In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-762V
Filed: March 24, 2025

KEDIALA MAGASSOUBA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioner.
Irene Angelica Firippis, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On June 24, 2020, petitioner filed a petition under the National Childhood Vaccine Injury Act, 24 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA"), right arm pain, and a subcutaneous tissue mass that was caused-in-fact or, in the alternative, significantly aggravated, by the influenza ("flu") vaccination that she received on August 30, 2017. (ECF No. 1, p. 1.) Petitioner alleges that her shoulder injury meets the requirements under the Vaccine Injury Table to qualify as a table SIRVA. (*Id.* at 3.)

For the reasons set forth below, I conclude petitioner received the vaccination at issue in the shoulder opposite her alleged injuries. This finding is dispositive, and the case is therefore dismissed.

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (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, upon review, I agree that the identified material fits within this definition, I will redact such material 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, *et seq.*

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(i); § 300aa-14(a).

As relevant here, the Vaccine Injury Table lists SIRVA as a compensable injury if it occurs within 48 hours of administration of a flu vaccine. § 300aa-14(a) as amended by 42 C.F.R. § 100.3. Table Injury cases are guided by a statutory "Qualifications and aids to interpretation" ("QAI"), § 300aa-14(b), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table, § 300aa-14(a). To be considered a Table SIRVA petitioner must show that his/her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . 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, and any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner could still demonstrate entitlement to an award by instead showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). To successfully demonstrate causation-in-fact, petitioner bears a burden to show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3(b)(1). Special masters must ensure each party has had a "full and fair opportunity" to develop the record. Vaccine Rule 3(b)(2). However, special masters are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Procedural History

This case was originally assigned to the Chief Special Master as part of the Special Processing Unit ("SPU"), which seeks to expedite cases having a significant

chance of informal resolution based on the allegations of the petition. (ECF Nos. 13-14.) Petitioner filed medical records, affidavits, and two medical journal articles marked Exhibits 1-12. Pertinent to the arguments discussed below, petitioner initially filed a pharmacy record that did not include the vaccine's lot number or the site of administration for the flu vaccination at issue. (Ex. 2, p. 2; ECF No. 16.) After issuance of a subpoena, petitioner filed a more detailed vaccination record that indicates that petitioner received the flu vaccination at issue in her left deltoid, opposite her alleged right shoulder injury. (Ex. 8, pp. 2-3.)

On March 25, 2022, respondent filed his Rule 4(c) report, asserting that petitioner failed to demonstrate entitlement to compensation. (ECF No. 33.) Respondent argued that (1) petitioner has not demonstrated that she suffered any vaccine-related injury because her vaccination record clearly indicates that she received the flu vaccine in her left shoulder, whereas she alleges an injury to her right shoulder and arm; (2) petitioner has not demonstrated a Table SIRVA because she has not established onset of her injury within 48 hours of vaccination; and (3) petitioner has not demonstrated that her August 30, 2017 flu vaccination caused-in-fact or significantly aggravated her alleged injuries. (*Id.* at 6-11.)

The Chief Special Master issued a scheduling order on July 29, 2022, instructing both parties to brief the following issues raised in respondent's Rule 4 report: (1) the site of vaccine administration and the location of petitioner's injury; (2) the timing of the onset of petitioner's injury; (3) whether petitioner's shoulder injury was caused-in-fact by the flu vaccination she received on August 30, 2017; and (4) whether petitioner's flu shot significantly aggravated an underlying shoulder injury. (ECF No. 34.) Petitioner submitted her brief on November 16, 2022, and respondent submitted his brief on December 23, 2022, with both parties maintaining their respective positions. (ECF Nos. 39-40.)

After the parties submitted their briefs, the Chief Special Master determined that this case was not suitable for resolution within SPU. (ECF No. 41, p. 2.) Initially, this case was reassigned to another special master on October 25, 2023 (ECF No. 42); however, on February 18, 2025, this case was then reassigned to the undersigned. (ECF No. 45.)

On February 28, 2025, I provided petitioner an opportunity to file any outstanding medical records[3] and indicated my intent to rule on the factual question of the injection site of petitioner's flu vaccination based on the parties' previously submitted briefs and the existing record. (ECF No. 46.) I advised that a fact finding as to injection site may be case dispositive, explaining that if I determined petitioner's vaccination had been administered in her left shoulder, then I intended to dismiss the case. I permitted the

[3] The Chief Special Master had ordered petitioner to complete the evidentiary record and submit briefing by no later than November 16, 2022. (Non-PDF Scheduling Order, filed Nov. 9, 2022.) In her brief, petitioner indicated that the medical records filed to that date were incomplete, noting that petitioner was in the process of obtaining medical records related to a CT scan and a general surgery consult. (ECF No. 39, p. 1, n.1.) Subsequently, in his responsive brief, respondent requested these outstanding medical records. (ECF No. 40, pp. 3-4, n.5-6.) However, no additional records were subsequently filed.

parties until March 14, 2025, to raise any objection to proceeding in this manner. (*Id*.) Petitioner did not file any additional medical records, and neither party raised any objection.

In light of the above, I have determined that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case on the existing record. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020). Accordingly, this matter is now ripe for resolution.

III. Summary of Record Evidence

a. Medical Records

On August 30, 2017, petitioner received a flu vaccine at Rite Aid Pharmacy. (Ex. 2, p. 2.) At the time of vaccination, she was 53 years old and had a history of diabetes mellitus. (Ex. 1, p. 13; Ex. 8, pp. 1-3.)

