In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-195V
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PUBLISHED

BRENDA ANDERSON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Findings of Fact; Shoulder Injury Related to Vaccine Administration ("SIRVA"); Influenza ("flu") vaccine; injection site location

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for petitioner.
Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT[1]

On February 24, 2020, petitioner, Brenda Anderson, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012)[2], alleging she suffered a shoulder injury related to vaccine administration ("SIRVA") following receipt of her October 11, 2018, influenza ("flu") vaccination at Rite Aid Pharmacy. (ECF No. 1.) In October of 2022, both parties confirmed that this case is ripe for a fact finding as to the injection site of the vaccination at issue and the timing of onset of petitioner's shoulder pain. (ECF Nos. 43-44.) For the reasons discussed below, I conclude that petitioner received the vaccination at issue in the arm opposite her alleged SIRVA. In light of this finding, it is not necessary to reach the further question of onset at this time.

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[1] Because this document contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the document 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 the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Procedural History

Petitioner filed medical records and an affidavit marked as Exhibits P1-P5 and a Statement of Completion March 6, 2020. (ECF Nos. 6, 8.) She later filed further medical records marked as Exhibits P6-P10 between April and February of 2021. (ECF Nos. 12, 16, 20, 22.) Petitioner filed a second Statement of Completion on February 24, 2021. (ECF No. 23.)

Based on the allegations of the petition, the case was initially assigned to the Chief Special Master for potential informal resolution as part of the Special Processing Unit or ("SPU"). (ECF No. 10.) However, respondent advised as of April 30, 2021, that he would be contesting petitioner's claim and subsequently filed a Rule 4 Report recommending that compensation be denied. (ECF Nos. 25, 27.) Respondent raised a number of issues. Most pertinent to this fact finding, respondent indicated that it is impossible to determine in which arm petitioner received her vaccination and disputed that there is preponderant evidence that her shoulder pain began within 48 hours of vaccination. (ECF No. 27, pp. 7-8.)

After respondent filed his report, the Chief Special Master issued an Order to Show Cause on August 18, 2021. (ECF No. 29.) Based on his review of the record, the Chief Special Master concluded that petitioner "has failed to provide preponderant evidence that the allegedly causal vaccination was administered in her right, rather than left, arm." (*Id*. at 1.) He further indicated that petitioner "needs to further address the timing for onset of the right shoulder pain she attributes to her alleged SIRVA, the evidence that her symptoms were not limited to her right shoulder area, and the evidence that other conditions or abnormalities may explain her symptoms. If she cannot better substantiate these issues, her claim risks dismissal." (*Id*.) Petitioner was ordered to show cause why her Table SIRVA claim should not be dismissed. (*Id*. at 4.)

In response to the Order to Show Cause, petitioner filed a supplemental affidavit (Ex. P11), four witness affidavits (Exs. P12-15), and additional medical records (Exs. P16-18). Petitioner also filed a written brief. (ECF No. 31.) Respondent subsequently filed a responsive brief. (ECF No. 32.) Petitioner filed a reply and additional medical records (Ex. P19) in December of 2021. (ECF Nos. 33-34.) A follow up status conference was held on March 15, 2022. (ECF No. 35.) The Chief Special Master ordered petitioner to file additional evidence he identified based on review of the affidavits that had been filed. (*Id*.) Petitioner subsequently filed a supplemental affidavit accompanied by calendar entries as ordered by the Chief Special Master. (ECF Nos. 36, 39; Exs. P20-22.)

Following further review, the Chief Special Master indicated that petitioner "has demonstrated that her claim cannot be appropriately dismissed at this time. Indeed, the factual issues in contention present difficult determinations that could go either way." (ECF No. 40, p. 1.) Accordingly, the Chief Special Master reassigned the case to the undersigned, indicating that "[f]urther proceedings shall be determined by the next special master assigned to the case." (*Id*. at 2.)

On September 9, 2022, I issued a Scheduling Order. (ECF No. 42.) After reviewing the history of the case, I advised the parties that "[a]s currently postured, it appears that fact findings as to the injection site for the vaccination at issue as well as onset of the alleged vaccine-caused shoulder pain will be necessary." (*Id*. at 2.) I noted, however, that in response to the prior Order to Show Cause petitioner had taken issue with the Chief Special Master's preliminary inclination to place more weight on a handwritten notation on petitioner's vaccination consent form indicating a left shoulder administration than a computer-generated notation indicating a right shoulder administration. (*Id.*) Specifically, I quoted the following from petitioner's brief: "If the Court has evidence, representations from vaccine administrators or otherwise that details the process and procedures by which a vaccine administrator completes the handwritten and computer documentation of a vaccine administration, then such information should be disclosed immediately to Petitioner's counsel." (*Id*. at 2 (quoting ECF No. 31, p. 12, n. 1).)

