In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-0936V

IJEOMA CHUKWUDUM, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: October 17, 2023

Sean Frank Greenwood, Greenwood Law Firm, Houston, TX, for Petitioner.

Mitchell Jones, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On July 31, 2020, Ijeoma Chukwudum filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she sustained a shoulder injury related to vaccine administration ("SIRVA") due to an influenza ("flu") vaccine which she received on October 31, 2017. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this ruling 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 ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the foregoing reasons, I find that Petitioner has put forth preponderant evidence that the onset of her shoulder pain occurred within 48 hours after the subject vaccination – and that she has otherwise satisfied the criteria and requirements for a Table SIRVA claim. She is thus entitled to compensation.

I. Relevant Procedural History

In March 2021, Petitioner completed her required filings approximately seven months after the petition. Exs. 1 – 9, ECF No. 7; Exs. 10 – 18, ECF No. 12. In August 2021, the case was deemed to be sufficiently complete and assigned to the SPU. ECF No. 16. Petitioner was later prompted to file any additional evidence of the onset of her shoulder pain while the case awaited Respondent's medical review. Scheduling Order, ECF No. 23; *see also* Exs. 19 – 24, ECF No. 32.

Between July – December 2022, the parties discussed settlement but ultimately reached an impasse. ECF Nos. 27, 34 – 39.[3] On February 9, 2023, Respondent filed his Rule 4(c) Report opposing the Table SIRVA claim solely on the grounds that Petitioner had not established the requisite onset. Rule 4(c) Report, ECF No. 41. Petitioner thereafter filed additional evidence as Exs. 25 – 28, ECF Nos. 43, 45, followed by a brief setting forth her position regarding onset. Motion for Decision filed June 12, 2023, ECF No. 46 (hereinafter ("Brief"). Respondent filed his own brief on the onset question. Response filed Aug. 11, 2023, ECF No. 48. A Reply was filed later that month, ECF No. 50, and the matter is ripe for adjudication.

II. Relevant Evidence

I have reviewed all of the evidence filed to date. I will only summarize or discuss evidence that directly pertains to the determinations herein, as informed by the parties' respective citations to the record and their arguments.

On October 13, 2017, Petitioner received the subject vaccine in her left deltoid at her place of employment. Ex. 2 at 1. She was then 37 years old and employed as a pharmacist, with no medical issues relevant to this claim's resolution.

[3] Petitioner has reported that her demand includes out-of-pocket expenses and lost wages. Status Report filed Jan. 18, 2022, ECF No. 22. Petitioner had filed a workers' compensation claim was resolved as of June 2022. Status Report filed May 2, 2022, ECF No. 25. Petitioner represented that no Medicaid lien existed in the case. Status Report filed Sept. 30, 2022, ECF No. 37.

On November 6, 2017,[4] Petitioner visited a medical assistant ("MA") at a dermatology practice for "follow up visit #5" regarding the prescription of the drug isotretinoin to treat facial acne. Ex. 13 at 14 – 17. On December 4, 2017, Petitioner attended "follow-up visit #6." *Id.* at 10 – 13. The resulting medical records do not address the vaccination or left shoulder pain.

On December 1, 2017, Petitioner notified her employer that she had "been having left shoulder pain" since receiving the flu vaccine on October 13th. Ex. 15 at 42. The employer recorded that an occupational health nurse would be managing Petitioner's case, all bills must be sent to Employer Solutions – Worklink, and all referrals must be made within the Worklink network. *Id.* The employer also scheduled Petitioner for a December 5, 2017, appointment at U.S. Healthworks.[5] *Id.* at 43.

Upon presenting to U.S. Healthworks, Petitioner wrote on an intake form: "I received the flu shot in my left arm on 10/13/2017. Since then, I have been having dull pain on my arm. Last week it progressed to sharp radiating pain from my left arm to my shoulder. Currently I have reduced range of motion of my left arm due to the pain." Ex. 15 at 52.[6]

At U.S. Healthworks, John Bernard, P.A., recorded the same history and on exam, documented left arm tenderness but full range of motion ("ROM"). Ex. 15 at 48. An X-ray of the left shoulder was normal. *Id.* The PA diagnosed a contusion and injection site reaction, for which he prescribed ibuprofen and metaxalone (a muscle relaxant) and ordered physical therapy ("PT") twice a week for two weeks. *Id.* at 49 – 50. The PA also submitted a status report in connection with her workers' compensation claim. *Id.* at 44.

On December 12, 2017, Petitioner saw her primary care provider ("PCP") for an annual evaluation, during which "no abnormal aches or pains" were noted. Ex. 13 at 11.