The vaccination record petitioner initially filed did not include information regarding the injection site of petitioner's flu vaccine. (Ex. 2, p. 2.) However, petitioner later filed updated pharmacy records reflecting that her flu vaccine was administered in her left deltoid. (Ex. 8, pp. 2-3.) Given the importance of this body of records, it is worth describing them in detail. Petitioner's Exhibit 8 consists of the following:

- A two-page Screening Questionnaire and Consent Form. (Ex. 8, pp. 1-2.) This form includes a top portion for Patient Information that petitioner partially filled out by hand with her name, date of birth, and gender. (*Id.* at 1.) Below that is a series of questions with boxes to mark "Yes," "No," or "Don't Know" that petitioner completed by hand. (*Id.*) Each question is answered with a handwritten "x" next to it. (*Id.*) These questions are followed on the next page by an acknowledgement and authorization statement signed by petitioner. (*Id.* at 2.) 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 Afluria 2017-2018 Syringe is affixed to the form. (*Id.*) Below that space are prompts to write in the lot number and expiration date for the vaccine that are completed by hand by the pharmacist who administered petitioner's flu vaccine. (*Id.*) Below these prompts, there is a prompt to identify the site of injection by circling either "RA" or "LA" (*i.e.*, right arm or left arm). (*Id.*) "LA" is circled by hand. (*Id.*) The signature of the vaccine administrator appears just below this prompt. (*Id.*) The form also includes prompts for the vaccine administrator's license number and NPI number, which were both completed by hand. (*Id.*) Lastly, the vaccine administrator dated the form by hand as "8/30/17." (*Id.*)

- One page marked as "Corp Pharmacy: *Service Details*." (Ex. 8, p. 3.) The Service Details confirm the date of vaccination as August 30, 2017. (*Id.*)

Information relating to the vaccine, medication name, vaccine manufacturer, lot number, expiration date, vaccine information statement, Rx number, store number, and vaccine administrator all appear on the form. (*Id.*) Route of administration is noted to be intramuscular, and site of administration is marked as "Left Deltoid." (*Id.*)

- One page marked as "Rite Aid: Customer Profile Report" for 8/30/2017 through 8/30/2017. (Ex. 8, p. 4.) This page confirms that petitioner received an "Afluria 2017-2018 Syringe" on August 30, 2017. (*Id.*) However, this page does not include any information relating to site of the injection. (*Id.*)

On November 9, 2017, seventy-one days post-vaccination, petitioner presented to her primary care clinic with complaints of a two-month history of persistent shoulder pain that was aggravated by physical activity. (Ex. 1, p. 13.) Petitioner reported that she received a "flu shot two months ago at RITE AID pharmacy on right arm." (*Id.*) She also reported that she experienced swelling and induration over the site of injection and noted limited and painful range of motion. (*Id.*) The physician assistant's physical examination of petitioner revealed "R upper arm - Small lump" without deformity, as well as slight tenderness and limited range of motion. (*Id.* at 14.) As a result, the physician assistant ordered an ultrasound of the soft tissue mass and recommended petitioner continue to treat her pain with over-the-counter pain medications and warm compression. (*Id.*)

On December 19, 2017, petitioner followed up with her primary care provider to review the findings of the ultrasound of her right shoulder. (Ex. 1, p. 7-8.) The physician assistant noted that right shoulder sonograph showed a "small, oval hypovascular echogenic lesion" that was suspected to be a granuloma and recommended an MRI with contrast. (*Id.* at 7.) The review of systems listed "Muscle Pain (right shoulder)," and physical examination of petitioner again revealed the small lump, limited range of motion, and tenderness in petitioner's right upper arm. (*Id.* at 8.) Petitioner returned to her primary care provider on December 28, 2017. (Ex. 1, pp. 5-6.) Physical examination of petitioner revealed "R upper arm - Palpable lump" described as firm and non-mobile with slight tenderness and limited range of motion. (*Id.* at 6.) The referral for an MRI with contrast was denied by petitioner's insurance. (*Id.*) Upon petitioner's expression of her desire to have the small tissue mass excised, the physician assistant referred her to a general surgeon for removal. (*Id.*)

On January 29, 2018, petitioner returned to her primary care provider to follow up for her right arm pain. (Ex. 1, p. 3.) She was seen by Dr. Ghazal Reihani, M.D., who noted that "[t]he arm pain has been occurring in a persistent pattern for months. The arm pain is described as moderate." (*Id.*) Under the diagnostic studies history, the record lists "sono arm lipoma 12/2017 - lipoma." (*Id.*) Physical examination of petitioner again revealed "R upper arm - Palpable lump" described as firm and non-mobile with slight tenderness and limited range of motion. (*Id.* at 4.) In her assessment, Dr. Reihani noted that the soft tissue mass in petitioner's right shoulder was "confirmed lipom[a] by gen surg Dr. Sheth 1/11/2018" and diagnosed petitioner with lipoma of

axilla. (*Id.*) Additionally, Dr. Reihani noted that Dr. Sheth's clinical impression was that petitioner's right arm pain was not related to the lipoma in her right shoulder. (*Id.* at 3-4.) As a result, Dr. Reihani referred petitioner to neurology as recommended by Dr. Sheth. (*Id.*)

Petitioner continued to present to her primary care provider in February and March of 2018, reporting persistent right arm pain that she had been experiencing for months. (Ex. 7, pp. 36-37, 42-43.) Physical examinations of petitioner at these appointments continued to reveal "R upper arm - Palpable lump." (*Id.* at 37, 43.) Records for these visits continued to document "12/2017 - lipoma" under diagnostic studies history. (*Id.* at 36, 42.)

On March 13, 2018, petitioner presented to the emergency department "reporting right arm pain x 'months.'" (Ex. 4, p. 3.) The emergency room nurse noted that petitioner "[h]ad flu injection on her R upper arm 5 months ago now came in with pain to area since then." (*Id.* at 5.) The emergency room physician noted that petitioner presented with a history of "right arm pain for 3 months. Had a flu shot to that arm and has hurt since." (*Id.* at 3.) Additionally, the physician noted that petitioner "had a CT scan of the shoulder with the PMD and they said there is some calcific tendinitis."[4] (*Id.*) The physician's physical examination of petitioner revealed "[n]ormal range of motion. The right arm is nontender, FROM. No tenderness to clavicle, elbow, wrist or hand. 2+ radial pulse. Normal sensation. Strength 5/5. No swelling." (*Id.* at 4.) After examining petitioner, the emergency room physician diagnosed petitioner with "Disorder of muscle, ligament, and fascia." (*Id.* at 2.)