I instructed the parties to review prior decisions addressing fact findings as to injection site and specifically noted that these cases have involved discovery from the pharmacy at issue, including pharmacist testimony bearing on the issue of how administration records are generated. (ECF No. 42, p. 2 (citing *Stoliker v. Sec'y of Health & Human Servs.*, No. 17-990V, 2018 WL 6718629 (Fed. Cl. Spec. Mstr. Nov. 9, 2018); *Mezzacapo v. Sec'y of Health & Human Servs.*, No. 18-1977V, 2021 WL 1940435 (Fed. Cl. Spec. Mstr. Apr. 19, 2021); *Hanna v. Sec'y of Health & Human Servs.*, No. 18-1455, 2021 WL 3486248 (Fed. Cl. Spec. Mstr. July 15, 2021).) I allowed the parties 30 days to file status reports confirming whether they still believed the record is ripe for a fact finding as to injection site and onset after reviewing these cases. (*Id*.)

On October 7, 2022, respondent filed a status report confirming that respondent believes the record to be ripe for the proposed fact findings. (ECF No. 43.) On October 11, 2022, petitioner filed a status report advising that "the record is ripe for a ruling as to onset and site of vaccination. Petitioner had briefed these issues in response to the Court's Show Cause Order and filed a Response on October 18, 2021 and a Reply on December 6, 2021." (ECF No. 44.)

Accordingly, on October 12, 2022, I issued an Order (Non-PDF) advising that I intend to issue a fact finding as to date of onset of petitioner's alleged vaccine-caused shoulder pain as well as the injection site of the vaccination at issue based on the existing record.

II. Factual History

a. As reflected in medical records

There is no dispute that petitioner received a flu vaccination at Rite Aid Pharmacy on October 11, 2018. However, the record of vaccination that petitioner has filed as Exhibit P1 has conflicting information regarding the site of injection. Given the

importance of this body of records, it is worth describing them in detail. Petitioner's Exhibit P1 consists of the following:

- A cover page by RecordTrak (a record retrieval service) (Ex. P1, p. 1);

- A letter dated February 4, 2020, by the manager of legal services for Rite Aid Pharmacy confirming that "the immunization administration records for the vaccination administered to Brenda Anderson on October 11, 2018" are enclosed in response to the request by RecordTrak (Ex. P1, p. 2);

- A "Customer Profile Report" for the date October 11, 2018, reflecting that Glen D. Macpherson prescribed a FluaRix Quad Syringe with the status marked as "SOLD" and a date of service of "10/11/2018" (Ex. P1, p. 3);

- Three mostly blank pages marked as "Service Details." (Ex. P1, pp. 4-6.) The Service Details again confirm a service date of October 11, 2018. (*Id.* at 5.) The vaccine manufacturer, lot number, expiration date, Vaccine Information Sheet date, syringe, store number, and administrator, are all confirmed. (*Id*.) Route of administration is noted to be intramuscular and site of administration is marked as "Right Deltoid" (*Id*.); and

- A two-page Screening Questionnaire and Consent Form. (Ex. P1, pp. 7-8.) This form includes a top portion for Patient Information that is filled out by hand with petitioner's personal information. (*Id*. at 7.) Below that is a series of screening questions with boxes to mark "Yes," "No," or "Don't Know." (*Id*.) Each question has a handwritten checkmark answer. (*Id*.) These questions are followed on the next page by an acknowledgment and authorization statement signed by petitioner. (*Id*. at 8.) Below the authorization is a portion of the form with the heading "PHARMACY USE ONLY." (*Id.*) There is a space on the form with the instruction "Place RX Label Here" and a label for petitioner's intramuscular FluaRix Quad Syringe is affixed to the form. (Ex. P1, p. 8.) Below that space are prompts to write in the lot number and expiration date for the vaccine. (*Id*.) On petitioner's form, these spaces have been left blank. (*Id.*) Below these prompts, there is a prompt to identify the site of injection by circling either "RA" or "LA" (*i.e.* right or left arm). On petitioner's form, "LA" is circled. (*Id*.) The signature of the administrator and date of signature appear just below these prompts. The signature is best characterized as illegible but appears consistent with the administrator's name included in the service details on page 5. Additional prompts for license number and "NPI" number are left blank. (*Id*.)