At the December 13, 2017, PT initial evaluation, Petitioner reported that her left shoulder pain began "after receiving the flu vaccination" on October 13, 2017. Ex. 4 at 9. An exam documented moderately restricted ROM and diminished strength. *Id.* at 9 – 10.

[4] Respondent's Rule 4(c) Report and subsequent briefing inadvertently state that the first post-vaccination dermatology encounter was on November **16,** 2017.

[5] Respondent refers to this facility as Concerta or Concentra Urgent Care. *See generally* Rule 4(c) Report and Response. That name appears on the certification form. Ex. 15 at 1. However, each medical encounter record bears a U.S. Healthworks logo. *See generally* Ex. 15.

[6] This is repeated verbatim in a computerized, undated "workplace incident report." Ex. 3 at 1.

She attended a total of four formal PT sessions that month, during which she was also instructed on a home exercise program ("PT"). *See generally* Ex. 4.[7, 8]

On January 4, 2018, Petitioner returned to the same dermatology MA for another follow-up on her acne. Ex. 13 at 6 – 9. The MA recorded: "Pt [Petitioner] is having muscle ache after a flu shot that was done in October. Pt [Petitioner] will d/c [discontinue] isotretinoin and see if coming off will make a difference." *Id.* at 8.[9] The medical records do not include any physical exam, assessment, treatment plan, or any other details regarding the "muscle ache" and/or the left shoulder, however.

In January 2018, the PA recorded that Petitioner's injury was worse despite the course of PT and previously prescribed pain medications. He newly prescribed Mobic (a muscle relaxant) on January 11, 2018, and Ultracet (acetaminophen with tramadol) on January 22, 2018. Ex. 15 at 6 – 19.[10]

At a January 29, 2018, initial evaluation, orthopedist Gerard T. Gabel, M.D. recorded that Petitioner "got a flu shot back in October and started having pain, obviously with the shot, but it never settled down and has persisted." Ex. 6 at 40. Dr. Gabel assessed "post-flu injection with left frozen shoulder and left subacromial impingement," for which he injected cortisone to the subacromial space and glenohumeral joint. *Id.* Dr. Gabel also conferred with an occupational health nurse about Petitioner's case. *Id.*

On February 5, 2018, Petitioner returned to her dermatologist for another follow-up on her acne – but the ongoing left shoulder injury was not noted. Ex. 13 at 2 – 5.

At a February 12, 2018, occupational therapy ("OT") initial evaluation, Petitioner reported a similar history of receiving the flu vaccination on October 13, 2017. Ex. 7 at 9. She "initially noted pain at the time of the injection that became progressively worse over the next month." *Id.* She had restricted ROM on exam. *Id.* at 9 – 10.

[7] Petitioner's last PT session was December 22, 2017, but she was formally discharged from PT due to "failure to return" and "home program" on April 6, 2018. Ex. 4 at 12.

[8] Petitioner also saw PA Bernard on December 14 and 28, 2017. Ex. 15 at 20 – 39. Those records have been reviewed – but they do not particularly include additional information pertinent to the disputed onset issue or to my entitlement determination more generally (although they may be relevant to damages).

[9] Isotretinoin is a medication for the treatment of acne, which the dermatologist had prescribed beginning in June 2017. Ex. 13 at 35.

[10] The PA also recommended an MRI, Ex. 15 at 19, which was not obtained for several months.

In mid-February 2018, Petitioner followed up with Dr. Gabel. Ex. 6 at 36 – 39. She also mentioned "wanting a second opinion" regarding her left shoulder injury, upon seeing her PCP for an unrelated concern. Ex. 11 at 5 – 6.[11]

On February 26, 2018, Petitioner presented to a second orthopedist, Wayne O Alani, M.D. Ex. 8 at 1. He obtained an MRI which revealed a high-grade partial thickness tear of the supraspinatus; moderate to severe impingement of the subacromial space; and mild to moderate tendinitis of the long head of the biceps. Ex. 8 at 1, 3. Based on the MRI findings and his evaluation, Dr. Alani recommended surgical intervention. *Id.* at 2.[12]

On March 5, 2018, Petitioner returned to her original orthopedist Dr. Gabel. Ex. 6 at 34 – 37. He obtained a fluoroscopy-guided arthrogram and MRI, which revealed mild supraspinatus tendinopathy, and mild degenerative change of the superior labrum. *Id.* at 49 – 50. On April 2, 2018, Dr. Gabel injected cortisone to the subacromial space and glenohumeral joint and recommended further OT. *Id.* at 32.[13]

April 25, 2018, marked Petitioner's 13th and last OT session, at which she had improved ROM but continued pain. Ex. 7 at 44 – 45. In a record from a few days later, Dr. Gabel recorded that the most recent cortisone injection had helped, and that Petitioner should continue exercises concentrating on range of motion, which "she can do… on her own." Ex. 6 at 30.

