In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 23-1311V

KEVIN W. CRAIG, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 5, 2025

Joseph G. Muzic, Jr., Saidis, Shultz & Fisher, Mechanicsburg, PA, for Petitioner.

Lauren Kells, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW[1]

On August 15, 2023, Kevin W. Craig 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 as a result of an influenza ("flu") vaccine received on October 21, 2021, he suffered a shoulder injury related to vaccine administration ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition, ECF No. 1; *see also* Amended Petition filed Apr. 29, 2024, ECF No. 19 (adding citations to the medical history).

[1] Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion 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).

In June 2024, the case was assigned to the SPU (an adjudicatory system for expedited resolution of certain Vaccine Act claims). ECF No. 24. The parties engaged in settlement discussions but reported an impasse in May 2025. ECF No. 41. Respondent thereafter filed his Rule 4(c) Report opposing compensation on July 21, 2025. ECF No. 42.[3] Upon reviewing the case file, I have determined that the parties' positions regarding onset are sufficiently developed (without need for briefing) and the issue is ripe for adjudication.

I. Authority

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. 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)).

[3] As Respondent notes (Rule 4(c) Report at n. 1), Petitioner's filings are somewhat duplicative and inadequately labeled. I reviewed, and cite, the following filings:

- Ex. 1, ECF No. 19-2 – Statement of Petitioner;
- Ex. 2, ECF No. 19-3 – Initial Proof of Vaccination;
- Ex. 3, ECF No. 19-4 – Orthopedic Institute of PA ("OIP");
- Ex. 4, ECF No. 19-5 – UPMC Good Hope Family Physicians;
- Ex. 5, ECF No. 19-6 – Arlington Orthopedics;
- Ex. 6, ECF No. 19-7 – Susquehanna Valley Surgical Center;
- Ex. 7, ECF No. 20 – Vaccine Administration Records;
- Ex. 8, ECF No. 38-2 – Orthopedic Institute of PA ("OIP") – Updated;
- Ex. 9, ECF No. 38-3 - Orthopedic Institute of PA ("OIP") – Updated 2;
- ECF No. 38-1 - UPMC Good Hope Family Physicians – Updated. This filing should likely be assigned Exhibit 10.

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] 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;
>
> (ii) Pain occurs within the specified time frame;

[4] 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).

(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).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

II. Findings of Fact and Conclusions of Law - Onset

I have reviewed all of the filings submitted by both parties to date but focus on the disputed issue of onset.

- Upon receiving the flu vaccine in his left deltoid on October 21, 2021 (at a local pharmacy), Petitioner was 56 years old with no history of left shoulder pain or dysfunction. Ex. 4 at 6-7; Ex. 7 at 2-3; *accord* Rule 4(c) Report at 2.

- Eighteen (18) days later, on November 8, 2021, at the Orthopedic Institute of Pennsylvania, a nurse practitioner ("NP") evaluated Petitioner's chief complaint of **"an acute[5] onset of shoulder pain after receiving his flu injection 2 weeks ago."** Ex. 3 at 2 (emphasis added). Petitioner reported that "[I]nitially it just started with pain. However, he has a tremendous amount of pain now, especially when he attempts to lift his arm. He has never had shoulder issues before… His pain is an 8/10." *Id.* On physical examination, the left shoulder was tender on palpation. *Id.* Range of motion ("ROM") was painful and limited. *Id.* The NP assessed "SIRVA," to be treated with meloxicam, baclofen, and home exercises. *Id.*

[5] Acute is defined as "having a *short* and relatively severe course." Dorland's Med. Dictionary Online *Acute*, https://www.dorlandsonline.com/dorland/definition?id=830&searchterm=acute (last accessed Sept. 5, 2025) (emphasis added).

- At a November 21, 2021 orthopedics follow-up, a different NP reviewed Petitioner's history as follows: "[Petitioner] has been "having pain for four weeks now. He had been seen two weeks ago and diagnosed with a SIRVA of the shoulder which is **after his flu injection was administered."** Ex. 3 at 10 (emphasis added). His pain rated 8-10/10. *Id.* The physical exam found "significantly reduced" ROM. *Id.* X-rays found no acute abnormalities or evidence of degenerative changes. *Id.* The NP assessed SIRVA and adhesive capsulitis, for which she administered a steroid injection; prescribed meloxicam; and ordered formal physical therapy ("PT") within the same orthopedics practice. *Id.* at 10-11.

- The November 30, 2021 PT initial evaluation record provides that Petitioner "presented with signs and symptoms **consistent with SIRVA."** Ex. 3 at 4 (emphasis added). This record lists the "date of onset" as October 16th. *Id.* (but see below orthopedics record in which Petitioner misreported the *vaccination date* as October 16th). *See also generally* Ex. 3 (reflecting 23 PT sessions ending Mar. 2, 2022 – without additional information about injury onset).

- At a December 30, 2021, orthopedics appointment, a physician recorded: "[Petitioner] had adhesive capsulitis after an injection. He had a flu injection back on 10/16/2021. **He began noticing left shoulder pain the day after the injection which progressively became worse…"** Ex. 3 at 12 (emphasis added). After observing limited ROM on exam and the normal x-ray findings, the physician assessed Petitioner with "left shoulder pain after a flu injection. It sounds like he had a reaction and had adhesive capsulitis…" *Id.* Petitioner reported temporary improvement from the November 21st steroid injection. *Id.*; *see also* Ex. 3 at 34 (June 12, 2022 orthopedics follow-up evaluation and second steroid injection).