On April 25, 2018, petitioner was evaluated by neurologist, Migdana Kepecs, M.D., for her continued right arm pain. (Ex. 3, pp. 2-9.) Dr. Kepecs documented petitioner's history of right arm pain, noting that petitioner "had a flu shot in September and subsequently developed pain near the site. She has difficulty lifting her arm and putting on a blouse due to the pain." (*Id.* at 3.) Additionally, Dr. Kepecs reviewed petitioner's ultrasound findings from December 2017 and remarked "[w]hile non-specific, granuloma is a primary consideration given the provided history. Lipoma could have a similar appearance although reported associated pain would be atypical. Clinical follow-up is recommended." (*Id.*) Upon physical examination of petitioner, Dr. Kepecs noted "[t]here was a lump near the right shoulder" and diagnosed her with "[p]ain of right upper extremity." (*Id.* at 4-5.) She documented that petitioner's right arm pain was most likely not of central nervous system or peripheral nervous system etiology. (*Id.* at 5.) Dr. Kepecs recommended that petitioner follow-up with her primary care provider for her continued right arm pain and the "lesion" seen on the ultrasound. (*Id.* at 6.)

In October of 2018, petitioner returned to her primary care provider. (Ex. 7, pp. 33-34.) At this appointment, petitioner reported that her right arm pain was improving

[4] As explained above, the records associated with petitioner's CT scan were not filed. Of note, calcific tendinitis could be an explanation for an acute onset of shoulder pain that would not readily implicate a vaccination. *Molina v. Sec'y of Health & Human Servs.*, No. 20-845V, 2024 WL 4223393 (Fed. Cl. Spec. Mstr. Aug. 15, 2024).

and that she did not feel an MRI was necessary. (*Id.* at 33.) Petitioner's physical examination revealed full range of motion. (*Id.* at 34.) As a result, petitioner's right arm pain was marked as "resolved." (*Id.*)

b. Medical Literature

Petitioner filed two case reports regarding the occurrence of granulomas post-vaccination. (Takahiro Suzuki et al., *Subcutaneous Granuloma Annulare Following Influenza Vaccination in a Patient with Diabetes Mellitus*, 32 DERMATOLOGICA SINICA 55 (2024) (Ex. 9); Miguel Fernando García-Gil et al., *Generalized Granuloma Annulare After Pneumococcal Vaccination*, 96 ANAIS BRASILEIROS DERMATOLOGIA 59 (2021) (Ex. 10).) In the first case report by Suzuki et al., the authors report on a 76-year-old woman who presented with a one-month history of a tender subcutaneous nodule on her upper left arm after receiving a flu vaccine in the same site one month prior. (Suzuki et al., *supra*, at Ex. 9, p. 1.) A histological analysis was completed, and the authors diagnosed the lesion as a granuloma annulare following an influenza vaccination. (*Id.*) In the case report, the authors note that "[i]t is well known that [granuloma annulare] is occasionally associated with diabetes mellitus." (*Id.*) Thus, the authors concluded that the woman had a predisposing factor for granuloma annulare. (*Id.*)

Given that there was no granuloma annulare lesion at the site before vaccination and that there was no reoccurrence at either the same site or another site, the authors found it "tempting to speculate that diabetes mellitus served as a predisposing factor for [granuloma annulare] and vaccination directly triggered [granuloma annulare] in [the] patient." (Suzuki et al., *supra*, at Ex. 9, p. 1.) The authors referenced eleven other cases of a post-vaccination granuloma annulare but noted that only two of those cases were of the subcutaneous type. (*Id*.) None of those eleven cases involved the influenza vaccine. (*Id.*) Based on their review of those eleven cases, the authors hypothesized that a specific "vaccine antigen may evoke a T cell-mediated, granuloma-inducing immune reaction in predisposed individuals," such as their patient. (*Id.* at 2.)

In the second case report by García-Gil et al., the authors report on a 57-year-old woman who presented with multiple asymptomatic, cutaneous lesions clustered in an annular pattern and distributed along her abdomen and lower extremities. (García-Gil et al., *supra*, at Ex. 10, p. 1.) The authors noted that the cutaneous lesions first presented twelve days following pneumococcal vaccination. (*Id.*) The woman "was diagnosed with generalized [granuloma annulare] following pneumococcal vaccination based on the clinical appearance of the lesions, histopathological findings, and temporal relationship between the vaccinations and skin lesions." (*Id.* at 2.) The woman's lesions eventually resolved within two months of their initial appearance. (*Id.*)

The authors acknowledge that "[t]he occurrence of granuloma annulare (GA) triggered by vaccination is rare," noting that only thirteen cases of post-vaccination granuloma annulare have been reported in the medical literature. (García-Gil et al., *supra*, at Ex. 10, pp. 1-2.) Additionally, the authors concede that the exact mechanism by which granuloma annulare formation is activated is unknown. (*Id.* at 2.) Although

they acknowledge that traumatic inoculation is a possible mechanism of post-vaccination granuloma annulare, the authors conclude that "[t]he traumatic inoculation hypothesis is less convincing, because [granuloma annulare] exclusively located at the vaccination site has been observed in few cases." (*Id.*) Rather, the authors find the hypothesis of a possible immunological pathogenesis far more convincing, as the majority of reported cases of granuloma annulare following vaccination are of the generalized form. (*Id.* at 5.)

c. Affidavit Testimony

Petitioner filed three affidavits in this case. (Exs. 5, 11-12.) In her first affidavit, filed on October 5, 2020, while recounting her experience receiving her flu vaccination on August 30, 2017, petitioner recalls "[w]hen I received the shot, it was very painful. A little later I noticed a swelling in my arm. The swelling grew over the next few days with sharp pain. I was not able to move my arm or lift items without pain." (Ex. 5, ¶ 3.) She went on to state that "I still have swelling around the injection site. I still have pain periodically." (*Id.* ¶ 10.) However, petitioner did not identify the injection site of her flu vaccine or specify which arm she experienced swelling and pain in.