In May 2018, Petitioner attended fourteen (14) sessions of chiropractic treatment for her left shoulder injury. *See generally* Ex. 14. That same month she saw a third orthopedist, Pradeep Kodali, M.D., for her left shoulder injury. Ex. 9 at 16. Dr. Kodali assessed adhesive capsulitis, for which he recommended surgical intervention. *Id.* at 17.

At a May 14, 2018, initial consultation, occupational medicine and pain management specialist Ahmed A. Khalifa, M.D., recommended surgical intervention for Petitioner's left shoulder injury. Ex. 5 at 23. Petitioner declined surgery in favor of a pain management program consisting of twenty (20) sessions ending on July 10, 2018, and six "aftercare" sessions ending on July 31, 2018. *See generally* Ex. 5.

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[11] The PCP recorded a referral to a Dr. Rogers. Ex. 11 at 6. However, no records from any such provider have been filed, and Petitioner states that she instead saw the orthopedist Dr. Alani. Ex. 1 (Petitioner's Affidavit) at ¶ 15; *accord* Petitioner's Status Report filed Aug. 25, 2023, at ECF No. 49.

[12] There are no further records of treatment with Dr. Alani.

[13] Respondent's Rule 4(c) Report and subsequent briefing inadvertently state that this MRI was obtained in March **2019**.

On September 19, 2018, Dr. Gabel recorded that Petitioner's shoulder ROM had improved, but she had persistent impingement and pain, for which further injections would not necessarily be helpful. Ex. 6 at 26. Petitioner would consider whether her pain was severe enough to warrant surgical intervention. *Id.*

On October 10, 2018, Petitioner reported that she was following a home exercise program, but she had ongoing soreness, for which Dr. Gabel prescribed Medrol. *Id.* at 24.

On November 5, 2018, Petitioner returned to Dr. Kodali, who prescribed Meloxicam, and again recommended surgical intervention. Ex. 9 at 13 – 14. Two days later, she again saw Dr. Gabel, who also recommended surgical intervention. Ex. 6 at 21 – 23. Petitioner's employer initially declined to cover the surgery, but Dr. Gabel requested reconsideration. *See* Ex. 5 at 13 – 14; Ex. 6 at 18 – 22. On January 7, 2019, Dr. Gabel performed an arthroscopic glenohumeral debridement and subacromial decompression. Ex. 17 at 53 – 54.[14]

From January 28 – March 21, 2019, Petitioner underwent twelve (12) sessions of post-operative PT. *See generally* Ex. 18. She also followed up post-operatively with Dr. Gabel. Ex. 6 at 3 – 13. He injected cortisone to the left subacromial space on February 18, 2019. *Id.* at 11. On June 20, 2019, Dr. Gabel recorded that Petitioner had full ROM, essentially negative impingement, and good strength. *Id.* at 3. She had no ongoing restrictions but would use good judgment. She was at maximum medical improvement ("MMI") and should contact Dr. Gabel "if anything flare[d] up." *Id.*

On October 23, 2019, Petitioner underwent an annual wellness examination, which did not document any complaints pertaining to her shoulder and noted full ROM and strength on exam. Ex. 16 at 14.

After a lengthy treatment gap, on February 22, 2022, Petitioner returned to Dr. Gabel, who recorded: "She has had a little bit of pain from time to time, but over the last couple of months it has been more sore. She has not had any interval management. She has tried some anti-inflammatories with a partial response." Ex. 9 at 2. Dr. Gabel's exam found "good motion" but positive Hawkins and Neer's tests. *Id.* He assessed recurrent inflammation of the left shoulder, for which he offered another injection, which was deferred by Petitioner. *Id.* He prescribed Medrol and meloxicam and recommended light activity. *Id.* He also referred Petitioner to a therapist and told her to follow up in one month – but no further treatment records have been filed.

[14] While not pertinent to the disputed onset issue or to my entitlement determination more generally, it is unclear whether the surgery was ultimately authorized as part of Petitioner's workers' compensation claim, paid for via separate insurance, or paid for out-of-pocket.