Fifteen days post-vaccination, petitioner presented for care at an urgent care facility on October 26, 2018. (Ex. P3, p. 6.) The reason for visit was "arm pain x 4 days, patient has right neck and arm pain that radiates up and down." (*Id*.) The diagnosis was right arm pain and muscle stiffness. (*Id*.) The history of present illness

did not include any reference to a prior vaccination. (*Id*. at 12.) Petitioner described her pain as an ache and indicated it is worse with movement. (*Id.*) She denied any injury. (Ex. P3, p. 12.) Review of systems was positive for both neck and muscle pain. (*Id*.) Physical exam revealed normal range of motion. (*Id*.) The assessment was "[t]his is likely a musculoskeletal issue" and petitioner was given a TORADOL injection from which she reported significant improvement and prescribed Flexeril for muscle spasms. (*Id.* at 13.) If symptoms were not resolved, she was instructed to follow up with her primary care physician for possible physical therapy. (*Id*.)

Petitioner returned to the urgent care clinic five days later on October 31, 2018. (Ex. P3, p. 35.) This time the date of onset is reported as October 13. (*Id.*) The history of present illness indicates petitioner felt she had been improving, but "then she was grocery shopping and somehow re-injured the area." (*Id*. at 40.) It is noted that petitioner does not have a primary care physician. Review of systems remained positive for both neck pain and muscle pain, but petitioner had full range of motion on physical exam. (*Id*. at 40-41.)

On November 2, 2018, petitioner established care with a primary care provider, a family nurse practitioner. (Ex. P3, p. 69.) Petitioner's history of prior vaccinations was documented. (*Id.* at 63.) Her October 11, 2018, flu vaccine was included, but no injection site was listed. (*Id.*) At this visit, petitioner's chief complaints are "health maintenance" and "arm pain." (*Id*. at 69.) Petitioner associated her arm pain to her vaccination for the first time at this encounter. The history of present illness indicates in relevant part that "[s]he is here today with the complaint of right arm pain that started 2 days after receiving a flu shot on 10/11/2018 in her left arm. The arm pain has significantly improved and is intermittent." (*Id*.) Petitioner explained that she has an allergy to eggs and that she is concerned that may be causing her post-vaccination arm pain. (Ex. P3, p. 69.) On physical exam, mild pain was present on palpation in the right deltoid, but no other pain was reproducible. (*Id.* at 71.) The diagnoses were right deltoid tendinitis and right trapezius neck strain. (*Id*.)

Petitioner subsequently underwent a physical therapy evaluation on December 13, 2018. (Ex. P4, p. 115.) Petitioner reported that her right arm "has been very painful, insidious onset." (*Id*.) No further discussion of onset was described; however, the physical therapist marked the date of onset as October 12, 2018, which would be the day after her vaccination. (*Id*.) Petitioner continued physical therapy through August of 2019. (*Id*. at 1.) However, she did not have occasion to revisit the initial onset of her condition until she first presented for orthopedic care on April 2, 2019, approximately six months post-vaccination. (Ex. P5, p. 17.) At that time, petitioner reported "she had a flu shot at rite-aid in October of 2018. Two days later she began to experience sudden onset global right shoulder pain." (*Id*.) The orthopedist indicated that "[a]t this point I have seen several cases of SIRVA this year and her history and physical exam are consistent with this." (*Id.*) Petitioner apparently reraised her concern regarding a possible allergy as the orthopedist indicated that he does not feel petitioner's condition is related to an allergy. (*Id*.)

The remainder of petitioner's medical records are less informative with respect to either the initial onset or her shoulder pain or the site of her vaccine injection.

b. Additional Evidence

In her first affidavit, dated February 25, 2020, petitioner avers that she began experiencing severe pain the day of her vaccination, which she described as feeling like her shoulder was separating from the socket. (Ex. P2, p. 2.) She recalls going to the grocery store the following day to get extra strength pain reliever, a heating pad, and a topical cream. (*Id.*) She indicates her shoulder "slowly got worse" over the following days. (*Id*. at 3.)