- A September 21, 2022 MRI of Petitioner's left shoulder was indicative of moderate to high-grade tearing of the infraspinatus tendon, mild tearing of the subscapularis tendon, thinning of the long head of the biceps, and mild fluid within the subacromial subdeltoid bursa. Ex. 6 at 16.

- On November 7, 2022, an orthopedic surgeon at Arlington Orthopedics-UPMC initially evaluated Petitioner's left shoulder injury. Ex. 5 at 2. Petitioner reported that **"the pain has been going on since about a year ago and was post-flu shot.** Two weeks after that, he could not move his shoulder…" *Id.* (emphasis added). The surgeon diagnosed an incomplete tear of the rotator cuff; impingement syndrome; tendinitis; bursitis; and chronic pain. *Id.* at 5. Because the injury had failed conservative treatment and persisted for over a year, the surgeon recommended surgical intervention (and Petitioner agreed). *Id.* That surgery – consisting of an arthroscopic rotator cuff repair, acromioplasty with

decompression, and debridement of the anterior and superior labral tear took place on November 18, 2022. Ex. 6 at 2-3

- Within the December 22, 2022, PT post-operative initial evaluation record, the history of present illness reads: "[C]hronic shoulder pain for the past year with the **initial onset in October 2021 when he got the flu shot** and was injected too far superiorly. This led to inability to move his arm and chronic pain and difficulty with reaching OH [overhead] or up behind his back." Ex. 8 at 54 (emphasis added). This record lists the date of onset as "10-01-21." *Id.* After 29 post-operative PT sessions, Petitioner was discharged to a home exercise program on April 7, 2023. Ex. 8 at 7-57; Ex. 9 at 2-51; *see also* Ex. 5 at 30-35 (April 6, 2023 orthopedic follow-up exam). Petitioner's treatment course ended at that point, roughly 18 months post-vaccination.

Within the Rule 4(c) Report, Respondent's sole argument against compensation for a Table SIRVA is that "Petitioner has not preponderantly proven that his pain occurred within" 48 hours after the October 21, 2021 vaccination. Rule 4(c) Report at 8, citing 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii). Respondent argues more specifically that Petitioner's "initial reports regarding onset are vague and unclear." *Id.*

In presenting this argument, Respondent interprets certain wording in the medical records quite stringently. He notes, for example, that Petitioner's report on November 8, 2021, of pain beginning "two weeks ago" would date back exactly to October 25th, which was four days post-vaccination. Response at 8, citing Ex. 3 at 2. And Petitioner's report on November 21, 2021, of pain "for four weeks now" would date back exactly to October 24th –three days post-vaccination. Ex. 3 at 10. Respondent also notes that Petitioner reported a specific onset date of October 16th – which was *before* vaccination. *Id.* at 4. Finally, Respondent contends that Petitioner did not specifically identify "pain within the requisite window of onset" until 70 days post-vaccination. *Id.* at 12.

I agree with Respondent that these medical records are *somewhat* inconsistent in pinpointing a specific calendar date for Petitioner's start of shoulder pain. But they consistently explain that the pain was caused by, and began shortly after, the vaccination. Ex. 3 at 2 ("acute onset… after receiving his flu injection"); *id.* at 12 ("the day after injection…"). Within the Program, such terms are typically understood to "mean *very* close in time – immediately, or at most within a day or two" after vaccination. *Flowers v. Sec'y of Health & Hum. Servs.*, No. 20-285V, 2024 WL 2828211, at *11 (Fed. Cl. Spec. Mstr. May 8, 2024), *mot. for rev. den'd*, 173 Fed. Cl. 613 (2024). Moreover, Petitioner reported the same (albeit incorrect) specific calendar date for *both* the vaccination and onset. Ex. 3 at 4, 12. When viewed holistically, the evidence preponderates in favor of Petitioner's

allegation of shoulder pain beginning within 48 hours after the vaccination, consistent with a Table SIRVA.

Conclusion and Scheduling Order

Respondent has not raised any other objections to entitlement for a Table SIRVA, *see generally* Rule 4(c) Report. And from my review to date, the medical record evidence very likely establishes such an injury.

However, Petitioner's filings are incomplete. Specifically, Vaccine Act Section 11(c)(1) requires that a Petition contain "an affidavit and supporting documentation" for all pleading requirements, including that the petitioner "has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death." *See also* PAR Initial Order (ECF No. 5) at 5 (requiring "an affidavit from Petitioner addressing the requirements of § 11(c)(1), to include the lack of or disposition of any prior civil action").

This case's *Petition* addresses the above issues – but it lacks corroboration. *See* Petitioner's Statement at Ex. 1 (ECF No. 19-2). It is further noted that this statement is neither a *notarized* affidavit nor made under penalty of perjury, *see* 28 U.S.C. § 1746 (providing that such a statement may be given "like force and effect" as a notarized affidavit).

Within 30 days, by no later than Monday, October 6, 2025, Petitioner shall file a notarized affidavit or comparable statement, and any other documentation if needed, as required under Section 11(c)(1). Petitioner shall file a supplemental Statement of Completion when finished.

Within 30 days after Petitioner's filing of a supplemental Statement of Completion, Petitioner shall file a Joint Status Report proposing further proceedings and deadlines in the case (for e.g., Respondent's filing of an Amended Rule 4(c) Report; further efforts towards informal resolution of the claim; briefing of all remaining issues bearing on entitlement and damages).[6]

IT IS SO ORDERED.

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

[6] It is also noted that a status conference may be requested, if that would be helpful to either party, via either a status report or email to the assigned OSM staff attorney.