In her second affidavit filed on November 16, 2022, petitioner specifically addresses the site of the flu vaccination at issue. (Ex. 12.) She avers as follows:

> On August 30, 2017, I received my yearly flu shot in my right arm at my local Rite Aid. I remember getting the shot in my right arm, as the way the chairs were set up at Rite Aid in their immunization area, it was easier for the provider to reach my right arm. I also prefer receiving vaccines in my right arm and try to get them in my right arm whenever possible.

(*Id.* ¶¶ 2-3.)

Petitioner also filed an affidavit by her husband, Falou Thiam, on November 16, 2022. (Ex. 11.) Mr. Thiam states that:

> In August 2017, my wife received her flu shot in her right arm at Rite Aid. After she received the shot, I remember her showing me how her right arm was swelling where she received the shot. I remember her telling me how much it hurt. She continued to complain about the pain. It did not appear to go away. She then started to complain to me about how painful it was when she tried to raise her arm or lift items with her right arm.

(*Id.* ¶¶ 3-5.) Mr. Thiam recalls that, when petitioner finally did see her doctor for her right shoulder pain in November 2017, "there was really nothing they could do for her." (*Id.* ¶ 7.) He states that petitioner continues to complain of her pain in her right arm. (*Id.* ¶ 8.)

IV. Party Contentions

Petitioner asserts that, apart from the vaccination record from Rite Aid (Ex. 8), every single one of petitioner's post-vaccination medical records support the conclusion that petitioner received the flu vaccination at issue in her right shoulder. (ECF No. 39, p. 7.) She argues that the medical record of her encounter on November 9, 2017, at which she first reported her alleged injury, is particularly compelling evidence that her flu shot was administered in her right arm. (*Id.* (citing Ex. 1, p. 13).) First, petitioner stresses that the medical record clearly indicates that the pain in her right arm began after the administration of her flu shot. (*Id.*) Second, she notes that the encounter documented physical evidence of receipt of the vaccine in her right shoulder, specifically, findings of "swelling and induration over the injection site." (*Id.*) Lastly, petitioner argues that, at that appointment, her provider diagnosed her with "arm pain status post flu shot." (*Id.* at 7-8.)

In addition, petitioner asserts that the affidavits filed in this case support the finding that her flu vaccine was injected in her right shoulder. (ECF No. 39, p. 8.) In her second affidavit, petitioner recalls that the flu vaccine was administered in her right deltoid due to the way the chairs were positioned at the pharmacy. (*Id.* (citing Ex. 12).) Petitioner argues that her recount of her vaccination experience is further supported by the affidavit submitted by her husband, who confirmed that petitioner received her flu vaccine in her right arm and subsequently suffered pain, swelling, and limited range of motion in her right arm. (*Id.* (citing Ex. 11).) As a result, petitioner asserts that the affidavit testimony, coupled with her contemporaneous medical records, including the objective findings of her provider, provide overwhelming evidence that petitioner's flu vaccine was administered in her right deltoid. (*Id.*)

Furthermore, petitioner contends that the presence of the granuloma in her right deltoid serves as evidence that she was vaccinated in her right shoulder. (ECF No. 39, pp. 8-9.) Petitioner distinguishes granulomas from lipomas in that granulomas are "caused by the body's response to something," while a lipoma is merely a growth of fatty tissue. (*Id.* at 8.) She argues that the general surgeon's finding that petitioner's right arm pain was not caused by a lipoma is evidence that the small tissue mass in petitioner's right arm was "something other than a lipoma and likely a granuloma." (*Id.* at 4.) Additionally, petitioner contends that "[g]ranuloma is a known potential side effect of vaccination." (*Id.* at 8 (citing Suzuki et al., *supra*, at Ex. 9; García-Gil et al., *supra*, at Ex. 10).) Petitioner cites the case report by García-Gil et al., in which the authors note that the trauma of injection or the immune response involved in vaccination could explain the mechanism by which granuloma formation is triggered after a vaccination. (*Id.* (citing García-Gil et al., *supra*, at Ex. 10, pp. 1-2).) She also cites to the case report by Suzuki et al., stressing the authors' recognition of diabetes mellitus as a predisposing factor for granulomas and their hypothesis that "vaccine antigen may evoke a T cell-mediated, granuloma-inducing immune reaction in predisposed individuals." (*Id.* at 8-9 (citing Suzuki et al., *supra*, at Ex. 9, pp. 1-2).) Therefore, petitioner asserts that these case reports demonstrate that her granuloma was likely caused by her flu vaccine and,

since her granuloma was on her right shoulder, it follows that the injection site for petitioner's flu vaccine was also her right shoulder. (*Id.*)

In contrast, respondent argues that the record evidence in this case does not support a finding that petitioner's flu vaccine was administered in her right shoulder. (ECF No. 40, pp. 6-8.) Respondent asserts that petitioner's contemporaneous vaccination record clearly identifies the injection site as the petitioner's left deltoid. (*Id.* at 6 (citing Ex. 8, pp. 2-3).) He argues that medical records created contemporaneously with the events they describe are particularly persuasive in the Vaccine Program.[5] (*Id.*) Respondent emphasizes that the pharmacist who administered petitioner's flu vaccine circled "LA" next to the prompt for injection site, indicating that the vaccine was administered in petitioner's left arm. (*Id.*) He contends that this was a specific action on the part of the pharmacist administering the vaccine to identify the site of the vaccination and that this action was performed close in time to the vaccination itself. (*Id.* at 6-7.) Such handwritten vaccination records, respondent stresses, have been afforded greater weight in the Vaccine Program.[6] (*Id.* at 7.) Additionally, respondent states that the record offers no evidence of petitioner attempting to correct or amend the vaccination record. (*Id.*)