Petitioner explains that by the time of her first medical encounter on October 26, 2018, she had radiating pain from her shoulder into her neck and arm. (Ex. P2, p. 3.) She did not have any sense at that time that her symptoms were due to her flu shot. (*Id*.) Rather, she was concerned she may have a cardiac condition. (*Id*.) According to her affidavit, petitioner reported that her symptoms worsened four days prior to this encounter rather than having initially started at that time. (*Id*.) She avers that when she returned to urgent care "I mentioned that I had pain in my right shoulder and arm dating back to when I received the flu shot at Rite Aid." (Ex. P2, p. 4.) She further states that she "still did not know if the flu shot was related but [she] kn[e]w that the pain in [her] shoulder was somewhat similar and [she] had no injuries or trauma that could have caused this shoulder pain." (*Id*.)

Petitioner confirms that when she first presented to her primary care physician in November of 2018 "I explained how my shoulder pain began after receiving the influenza vaccine at Rite Aid and I was concerned that the interaction between the flu shot and my egg allergy had something to do with my right shoulder pain." (Ex. P2, p. 4.) She indicates that it was only at her first orthopedic appointment that she was later educated about the relationship between her shoulder pain and the flu shot. (*Id.*)

Petitioner's first affidavit does not address the injection site of her vaccination. Petitioner filed a second affidavit dated October 3, 2021, that specifies that she recalls being vaccinated in her right shoulder rather than left shoulder. (Ex. P11, p. 1.) Petitioner does not specify her basis for being able to recall the site of her vaccination. (*Id*.) The second affidavit otherwise repeats the same history of onset as described in the first affidavit. (*Id*.)

In addition to her own affidavits, petitioner presented statements from four fact witnesses.

L.F. Williams has known petitioner for twenty years and been her business consultant for eight years. (Ex. P12, p. 1.) In L.F.'s first statement, he recalls that he was meeting with petitioner "a few times a week" to work on a business plan during the fall of 2018. (*Id.*) He states that "I was very well aware that [petitioner] received the flu vaccine in her right shoulder on October 11, 2018. On October 11, 2018, I met with her

for one of our weekly meetings as we were scheduled to meet that afternoon." (*Id.* at 2.) According to Mr. Williams, "[s]he complained to me that her right shoulder was hurting following the flu vaccination during our meeting. I did see her right shoulder looking red and inflamed." (*Id.*) He described her as having pain and discomfort on many subsequent occasions. (*Id*.) Petitioner filed a copy of a calendar for October of 2018 that marks a meeting between Mr. Williams and petitioner at 3:45pm on October 11, 2018. (Ex. P20.) Below it is a note that references the meeting and states "[w]e brainstormed for about 1 hour and ended meeting as she didn't feel well." (*Id.*)

After petitioner filed this witness statement and calendar, respondent filed a response. (ECF No. 38.) Respondent argued that the calendar entries are both vague and unreliable. (*Id.* at 2.) Respondent noted that the entries were written in the past tense, clearly drafted after the events took place, and therefore unclear as to whether they are contemporaneous to events. (*Id.*) In a subsequent statement, Mr. Williams indicates the calendar was created in May of 2019 when he transferred all of his prior handwritten meeting and calendar notes into an electronic format. (Ex. P22, p. 2.) He states that he did not edit or change the notes when he copied them over into the electronic format. (*Id*.) Mr. Williams also provided additional notes from October of 2018 filed as Exhibit P21. These notes confirm the fact of the October 11, 2018, meeting from 3:45 PM to 4:45 PM, but do not include any notation suggesting the meeting was cut short. (Ex. P21.)

Dr. Chana Jackson is petitioner's niece. (Ex. P13, p. 1.) She states that she spoke to petitioner on October 11, 2018, and indicates that:

> I remember [the] October 11, 2018, conversation because I received my vaccination the day before [petitioner] received her vaccination. I remember us discussing and comparing how different our levels of pain were immediately following the flu vaccination. I told [petitioner] that my flu vaccination was not particularly painful and went without a hitch. [Petitioner] informed me that she was experiencing significant pain in her right shoulder and arm following flu vaccination and described her right shoulder looking red and swollen. I am not a medical doctor, and I tossed a possibility of her being allergic to something in the vaccine and the allergy manifesting itself as pain at the site of injection in her right shoulder and arm.

(*Id*. at 1-2.) Dr. Jackson further specifies that petitioner complained of both pain and decreased range of motion in her right shoulder on the date of vaccination. (*Id.* at 3.)

Mary Johnson is petitioner's cousin and "prayer partner." (Ex. P14.) Ms. Johnson states that:

> I knew that [petitioner] received a flu vaccine on October 11, 2018. Being each other's praying partners, [petitioner] asked me to pray for her before she went to get her vaccination on October 11, 2018. Afterward, she informed me that she was in significant pain, and we prayed for her

> recovery. [Petitioner] came over with her daughter on many occasions, and we all prayed for [petitioner's] right shoulder to heal. I specifically remember [petitioner] referring to her right shoulder and arm after receiving her October 11, 2018 vaccination.

