Health Group. At that visit, petitioner identified the injection site to be the proximal deltoid region of her right arm. See Exhibit 2 at 3. Dr. Hirpara ordered an MRI and referred petitioner to an orthopedist at the Carroll Health Group, Dr. Rollo. The MRI of petitioner's right shoulder was performed on December 6, 2016.

Petitioner saw Dr. Rollo on December 14, 2016 and January 11, 2017. At the December 14, 2016 visit, petitioner again linked her right shoulder pain to the influenza vaccination she received. See Exhibit 6 at 5. Dr. Rollo prescribed PT for petitioner's right shoulder, which petitioner began at Wellspan Rehabilitation on December 28, 2016.

Petitioner's initial PT evaluation was performed by Elliot Kohr, DPT.¹⁵ In the record from that evaluation, he documented petitioner "report[ed] receiving a right shoulder flu shot on October 17, 2016." Exhibit 7 at 69.

Petitioner sought a second opinion from Dr. Bischoff, an orthopedist at Wellspan Hanover Orthopedics, on February 7, 2017. Dr. Bischoff treated petitioner through August 2017, performing her surgery on March 15, 2016. At her initial visit with Dr. Bischoff, petitioner described the injection as "given high." Exhibit 3 at 10. While Dr. Bischoff was examining her right shoulder, petitioner "point[ed] [to] just inferior to the later edge of the acromion, as to where the injection was given." *Id.*

Respondent correctly observes that this information was provided by petitioner, but she did so relatively close in time to vaccination (within four months), for the purpose of obtaining medical treatment. Moreover, the recorded observations of Dr. Hirpara corroborate the information provided by petitioner. When Dr. Hirpara examined the injection site identified by petitioner on December 1, 2016, he observed swelling, redness, and tenderness at the injection site. See Exhibit 2 at 3-4. Although he characterized these symptoms as minimal, Dr. Hirpara's observations provide substantial corroborating evidence that the vaccination was administered in petitioner's right deltoid as she reported.

Furthermore, the information provided by petitioner during her treatment and the observations and conclusions of her treating physicians are consistent with diagnostic findings and the clinical course of a SIRVA injury in petitioner's right arm. The MRI of petitioner's right shoulder performed on December 6, 2016 revealed "[b]ursal sided, partial tearing of the distal supraspinatus tendon with a background of mild tendinosis," "[m]ild tendinosis of the distal infraspinatus tendon," and mild osteoarthritis in the acromioclavicular (AC) and glenohumeral joints. Exhibit 4 at 2. During her March 15, 2017 shoulder surgery, Dr. Bischoff described petitioner's bursa as enlarged and hyperemic. Exhibit 3 at 13.

¹⁵ DPT stands for Doctorate of Physical Therapy.

Petitioner consistently reported that her right shoulder/arm pain occurred upon vaccination and increased in severity when she attempted to lift her arm above her shoulder or to lift a heavy object. *E.g.*, Exhibits 2 at 3 (visit with Dr. Hirpara); 6 at 5 (initial visit with Dr. Rollo). Petitioner was described as experiencing right shoulder pain when demonstrating her ROM. *E.g.*, Exhibits 6 at 2 (initial visit to Dr. Rollo); 3 at 10 (initial visit with Dr. Bischoff). At her second visit with Dr. Rollo, the ROM for petitioner's right shoulder was observed to be limited to 80 degrees. Exhibit 6 at 2. Petitioner attended eight PT sessions at Wellspan Rehabilitation from late December 2016 to early February 2017. In the discharge report, completed by Lauren Miller, PT, it was noted that petitioner "showed minimal to no progress with range of motion or strength" in her right shoulder. Exhibit 7 at 56. The severity of petitioner's right shoulder pain decreased while on steroids but returned to its previous level when the medication was stopped. Exhibit 6 at 2.