In her July 2020 affidavit, Petitioner recalls that she felt distinct pain upon receiving the subject flu vaccination. Ex. 1 at ¶ 3. She tried taking Tylenol and ibuprofen, and different home remedies including heat therapy, Bengay, and a topical analgesic heat rub: "all to no avail before I eventually reported the pain to my employer." *Id.*

In May 2023, her husband recalled that beginning on the date of vaccination, Petitioner experienced severe pain in her arm, much worse than the mild soreness associated with getting a vaccine. Ex. 25 at ¶ 2. Petitioner used her experience as a pharmacist to try simple remedies to reduce the pain, but over the next two days, she complained that the pain has escalated. *Id.* A friend also recalled Petitioner complaining of severe pain beginning one day after the vaccination and telling Petitioner to seek medical attention two weeks into the course. Ex. 26 at ¶ 2.[15]

III. Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed.

[15] The husband and friend's initial declarations both inadvertently stated a vaccination date of October **16**, 2017. Exs. 25 – 26. The husband and friend each subsequently declared that the vaccination date was indeed October 13, 2017, and that the remainder of their testimony was unaffected by that typographical error. Exs. 27 – 28. All declarations at Exs. 25 – 28 are signed under penalty of perjury in accordance with 28 U.S.C.A. § 1746. In July 2022, Petitioner filed another friend's statement as Ex. 20 – but it is undated, and neither notarized nor sworn under penalty of perjury and thus warrants much less, if any, consideration.

Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[16] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). 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 (even if the condition causing the neurological abnormality is not known). 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;

[16] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(ii) Pain occurs within the specified time frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Factual Finding Regarding QAI Criteria for Table SIRVA

In opposing compensation, Respondent argues only that Petitioner has not established the onset of left shoulder pain within 48 hours after the administration of the flu vaccine on October 13, 2017. Rule 4(c) Report at 9 (citing 42 C.F.R. §§ 100.3(a), (c)(10)(ii)).

Respondent emphasizes the first two medical encounters, which lack documentation of shoulder pain. Rule 4(c) Report at 9. But those encounters were periodic follow-ups focusing on a prescription medication for facial acne – not an obvious context in which Petitioner would be expected to request treatment for an unrelated issue.

A subsequent dermatology record is in fact corroborative of the alleged injury, since it memorializes the proposal that Petitioner would discontinue the acne medication in an effort to alleviate her "muscle ache [present] after a flu shot that was done in October." That is consistent with Petitioner's explanation that she reported her shoulder injury when she believed it to be relevant. Reply at 4. And even that record lacks any pertinent exam or assessment – confirming that the MA was focused on her separate and unrelated area of specialty.

Respondent also argues that the initial two-month treatment delay has "no explanation." Response at 9. But Petitioner explains that she used her personal medical knowledge and training while initially attempting to self-manage her injury. Brief at 3. She then sought recourse with her employer – which had required the subject vaccination, and subsequently assumed management of her medical care, and at least some of the expenses thereof, in the context of her worker's compensation claim. And once Petitioner

received medical attention, various providers recorded her consistent history[17] of shoulder pain persisting "since" or "after" the vaccination. Certain records are even more specific, such as the OT initial evaluation, which provides that Petitioner "initially noted pain *at the time of the injection* that became progressively worse over the next month." Ex. 7 at 9 (emphasis added). There is also no evidence that Petitioner's shoulder pain began at any time *after* 48 hours of vaccination. Thus, Petitioner has established onset within the Table timeframe.

Respondent does not dispute any other Table SIRVA requirements, and the record contains sufficient evidence showing Petitioner has satisfied the other QAI criteria. *See* 42 C.F.R. § 100.3(c)(10)(i) & (iii)-(iv). A thorough review of the record in this case does not reveal a prior or current condition or abnormality which would explain Petitioner's condition or pain and limited range of motion ("ROM") other than in Petitioner's injured left shoulder. Thus, all elements of a Table SIRVA claim have been preponderantly established.

C. Other Requirements for Entitlement

All elements of a Table SIRVA claim have been preponderantly established. Accordingly, Petitioner need not prove causation-in-fact. Section 11(c)(1)(C). However, she must satisfy the other requirements of Section 11(c) regarding the injury's severity, the vaccination received, and the lack of other award or settlement. Section 11(c)(A), (B), and (D). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence which fulfills them.

Conclusion and Scheduling Order

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a Table SIRVA.**

Thus, the case will now proceed to the damages phase. The parties are encouraged to revisit their previous discussions and endeavor to agree on an appropriate award of compensation.

[17] Although these entries were based upon information provided by Petitioner, they still should be afforded greater weight than more current representations, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care. The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when it is provided by Petitioner.

By no later than Friday, December 15, 2023, Petitioner shall file a joint status report updating on the parties' efforts towards an informal resolution of damages. If the parties have determined that informal resolution of damages is not possible, they shall jointly propose a briefing schedule. Any such briefing shall include comparison to prior reasoned opinions addressing the appropriate award for pain and suffering for Table SIRVA claims.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master