(*Id.* at 2.)

Delord McMath is petitioner's landscaper and friend; and he indicates that he typically sees petitioner about twice a month from April through October. (Ex. P15.) Mr. McMath states that "[i]n October 2018, after her flu vaccination, I saw [petitioner] in person, and she complained that her right shoulder was hurting from getting the recent flu shot in her right shoulder." (*Id*. at 1.)

III. Party Contentions

In her response to the Chief Special Master's Order to Show Cause, petitioner argued that there is preponderant evidence both that she received the vaccination at issue in her right arm and that onset of her shoulder pain occurred within 48 hours of vaccination. (ECF No. 31, p. 1.)

Petitioner argues that reliance on her handwritten vaccine consent form as evidence regarding the site of injection is "belied by the totality of the evidence in the record." (ECF No. 31, p. 12.) Petitioner argues that the right arm injection is evidenced by the computer-generated aspect of the Rite Aid Pharmacy record which is further corroborated by her affidavit and witness statements. (*Id.* at 12-13.) Petitioner argues that the "only" piece of evidence that identifies a left arm administration is the consent form which circled "LA." (*Id*. at 13.) Petitioner argues that "[t]he Court cannot place more weight on a handwritten consent form versus a computer-generated consent form where there is no evidence in the record from Rite Aid about how those forms and documents were generated." (*Id*.) Instead, petitioner argues that "the Court must carefully examine the subsequent medical records and affidavits to determine if the totality of the evidence provide[s] preponderant proof of a right shoulder vaccination site." (*Id*.)

In that regard, petitioner stresses her repeated presentation to her medical providers for a right shoulder injury. (ECF No. 31, pp. 14-18.) Petitioner stresses in particular that her orthopedist assessed her as having a SIRVA and argues that it "defies logic" to conclude that he would assess a right shoulder SIRVA if petitioner "was truly vaccinated in [the] left shoulder." (*Id*. at 19.) Petitioner acknowledges that she reportedly told her primary care physician that she was vaccinated in her left shoulder, but argues this must be understood as a typographical error given that she was presenting for a right shoulder injury. (*Id*. at 16.) Petitioner contends that given that the assessment was right deltoid muscle pain the entire medical record would be "illogical" if the notation regarding a left arm administration were accepted. (*Id*.)

With regard to onset, petitioner argues that her medical records place onset of her condition within two days of her vaccination beginning with her October 31, 2018 urgent care visit. (ECF No. 31, p. 21.) Petitioner stresses that her orthopedist assessed her history as being consistent with a SIRVA. (*Id*. at 23.) Petitioner further stresses the statements of her witnesses. (*Id*. at 24-25.)

In response to petitioner's show cause response, respondent argues in favor of the special master placing greater weight on petitioner's handwritten vaccine consent form to evidence the injection site. (ECF No. 32, p. 1.) Respondent stresses that a left arm administration is consistent with administration into her non-dominant arm, a common practice. (*Id*. at 2.) Citing petitioner's November 2 report to her primary care provider, respondent also disputes petitioner's contention that the handwritten consent form is the "only" evidence of a left arm administration. (*Id*.) Respondent contends that petitioner's reliance on her treatment for a right shoulder injury as evidence regarding the site of injection is "circular logic." (*Id*. at 3.) Respondent stresses, for example, that the orthopedist's assessment of SIRVA was based on petitioner's own representation with no evidence the orthopedist verified the injection site. (*Id*. at 3-4.) With regard to onset, respondent argues that the most contemporaneous medical records are inconsistent with onset falling within 48 hours of vaccination. (ECF No. 32, pp. 6-8.) Respondent argues in favor of accepting the contemporaneous medical records in preference to the unnotarized witness statements provided by petitioner with respect to both onset and injection site. (*Id*. at 5-6.)

Petitioner was provided the opportunity to file a reply. (ECF No. 33.) Petitioner's reply stresses substantially the same points that are addressed in her initial show cause response.

IV. Legal Standard

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove their claim by a preponderance of the evidence. A special master must consider the record as a whole, but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he 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." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Thus, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule is not absolute. Afterall, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs*., No. 03-1192V, 2006 WL

2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." 2005 WL 6117475, at *19 (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992)). Importantly, however, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy*, 23 Cl. Ct. at 733 (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the Special Master must consider the credibility of the individual offering the testimony. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417.