Respondent suggests that petitioner may reasonably have been mistaken about the injection site of her flu vaccine when she first reported right arm pain to her primary care provider given the fact that seventy-one days had passed since the date of vaccination. (ECF No. 40, p. 7.) He stresses that, while petitioner reported experiencing swelling at the site of vaccination, the physical examination of her right shoulder at that first post-vaccination encounter only revealed a small lump, slight tenderness, and limited range of motion. (*Id.* (citing Ex. 1, pp. 13-14).) Accordingly, respondent argues that petitioner's flu vaccine was unrelated to the subcutaneous mass that was identified seventy-one days post-vaccination. (*Id.*) Respondent asserts that the evidentiary record lacks any evidence suggesting that Rite Aid erred in its recording of the administration of petitioner's flu vaccine. (*Id.*) While petitioner later made statements attributing her right arm pain to her flu vaccine and identifying her right shoulder as the injection site, respondent contends that these statements are not sufficient to overcome the contemporaneous vaccine administration records. (*Id.*)

Lastly, respondent contends that the presentation of the subcutaneous mass in petitioner's right arm is not evidence that the vaccine was administered in the right shoulder. (ECF No. 40, pp. 7-8.) He asserts that subcutaneous masses, including granulomas, often develop spontaneously and are not painful.[7] (*Id.*) Respondent also

[5] Citing *Cucuras v. Secretary of Health & Human Services*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

[6] Citing *Syed v. Secretary of Health & Human Services*, No. 19-1364V, 2021 WL 2229829, at *5 (Fed. Cl. Spec. Mstr. Apr. 28, 2021); *Anderson v. Secretary of Health & Human Services*, No. 20-195V, 2022 WL 17484352, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2022).

[7] Citing *Lipoma*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/lipoma/symptoms-causes/syc-20374470 (last visited Mar. 1, 2022); *Granuloma annulare*, MAYO CLINIC,

highlights that the record suggests petitioner experienced calcific tendinitis, which is a painful condition unrelated to any vaccine or subcutaneous mass. (*Id.* at 8 (citing Ex. 4, p. 3).)

V. Legal Standard for Fact Finding

Pursuant to § 300aa-13(a)(1), a petitioner must prove the factual underpinnings of their claim by a preponderance of the evidence. That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (alterations in original). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

A special master must consider the entire record, but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury. § 300aa-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*, 993 F.2d at 1528.

Thus, medical records that are clear, consistent, and complete 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).

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

https://www.mayoclinic.org/diseases-conditions/granuloma-annulare/symptoms-causes/syc-20351319 (last visited Dec. 13, 2022).

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 the decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 416-17 (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 of Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), *aff'd sub nom. LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417.

The factual question of injection site does arise repeatedly, especially in the context of SIRVA. In that context:

> it is important that special masters recognize that vaccine administration records can sometimes by incorrect and that they should not be accepted reflexively. However, that is a far cry from presuming they are to be distrusted generally or without good reason. Vaccine administration records are still, after all, contemporaneous medical records.

Anderson v. Sec'y of Health & Human Servs., No. 20-195V, 2023 WL 2237320, at *10 (Fed. Cl. Spec. Mstr. Feb. 2, 2023). Nonetheless, "treatment records are [also] probative on this issue because they are contemporaneous documents recorded by disinterested persons memorializing the fact that petitioner at that time understood her vaccination to have been administered in her [affected] shoulder, believed that to be relevant to assessing her condition, and sought treatment accordingly." *Hanna v. Sec'y of Health & Human Servs.*, No. 18-1455V, 2021 WL 3486248, at *9 (Fed. Cl. Spec. Mstr. July 15, 2021); *see also Mezzacapo v. Sec'y of Health & Human Servs.*, No. 18-1977V, 2021 WL 1940435, at *7 (Fed. Cl. Spec. Mstr. Apr. 19, 2021). Thus, there is an established track record of prior cases in which vaccine injection site has been considered based on the totality of the evidence, even where the administration record itself conflicts with petitioner's allegation. *Christensen v. Sec'y of Health & Human Servs.*, No. 19-0007V, 2022 WL 1020386 (Fed. Cl. Spec. Mstr. Feb. 28, 2022); *Syed v. Sec'y of Health & Human Servs.*, No. 19-1364V, 2021 WL 2229829 (Fed. Cl. Spec. Mstr. Apr. 28, 2021); *Irwin v. Sec'y of Health & Human Servs.*, No. 19-956V, 2021 WL 5504701 (Fed. Cl. Spec. Mstr. Oct. 18, 2021); *Baker v. Sec'y of Health & Human Servs.*, No. 19-1771V, 2020 WL 6580192 (Fed. Cl. Spec. Mstr. Oct. 9, 2020); *Boyd v. Sec'y of Health & Human Servs.*, No. 19-1107V, 2021 WL 4165160 (Fed. Cl. Spec. Mstr. Aug. 12, 2021). Importantly, however, while subsequent treatment records can provide some evidence as to the injection site, patient histories in later medical records that conflict with contemporaneous record records will generally be afforded less weight. *See, e.g.*, *R.K. ex rel. A.K. v. Sec'y of Health & Human Servs.*, No. 03-0632V, 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. for*

rev. denied, 125 Fed. Cl. 57 (2016), *aff'd per curiam*, 671 F. App'x 792 (Fed. Cir. 2016); *see also, e.g.*, *Vergara v. Sec'y of Health & Human Servs.*, No. 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)).

VI. Discussion

a. The vaccination records are clear and consistent and therefore entitled to significant weight

There is no question that the most contemporaneous evidence of the site of injection of petitioner's flu vaccine is the pharmacy records produced by Rite Aid Pharmacy. (Ex. 8.) Accordingly, such records should be afforded significant weight if they appear to be reliable. *See Hanna*, 2021 WL 3486248, at *7. "However, the weight afforded to contemporaneous records is contingent, at least in part, on their clarity and consistency." *Id.* In this case, it is significant that both the handwritten consent form and the computer-generated "Service Details" record are clear and consistent in noting a left arm administration. (Ex. 8, pp. 1-3.)