The first orthopedist seen by petitioner, Dr. Rollo at Carroll Health Group, initially opined that he did not believe petitioner's right shoulder injury was caused by her influenza vaccination. Exhibit 6 at 7. However, after familiarizing himself with medical literature showing infiltration of the bursa is possible in thin women, he took a neutral position regarding causation. *Id.* at 2-3 (reflecting petitioner's injury could or could not be caused by her vaccination). The second orthopedist who treated petitioner, Dr. Bischoff at Wellspan Hanover Orthopaedics, clearly linked petitioner's right shoulder pain to the influenza vaccination she received. *See* Exhibit 3 at 10. He stated, "[m]y opinion is that the shoulder pain is coming from this injection, and there is an entity called SIRVA, . . . that is rare, but it is described in the literature." *Id.*

The only evidence in this case which contradicts petitioner's claim that she received the vaccination alleged as causal in her right injured arm is the record of vaccination. See Exhibit 2 at 5. This record was revised on at least one, and possibly three occasions. Revisions are noted on the date of administration, October 17, 2016, and twice on December 20, 2016. Additionally, the record contains a notation stating it has been edited to correct the site of vaccination, from left thigh to left deltoid. *Id.* Given that the site of administration was originally identified as petitioner's left thigh, it is not unreasonable to conclude that the revised record, noting vaccination in petitioner's left deltoid, may still be incorrect.

According to petitioner, she was not aware of any issue regarding her vaccination record until early January 2017. See Exhibits 9 at ¶ 5 (petitioner's sworn affidavit executed on December 15, 2017); 10 at 7 (unsigned copy of petitioner's written response to the denial of her request to amend her vaccination record dated August 14, 2017). She says that, prior to that time, on December 9, 27, and 29, 2016, she spoke to individuals at her PCP's clinic regarding what she viewed as their responsibility for her shoulder injury and mounting medical bills. Exhibit 10 at 6. In early January 2017, she discovered the record had been revised previously and documented that the vaccine was administered in her left deltoid. Exhibit 9 at ¶ 5.

Given the three alterations made to the vaccine administration record and the fact that its original information was erroneous, the undersigned assigns less evidentiary weight to this record. The undersigned is further swayed by the timing of the alteration(s) in December 2016, which appears to have occurred after petitioner called her PCP and raised concerns about her shoulder injury.

For all of the above reasons, the undersigned finds there is preponderant evidence showing petitioner received the influenza vaccination alleged as causal in her right injured arm.

C. Onset of Pain

After reviewing the entire record in this case, the undersigned also finds that the onset of petitioner's pain occurred within 48 hours of vaccination. When seeking treatment for her shoulder pain, petitioner consistently indicated that her pain occurred immediately after receiving the influenza vaccination on October 17, 2016.

For example, when petitioner first sought treatment from Dr. Hirpara at Carroll Health Group on December 1, 2016, she described her pain as "present since" vaccination. Exhibit 2 at 3. At her first visit to the orthopedist at Carroll Health Group, Dr. Rollo, petitioner identified the onset of her pain as occurring "after receiving a flu shot." Exhibit 6 at 5. When evaluated by her physical therapist, Dr. Kohr, DPT, petitioner "report[ed] significant pain <u>during</u> her flu shot" which progressed over the next two weeks. Exhibit 7 at 69 (emphasis added). Petitioner again described her onset as occurring after vaccination when seeking a second orthopedic opinion from Dr. Bischoff at Wellspan Hanover Orthopaedics. Exhibit 3 at 10.

In her affidavit, petitioner alleges immediate and severe pain upon vaccination. Exhibit 9 at 1. The undersigned finds that the medical records support this assertion. Thus, there is preponderant evidence that the onset of petitioner's pain occurred within 48 hours of her October 17, 2016 vaccination.

V. Conclusion

Respondent's motion to dismiss is based solely on his assertion that the evidence shows petitioner received the vaccination alleged as causal in her left, rather than right, arm. In light of the undersigned's finding that petitioner received this vaccination in her right injured arm, respondent's motion to dismiss is **DENIED**.

Although petitioner requested that the undersigned issue a decision on entitlement, the undersigned will defer ruling on entitlement at this time. The undersigned requests that petitioner submit a demand to respondent within 30 days.

Petitioner shall file a status report indicating that she has forwarded her demand and supporting documentation to respondent by no later than <u>Friday</u>,

November 09, 2018. Respondent shall file a status report 30 days thereafter updating the undersigned on the parties' settlement discussions.¹⁶

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey Chief Special Master

¹⁶ The exact date for respondent's status report will be set after petitioner has filed her status report.