V. Discussion

a. Injection Site

i. Rite Aid records

There is no question that the most contemporary evidence regarding the site of petitioner's vaccination is the body of records produced by Rite Aid Pharmacy at Exhibit P1. However, these records are inconsistent in that the computer input indicates administration in the right arm and the handwritten consent form indicates left arm administration. Respondent argues in favor of accepting the left arm notation while petitioner argues, in effect, that these two notations are in equipoise. However, the evidence preponderates in favor of accepting the left arm notation contained on the consent form. Petitioner's argument that it is impossible to place different weight on the two injection site notations is unpersuasive. Petitioner has cited no authority for the proposition she advances that no reasonable inferences are possible based on these records. Prior cases in the program illustrate the point.

In a prior case, a CVS manager testified that it is policy in that chain to input the site of administration into the computer system *prior to* determining with the patient where the vaccine will be administered. *Stoliker,* 2018 WL 6718629, at *3. He further

indicated that this input cannot subsequently be changed at the individual pharmacy location. *Id.* In a subsequent case, a Rite Aid Pharmacy pharmacist (Ms. Perkucin) testified regarding a situation in which the petitioner's medical records included a computer-generated vaccination summary that had been provided by Rite Aid to the petitioner's physician. *Mezzacapo,* , 2021 WL 1940435 at *4. That electronic summary listed a vaccination site of a left arm administration while the record evidence as a whole suggested a right arm administration. *Id.* As in *Stoliker*, the pharmacist explained that the computer input is generated prior to vaccination so that the cost of the vaccination can be processed through the patient's insurance. *Id.* In contrast, the pharmacist explained that the clinic questionnaire and consent form is completed in connection with the administration of vaccinations. *Id*. Although the consent form was not produced in the *Mezzacapo* case, the pharmacist testified that the vaccination in that case was administered in the right rather than left shoulder based on her own review of the consent form on file at the pharmacy location. *Id*.

Although the prior *Mezzacapo* testimony involved the same chain of pharmacies as at issue in this case, I am mindful of the fact that the Ms. Perkucin's testimony is not evidence of record in this case. However, even setting aside any of this background information, the handwritten consent form is clearly entitled to greater weight based on the more limited record available in this case. By inclusion of both a patient questionnaire and pharmacy use portion with prompts for administration site, the consent form confirms on its face that it is intended for use during the encounter for vaccination. (*See* Ex. P1, pp. 7-8.) Further to this, the consent form is signed by both petitioner and the vaccine administrator and is further dated by the vaccine administrator. (*Id.*) This evidences that the consent form was completed in petitioner's presence and at the time of vaccination. Moreover, the consent form appears to have been completed as it should have been in the regular course and is therefore facially trustworthy.[3] In contrast, while the "service details" separately contained in the Rite Aid records contain some of the same information (Ex. P1, pp. 4-6), neither the specific purpose of that separate computer record nor the timing of its creation is evidenced based on the record that has been developed in this case. Additionally, although petitioner purports to recall having been vaccinated in her right arm, she does not discuss the basis for that recollection nor offer any specific recollection that would dispute the accuracy of the consent form or suggest the consent form was likely to have been completed with any error. (Ex. P11, p. 1.)

Significantly, petitioner was provided an opportunity to address the issue. After this case was reassigned to me, I noted that petitioner had raised the possibility that evidence could exist to differentiate the notations at issue. I ordered the parties to review the above-discussed cases and confirm whether they still believed the record was sufficiently complete for the instant finding of fact. (ECF No. 42.) Despite reviewing these prior cases, and despite having documentation of the identity of the

[3] For example, in the *Hanna* case, I assigned less weight to the administration record at issue in part because the actual prompts on the form for completing the injection site were left blank and the notation at issue in that case appeared in an unrelated portion of the form. 2021 WL 3486248, at *8. But that is not the case here.

vaccine administrator in this case (Ms. Buist (Ex. P1, p. 5)), petitioner requested that this fact finding be made on the existing record. (ECF No. 44.) Especially given that petitioner bears the burden of proof with respect to the factual predicates of her case, this further reduces the persuasiveness of petitioner's argument that any effort to distinguish or give different weight to the notations constitutes speculation.[4]

Thus, although the Rite Aid Pharmacy records contain an inconsistent notation, the handwritten consent form indicating a left arm administration is entitled to significant weight as a contemporaneous record and is entitled greater evidentiary weight than the separate computer-generated notation.