In several prior cases, it has been remarked that chain pharmacy records should not necessarily be viewed as presumptively accurate with respect to injection site. *E.g.*, *Mezzacapo*, 2021 WL 1940435, at *6 (the undersigned noting that "experience litigating SIRVA claims has shown that pharmacy vaccine administration records are not necessarily reliable in documenting injection site"); *Syed*, 2021 WL 2229829, at *5 (Chief Special Master noting that "I find it is not unusual for the information regarding site of vaccination in computerized systems to be incorrect"). In particular, deposition testimony by pharmacists in prior cases has indicated that the injection site may be preemptively put into the computer system prior to administration in order to permit the pharmacy to charge the customer/patient for the vaccination before actually completing the administration. *Stoliker v. Sec'y of Health & Human Servs*., No. 17-990V, 2018 WL 6718629, at *3-4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018); *Mezzacapo*, 2021 WL1940435, at *4. As a result, computer-generated chain pharmacy records have been noted to have a tendency to default to a left-shoulder administration, because that is the more commonly requested shoulder for a vaccine administration. *Hanna*, 2021 WL 3486248, at *8. However, the same is not necessarily true of consent forms. In *Mezzacapo*, a computer-generated record indicated that the petitioner had been vaccinated in the left shoulder. However, when the parties in that case deposed the administering pharmacist, that individual was able to testify that the vaccination had actually been administered in the opposite shoulder, because she had been able to review the separately created consent form, which was a record that had been maintained at the specific pharmacy location. 2021 WL 1940435, at *6.

Thus, for example, in *Anderson*, there was an inconsistency between the vaccination records produced by Rite Aid Pharmacy in that the computer-generated record indicated administration in the right arm and the handwritten consent form

indicated administration in the left arm. *Anderson v. Sec'y of Health & Human Servs.*, No. 20-195V, 2022 WL 17484352, at *8-9 (Fed. Cl. Spec. Mstr. Nov. 10, 2022), *mot. for reconsideration denied*, No. 20-195V, 2023 WL 2237320 (Fed. Cl. Spec. Mstr. Feb. 2, 2023). In comparing the evidentiary weight to be afforded to these two competing records, it was found that by including both a patient questionnaire and a pharmacy-only 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." *Id.* at *8. Further, the consent form was signed by the petitioner and the vaccine administrator, as well as dated by the vaccine administrator, evidencing that the consent form was completed at the time of vaccination and in the petitioner's presence. *Id.* Lastly, the consent form appeared "to have been completed as it should have been in the regular course" and was therefore facially trustworthy. *Id.* Accordingly, the handwritten consent form was afforded "significant weight as a contemporaneous record," and, moreover, was entitled to greater evidentiary weight than the computer-generated record. *Id.* at *9; *see also Marion v. Sec'y of Health & Human Servs.*, No.19-0495V, 2020 WL 7054414, at *8 (Fed. Cl. Spec. Mstr. Oct. 27, 2020) (Chief Special Master similarly crediting a handwritten consent form completed by the vaccine administrator as "substantial evidence").

However, this is not to say that a handwritten administration record will automatically be entitled to significant weight. For example, in *Hanna*, the original vaccination record was characterized as ambiguous and thus not entitled to significant evidentiary weight on the question of injection site. 2021 WL 3486248, at *8-9. In that case, the mostly handwritten vaccination record had a prompt for injection site, but it was left blank. *Id.* at *1. Instead, the record included "a handwritten notation that appears to be an 'L' within a circle" that "was written next to a sticker that provides the lot number and expiration date for the vaccine being administered." *Id.* In determining that the vaccination record was ambiguous, it was noted that the separate notation of "L" did not appear on the administration section of the form and included no other mark or explanation identifying it as a notation conveying injection site. *Id.* at *8. Similarly, in *Walker*, the petitioner was persuasive in arguing that her vaccination record fell short of being "strong, unequivocal" evidence of injection site. *Walker v. Sec'y of Health & Human Servs.*, No. 21-1325V, 2024 WL 1517362, at *7 (Fed. Cl. Spec. Mstr. Mar. 13, 2024). In that case, the petitioner observed that the vaccination record contained "at least one facially obvious error as well as other errors suspicious for unreliable recordkeeping." *Id.* Specifically, the administration record indicated that the flu vaccine at issue had been ordered two weeks after it was administered. *Id.* Additionally, issues with respect to the timestamp and expiration date were further suggestive of unreliable recordkeeping. *Id.* While "the identification of some errors does not lead invariably to the conclusion that other details were likewise incorrectly recorded," the presence of the errors "call[ed] into question the attention to detail of the person who created the record" and thus the record's reliability as a whole. *Id.*

Here, the handwritten intake form is entitled to significant weight, as in *Anderson* and in contrast to *Hanna*. The handwritten consent form in this case includes a patient questionnaire and a pharmacy-only use portion with a specific prompt for injection site.

(Ex. 8, pp. 1-2.) The form was also signed by both petitioner and the vaccine administrator and dated by the vaccine administrator as "8/30/2017," the date petitioner received her flu vaccine. (*Id.* at 2.) As in *Anderson*, these details evidence that the consent form was completed at the time petitioner received her flu vaccine and in her presence. By circling "LA" next to the prompt for injection site, it appears the vaccine administrator completed the form as should be done in the regular course, making the handwritten notation facially trustworthy. Therefore, like the handwritten consent form in *Anderson*, the handwritten consent form indicating that petitioner's flu vaccine was administered in her left shoulder should be afforded significant weight. (*Id.* at 1-3.) Additionally, the pharmacy records overall are clear and consistent. Unlike in *Anderson*, the computer-generated form in this case accords with the consent form in documenting a left shoulder administration. Petitioner has not come forward with any other perceived errors within this body of pharmacy records, as was the case in *Walker*. Accordingly, the vaccine administration records in this case are entitled to substantial weight as they are clear, consistent, and contemporaneous to events.

b. Petitioner's subsequent treatment records are not entitled to greater weight than the contemporaneously created vaccination record

Petitioner argues that apart from the vaccination record, every single medical record submitted in this case supports petitioner's contention that she received her flu shot in her right shoulder. (ECF No. 39, p. 7.) Subsequent treatment records can be important evidence regarding the injection site of a vaccination. *E.g.*, *Hanna*, 2021 WL 3486248, at *9; *Mezzacapo*, 2021 WL 1940435, at *7; *see also Walker*, 2024 WL 1517362, at *6. However, longstanding Vaccine Program understanding counsels that later patient histories generally garner less weight than more contemporaneous records. *See, e.g.*, *R.K.*, 2015 WL 10936124, at *76; *Vergara*, 2014 WL 2795491, *4.

In this case, petitioner waited approximately two and a half months before seeking treatment for her condition. (Ex. 1, p. 13.) In and of itself, this is not an unusual pattern of treatment and would not defeat a SIRVA claim. Afterall, "there is no such thing as an 'appropriate' time to seek treatment." *Lang v. Sec'y of Health & Human Servs*., No. 17-995V, 2020 WL 7873272, at *11 (Fed. Cl. Spec. Mstr. Dec. 11, 2020). However, treatment records are probative as to injection site, not because they constitute documentation of the vaccine administration, but because they memorialize the petitioner's understanding of the nature of her injury at the time of treatment. *Hanna*, 2021 WL 3486248, at *9. Thus, respondent reasonably suggests that the longer the time between vaccination and treatment, the greater the chance of reporting an incorrect history. (ECF No. 40, p. 7.) While not dispositive, petitioner's delay in seeking treatment is a consideration in balancing the record as a whole, especially because petitioner is seeking to rely on her later treatment records to overcome contemporaneously created administration records that explicitly contradict her claim.

Additionally, the histories contained in petitioner's treatment records for her shoulder complaint are not strong evidence with respect to the details of that history. The initial encounter record indicates that "pt received the flu shot two months ago at

RITE AID pharmacy on right arm – swelling and induration was noted over the site of injection, pt c/o persistent pain – limited and painful ROM noted." (Ex. 1, p. 13.) Although this notation documents that petitioner associated her injury with her vaccination, it does not indicate how long after the vaccination her symptoms occurred. Nor does it accurately date the occurrence of the vaccination, merely estimating that the vaccination occurred two months ago. Such limitations would not necessarily be significant if petitioner had sought treatment closer in time to her vaccination or if her prior vaccine administration record had been consistent with the provided history. On this record, however, these issues make it more difficult to credit the later treatment record in preference to the contemporaneous administration records, which are clear and consistent in themselves. Petitioner also subsequently associated her shoulder pain to her prior vaccination at both an emergency department encounter and to her neurologist. (Ex. 4, p. 3; Ex. 3, p. 3.) However, these subsequent reports are no more detailed or accurate than her initial report to her primary care provider. The emergency department records variously recorded either a three or five month history of symptoms (Ex. 4, pp. 3, 5), and the neurology record indicated that the vaccination at issue had occurred in September, rather than August (Ex. 3, p. 3).

Petitioner argues that the specific remark that "swelling and induration was noted over the site of injection" is of particular significance. (ECF No. 39, p. 7.) However, this begs the question at issue. Physical examination at that time was limited to observing a "[s]mall lump" with "[s]light tenderness" on petitioner's arm. (Ex. 1, p. 14.) Nothing in the medical record associates that lump with petitioner's injection apart from the history provided by petitioner herself, and nothing in the encounter confirms that the lump on petitioner's arm represents the type of swelling and induration petitioner described.

On the whole, petitioner's post-vaccination treatment records are entitled to some evidentiary weight. However, for the reasons discussed above, they do not outweigh the contemporaneously created vaccine administration record.

c. Petitioner's subcutaneous mass does not evidence the injection site of her prior vaccination

Petitioner further argues that the presentation of her alleged granuloma on her right shoulder serves as evidence that her flu vaccine was injected in her right shoulder. (ECF No. 39, pp. 8-9.) Petitioner suggests that granulomas are known to be a potential side effect of vaccination. (*Id*. at 8.) As discussed above, petitioner's initial post-vaccination physical examination by her primary care provider documented a "[s]mall lump" on her arm. (Ex. 1, p. 14.) An ultrasound was therefore recommended. (*Id*.) Petitioner argues that when she returned to her primary care provider on December 28, 2017, she was informed that a granuloma was suspected and that this was later confirmed when her neurologist subsequently reviewed her ultrasound. (ECF No. 39, p. 8 (citing Ex. 1, p. 7; Ex. 3, p. 3).) Although petitioner is correct that a granuloma was suspected by her primary care provider (Ex. 1, p. 7), she is not persuasive in contending that a granuloma was "confirmed" or even diagnosed.

The ultrasound showed a "small, oval hypovascular echogenic lesion contained in the subcutaneous fat." (Ex. 3, p. 3; Ex. 1, p. 7.) Although a granuloma was within the differential diagnosis (Ex. 3, p. 3; Ex. 1, p. 7), the finding itself was noted to be "nonspecific" (Ex. 3, p. 3). Thus, while the primary care provider suspected a granuloma, petitioner's initial diagnosis was "mass of subcutaneous tissue." (Ex. 1, p. 8.) Prior to being evaluated by the neurologist, petitioner was seen by a general surgeon. As of January 29, 2018, her primary care provider documented that "per gen surg note 1/11/2018 – pain is not related to lipoma – will refer to neuro per gen surg suggestion."[8] (*Id.* at 3.) Petitioner interprets this notation as indicating that the general surgeon felt petitioner's lump "was something other than a lipoma and likely a granuloma." (ECF No. 39, p. 4.) However, petitioner was diagnosed at this encounter as having "Lipoma of axilla," and the impression is accompanied by a note indicating that the diagnosis was "confirmed lipom[a] by gen surg Dr. Sheth 1/11/2018." (Ex. 1, p. 4.) Therefore, the more reasonable interpretation of Dr. Sheth's impression is that the mass was found to be a lipoma, which was therefore not the source of petitioner's pain. Consistent with this, petitioner's neurologist subsequently observed that lipomas and granulomas have similar presentations, but that lipomas typically are not painful. (Ex. 3, p. 3.) However, petitioner's neurologist did not conclude that petitioner's mass was a granuloma. (*Id.*) Although the neurologist characterized a granuloma as a "primary consideration," she indicated that the ultrasound finding was "non-specific." (*Id*.) The neurologist's impression was limited to "right arm pain," which she doubted to be neurologic ("doubt CNS or PNS etiology"). (*Id*. at 4.) She recommended primary care follow up, but characterized petitioner's presentation as consisting of "pain and mass." (*Id.*) This supports the conclusion that Dr. Kepecs did not diagnose or conclusively identify the lump in petitioner's right shoulder.