ii. Subsequent treatment records

Even assuming *arguendo* that the left and right notations contained within Exhibit P1 are in equipoise, petitioner is still not persuasive in suggesting that the evidence as a whole preponderates in favor of a right shoulder administration. Petitioner is correct that subsequent treatment records can be important evidence regarding the site of vaccination. For example, that was the finding in the prior *Hanna* case. 2021 WL 3486248, at *9. In that case, I specifically rejected respondent's argument that this type of attribution represents a circular logic. This case is distinguishable, however. In *Hanna,* the petitioner consistently reported to her treating physicians that she was experiencing a right shoulder injury she attributed to her recent vaccination from the very first time she sought care for that condition. *Id.* Here, however, petitioner did not initially attribute her condition to her vaccination when she sought treatment (Ex. P3, pp. 6, 35), and when she later did report the fact of having been recently vaccinated, she specified that the vaccine was administered in the opposite arm (*Id*. at 69). The November 2, 2018, notation of a left arm administration is the only time in petitioner's treatment history where the site of administration is specified in the months following her vaccination.

Petitioner argues that her report of a left shoulder injection to her primary care provider on November 2 must be understood as a typographical error or the record would otherwise be "illogical." (ECF No. 31, p. 16.) However, this argument is unpersuasive for several reasons. First, the record itself appears facially trustworthy. (Ex. P3, p. 69.) The history of present illness is reasonably detailed and petitioner has not presented any evidence to call this provider's recordkeeping practices into question generally. In fact, petitioner's interpretation of the record would render the left shoulder notation not merely incorrect, but also superfluous given the way the statement as a whole is written. Second, the left shoulder notation at issue is, in fact, consistent with

[4] *E.g., Hanna*, 2021 WL 3486248, at n. 8 (explaining in the context of injection site documentation that "[b]ecause petitioner offered no indication that she sought these witnesses out and did not otherwise develop the record in that regard, there is no reason to assume they would have provided evidence favorable to petitioner"); *Chinea v. Sec'y of Health & Human Servs*., No. 15-095V, 2019 WL 1873322, at *30, n. 40 (Fed. Cl. Mar. 15, 2019) (declining to fully credit "self-serving" amendments to medical records where, *inter alia*, the physician who amended the records was not made available to testify at hearing), *mot. rev. den'd*, 144 Fed. Cl. 378 (2019).

the contemporaneous consent form. Third, petitioner's rationale that the notation of a left arm notation is entirely inconsistent with petitioner's presentation for a right arm musculoskeletal injury is not persuasive.

Both this medical record and petitioner's own affidavit confirm that at the time of her November 2 encounter petitioner was experiencing more generalized arm and neck pain. Moreover, she believed the possible mechanism of injury was an allergic reaction rather than any direct musculoskeletal trauma at the injection site that would clearly necessitate a correlation between the injection site and the injury in the manner of a SIRVA. In that regard, it is important to note that petitioner's prior treatment records had not discussed her vaccination at all, that petitioner herself avers that she had not initially understood her neck and shoulder pain to be related to her vaccination, and that petitioner instead had previously feared she was experiencing a cardiac problem. (Ex. P2, p. 3.) And, although the provider ultimately assessed a right shoulder musculoskeletal condition, there is no evidence in the medical record that the treater accepted petitioner's attribution of her injury to her vaccination. Thus, there is nothing illogical at all about accepting this medical record at face value. Nor, given petitioner's own uncertainty regarding the relationship between her vaccination and her pain, does it provide strong evidence that the pain must necessarily correlate to the injection site.

Petitioner also stresses that her orthopedist later attributed her shoulder pain to a SIRVA. However, this record is based on petitioner's own report and is less contemporaneous. (Ex. P5, p. 17.) The fact of this case alone demonstrates that at some point in time subsequent to November 2, 2018, petitioner came to be convinced that her vaccination was administered in her right arm. However, as respondent notes in his response, there is no evidence to suggest that her orthopedist verified this fact before rendering his opinion. Given petitioner's earlier vaccination and treatment records, the more remote history she provided the orthopedist is entitled to less weight. *See e.g.*, *R.K. v. Sec'y of Health & Human Servs*., No. 03-632V, 2015 WL 10936124, at *76 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) (holding that more remote histories of illness do not have sufficient indicia of reliability to be credited over conflicting contemporaneous medical records and earlier reported histories), *mot. rev. denied* 125 Fed Cl. 57 (2016), *aff'd* 671 Fed.Appx. 792 (Fed. Cir. 2016); *see also e.g.*, *Vergara v. Sec'y of Health & Human Servs.*, 08-882V, 2014 WL 2795491, *4 (Fed. Cl. Spec. Mstr May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those *recorded in later medical histories*, affidavits, or trial testimony" (emphasis added).). Moreover, the orthopedist's ultimate conclusion is only as reliable as the underlying information. *See, e.g. Garner v. Sec'y of Health & Human Servs*., No. 15-63V, 2017 WL 1713184, at *11 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (explaining that "the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals."), *mot. rev. denied* 133 Fed Cl. 140 (2017).

iii. <u>Witness statements</u>

Finally, petitioner's witness statements lack sufficient credibility to be credited over the other evidence of record. As explained above, in order to be persuasive, witness statements should be "consistent, clear, cogent, and compelling." Ms. Johnson's and Mr. McMath's statements lack sufficient specificity to meaningfully confirm the details at issue in this fact finding. (Exs. P14, P15.) Mr. Williams and Dr. Jackson's statements are more specific; however, they are incompatible with petitioner's own recollection which is itself confirmed by the contemporaneous medical records. (Exs. P12, P13.)

Both Mr. Williams and Dr. Jackson state that they received specific complaints from petitioner on the date of her vaccination that she was suffering a right shoulder injury that she attributed to administration of her vaccination. (Exs. P12, P13.) Mr. Williams further states that at that time he visualized the injection site as red and inflamed and Dr. Jackson states that she suggested to petitioner that she was having an allergic reaction to the vaccination. (*Id.*) However, petitioner averred in two separate affidavits that she did not at that time relate her pain to her flu vaccination. (Ex. P2, p. 2; Ex. 11, p. 2.) Petitioner explicitly stated that as of her October 26, 2018, urgent care encounter "I had no sense that my flu shot could have been the cause of my ongoing symptoms." (*Id.*) This is confirmed by petitioner's contemporaneous medical records which reflect that she did not initially mention her vaccination to her treaters. (Ex. P3, pp. 6, 35.) Given this, it is far less likely that these specific conversations occurred as relayed, or, if they did, that they occurred on the date specified.

Mr. Williams's calendar entry provides some potentially corroborating evidence; however, the calendar entry itself does not confirm any shoulder issue and Mr. Williams acknowledged that the actual document filed in this case is not the original record, but a non-contemporaneous copy produced months later. (Ex. P22, p. 2.) His other notes do not specifically corroborate that the meeting was cut short. (Ex. P21.) Additionally, Dr. Jackson specifically recalls that petitioner had reduced range of motion as of the time of their conversation occurring on the date of vaccination (Ex. P13, p. 3); however, petitioner's subsequent treatment records from urgent care and her primary care provider evidence that she had full range of motion through early November of 2018 (Ex. P3, p. 13, 41, 71).

iv. Conclusion as to injection site

Based on all of the above, when considering the record as a whole, there is not preponderant evidence that petitioner's vaccination was administered in her right arm. Two significant contemporaneous medical records confirm petitioner's vaccination was administered in her left arm – the vaccine consent form itself and the first treatment record in which petitioner reported the fact of her prior vaccination. Petitioner is unpersuasive in suggesting that these records should be given reduced weight and/or that they are outweighed by the other evidence of record. In fact, petitioner's view of the evidence relies on the presence of an extraordinary coincidence that two key individuals – the vaccine administrator and petitioner's primary care provider – would

make the exact same recordkeeping mistake at different facilities nearly a month apart and with no readily available explanation for either error. It is all the more difficult to accept this coincidence when petitioner acknowledges that she did not herself initially perceive her shoulder pain as being related to her vaccination.

b. Onset

As with the site of injection, there is conflicting evidence of record regarding the initial onset of petitioner's shoulder pain. However, the above fact finding with respect to the injection site of petitioner's vaccination is presumptively dispositive. Because there is not preponderant evidence petitioner was vaccinated in the same arm as her injury, it is not necessary to resolve the onset of that injury occurring in the opposite arm.

VI. Conclusion

This finding of fact concludes that petitioner's October 11, 2018, flu vaccine was administered in her left arm, opposite the arm in which petitioner has alleged she suffered a SIRVA. (ECF No. 1.) Accordingly, the facts as I have found them appear to be incompatible with the allegations of the petition. A separate scheduling order will issue giving petitioner 30 days to respond to this finding of fact. Thereafter, I will determine whether this claim must be dismissed.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master