Based on the medical records provided, there is not preponderant evidence that petitioner's right shoulder mass was a granuloma. If anything, the medical records reflect that a lipoma was considered "confirmed" by at least one physician. (Ex. 1, p. 4.) In her brief, petitioner acknowledges that while a granuloma, which is not preponderantly demonstrated, could potentially be evidence of injection-related trauma, the same is not true of a lipoma, which is "just a growth of fatty tissue." (ECF No. 39, p. 8.) Thus, the presence of a lipoma or other unspecified mass on petitioner's right arm does not have any tendency to make a right arm administration of the subject vaccination any more likely.

Additionally, respondent stresses that both lipomas and granulomas can occur spontaneously (ECF No. 40, pp. 7-8), and there is no medical opinion on this record finding that petitioner's flu vaccine caused a granuloma. The opinions of treating physicians are ordinarily given significant weight as they are likely in the best position to determine whether the vaccine caused a given injury. *Capizzano v. Sec'y of Health &*

[8] The general surgeon's note was included in petitioner's primary care records. The medical records for petitioner's evaluation by the general surgeon were among the outstanding medical records identified in the prior order at ECF No. 46. As mentioned above, petitioner was given an opportunity to submit these records but did not do so.

Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Here, petitioner's neurologist at best felt that a granuloma was a "consideration" given petitioner's reported history (Ex. 3, p. 3), which falls short of expressing a conclusion that this is what occurred, especially given that the neurologist did not ultimately conclude that petitioner suffered a granuloma. While petitioner submitted two case reports on post-vaccination granulomas to support her argument that granulomas are a known side effect of vaccinations as a matter of general causation (as under *Althen* prong one), this evidence alone is insufficient to preponderantly show as a matter of specific causation (as under *Althen* prong two) that petitioner's own alleged granuloma was caused by her flu vaccine. (Suzuki et al., *supra*, at Ex. 9; García-Gil et al., *supra*, at Ex. 10.)[9]

Accordingly, the fact of petitioner's right arm subcutaneous mass, which she reported to her physicians as being located at her vaccine injection site, does not provide any significant evidence suggesting that her contemporaneous vaccine administration record is incorrect.

d. The affidavits are not entitled to greater weight than the contemporaneously created vaccination record

Contemporaneous records prepared independently of litigation are often more reliable than testimony of interested parties. *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993) (discussing the "widely held belief that written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later"); *see also Rogero v. Sec'y of Health & Human Servs.*, 748 F. App'x 996, 1001 (Fed. Cir. 2018) (noting that "it is a familiar and reasonable assessment that contemporaneous documentary evidence . . . prepared by professionals doing their jobs independently of litigation[] can be (though is not necessarily) more reliable than testimony of interested parties"). To overcome the weight afforded to contemporaneous medical records, testimony must be "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391. For example, in *Anderson*, the petitioner purported to recall receiving her vaccine in her right arm, but failed to discuss the basis for that recollection or offer any specific recollection that would challenge the accuracy of the consent form or suggest that the consent form was completed with any error. 2022 WL 17484352, at *8.

[9] Nor for that matter would the case reports be persuasive as to general causation without more. In general, case reports are not strong evidence. *Crutchfield v. Sec'y of Health & Human Servs.*, No. 09-0039V, 2014 WL 1665227, at *19 (Fed. Cl. Spec. Mstr. Apr. 7, 2014) ("[S]ingle case reports of Disease X occurring after Factor Y . . . do not offer strong evidence that the *temporal* relationship is a *causal* one—the temporal relationship could be pure random chance."), *aff'd*, 125 Fed. Cl. 251 (2014). *But see Paluck v. Sec'y of Health & Human Servs.*, 104 Fed. Cl. 457, 475 (2012) (explaining that case reports are not entirely devoid of evidentiary value). One of the case reports states that granuloma formation exclusively at the site of vaccine injection, as petitioner alleges in her case, is extremely rare, having only been reported in three cases. (García-Gil et al., *supra*, at Ex. 10, p. 2.) Additionally, both case reports concede that the mechanism by which a vaccine may trigger granuloma formation is not well understood. (Suzuki et al., *supra*, at Ex. 9, pp. 1-2; García-Gil et al., *supra*, at Ex. 10, p. 2.)

Here, the three affidavits submitted in this case were all by interested parties. Moreover, in her initial affidavit, petitioner failed to identify the site of injection of her flu vaccine or even specify which arm she experienced pain in. It wasn't until the parties were directed to brief the issue of injection site, among other issues, that petitioner filed the remaining two affidavits that identify the site of injection as petitioner's right shoulder. These affidavits were submitted more than five years after the date of vaccination. Petitioner did offer a basis for her recollection of administration of her flu vaccine in her right shoulder. Specifically, in her second affidavit, petitioner avers that she remembers receiving her vaccine in her right shoulder due to how the chairs were set up at the pharmacy. (Ex. 12, ¶ 3.) Yet, this is still relatively vague and not compelling. Petitioner also expresses having a general preference for right arm administration (*Id*.); however, there is no evidence of record documenting such a practice with prior vaccinations.

Although the affidavits have been considered, they are insufficient to outweigh the contemporaneous vaccine administration records.

II. Conclusion

Petitioner has my sympathy for what she has endured. Nonetheless, 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 as alleged. Rather, the evidence preponderates in favor of a finding that petitioner's vaccination was administered in her left deltoid. Further, petitioner cannot preponderantly establish that her August 30, 2017 flu vaccination, administered in her left arm, resulted in an injection-related injury affecting her opposite shoulder and arm, whether as a Table SIRVA or cause-in-fact claim. Accordingly, petitioner is not entitled to compensation and this case is dismissed.[10]

IT IS SO ORDERED.

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

[10] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.