

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0978V

LIZA ORBAN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 28, 2024

Michael A. Firestone, Marvin Firestone, MD, JD, and Associates, San Mateo, CA, for Petitioner.

Nina Ren, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING AND ORDER TO SHOW CAUSE¹

On February 22, 2021, Liza Orban filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) as defined by the Vaccine Injury Table, resulting from an influenza (“flu”) vaccine received on November 30, 2019. Petition at 1. Alternatively, Petitioner asserts that her shoulder injury was caused in fact by the flu vaccine. *Id.* The case was assigned to the Special Processing Unit of the Office of Special Masters.

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 (2018).

For the reasons discussed herein, I find that a preponderance of the evidence supports a finding that the onset of Petitioner's shoulder pain did *not* occur within 48 hours, the time set forth in the Table for a SIRVA. Furthermore, the record at present does not support a finding that the onset of Petitioner's shoulder pain occurred within any time that could plausibly support a finding of vaccine causation. Unless Petitioner can provide additional evidence remedying this evidentiary deficiency, her claim will be dismissed.

I. Relevant Procedural History

Just under a year after the case was activated, Respondent determined that he would defend this claim (ECF No. 29). On October 7, 2022, Respondent filed his Rule 4(c) Report setting forth his objections (ECF No. 30). Following a status conference, Petitioner filed a motion for a finding of fact on the issue of onset on May 10, 2023 (ECF No. 36). Respondent responded on June 22, 2023, and Petitioner replied on June 28, 2023 (ECF Nos. 37, 38). The issue of when Petitioner's shoulder pain began is now ripe for resolution.

II. Factual Finding

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 or her 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 & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y*

of Health & Human Servs., No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

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 Qualifications and Aids to Interpretation (“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;
- (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.*

B. Relevant Factual History

This ruling contains only a brief overview of facts relating to the onset of Petitioner’s symptoms.

1. Medical Records

Petitioner received a flu vaccine intramuscularly in her left arm on November 30, 2019. Ex. 16 at 10-11. Three weeks later (December 19, 2019), she was seen by her primary care physician (“PCP”) Dr. Joel Buchanan. Ex. 3 at 19. She had been experiencing headaches, and thought they could be related to her blood pressure. *Id.* She also reported pain in her right hip that had begun months earlier. *Id.* An examination was done, although the record does not indicate that the examination included her musculoskeletal system. *Id.* at 20. She was given a tetanus diphtheria acellular pertussis (“Tdap”) vaccine, advised to log her blood pressure at home, and use heat, ice, and stretches for her hip pain. *Id.* at 21. Although Petitioner asserts that she instructed the nurse to place the Tdap vaccine in her right arm because her she was experiencing left shoulder pain, the record does not indicate the arm of administration for this vaccine. *Id.* at 19-21, 24. The record also does not document any concerns with Petitioner’s left arm or shoulder. *Id.*

Petitioner had a screening mammogram on January 3, 2020. Ex. 3 at 17. The record does not document any concerns with her left arm or shoulder, although it appears that (consistent with the specific nature of this treater visit) no history was taken and no general physical examination was done. *Id.*

Petitioner saw Dr. Buchanan for a comprehensive physical examination and routine gynecological exam on January 20, 2020 – now almost two months after the relevant vaccination. Ex. 3 at 13. The review of systems section of the record indicates that Petitioner did not report decreased range of motion, joint pain, joint stiffness, joint swelling, or myalgia. *Id.* On examination, she had full range of motion in all joints and normal joints and muscles. *Id.* at 14. A pap smear was done, and Petitioner was given orders for a screening mammogram and colonoscopy. *Id.* at 15. She was also instructed to start iron for anemia and Tramadol for foot pain. *Id.* The record does not document any concerns or findings relating to Petitioner’s left shoulder or arm. *Id.*

Petitioner next saw the medical assistant in her PCP's office approximately six weeks later, on March 6, 2020. Ex. 3 at 11. It appears that this visit was just for a blood draw, and no examination was done. *Id.* at 11-12. Then, Petitioner had a telemedicine appointment with Dr. Buchanan on April 16, 2020, for right foot pain. *Id.* at 10. Dr. Buchanan ordered an x-ray and directed Petitioner to continue Tramadol. *Id.* Neither of these records mention Petitioner's left arm or shoulder.

On June 23, 2020 – nearly *seven months* after vaccination – Petitioner saw Dr. Buchanan for left shoulder pain. Ex. 3 at 8. She now reported a dull achy feeling when she reached to the side. *Id.* She stated that she “wakes up sore from it,” and it was painful to lift a coffee cup. *Id.* She reported that the onset of her shoulder pain was “months ago.” *Id.* She further explained that she thought that “the flu vacc[in]e that was given to her at Sam's Club was given too high.” *Id.* The record states that on examination, she had decreased range of motion in her *right* shoulder but otherwise normal joints and muscles.³ *Id.* at 9. Dr. Buchanan referred Petitioner to physical therapy (“PT”) and recommended home exercises. *Id.*

Two weeks later (July 6, 2020), Petitioner underwent a PT evaluation for left shoulder pain. Ex. 5 at 3. She reported that her symptoms began on November 30, 2019, explaining that the onset was “sudden following the flu shot.” *Id.* She stated that she saw her doctor for other immunizations in December 2019 and had them in the opposite arm. *Id.* at 4. She added that “due to the COVID-19 pandemic she was just recently able to get into the doctor.” *Id.* She reported a pain level of two out of ten at best and four out of ten at worst. *Id.* at 3. On examination, her left shoulder exhibited reduced and painful active range of motion, as well as reduced strength, compared to her right shoulder. *Id.* at 4. She had positive results on the Speed's bicep test on the left side. *Id.* at 5. She was found to have limited shoulder range of motion and strength that impacted her ability to perform functional activities such as dressing, carrying groceries, sleeping, and bathing. *Id.* at 6. On the medical history form for her July 6th PT evaluation, Petitioner listed an injury date of “Nov/Dec 2019” and noted the cause of her injury as “flu shot.” *Id.* at 62.

Petitioner returned to Dr. Buchanan on July 21, 2020, for evaluation of left shoulder pain. Ex. 3 at 6. At this visit, she reported that the onset of her shoulder pain was “weeks ago.” *Id.* On examination, she had decreased range of motion in her left shoulder but otherwise normal joints and muscles. *Id.* at 7. Dr. Buchanan ordered an x-ray and referred her to an orthopedist. *Id.*

³ Respondent states that this reference to Petitioner's right shoulder is “likely a scrivener's error, as the medical records otherwise refer to petitioner's left arm.” Respondent's Response at *3 n. 2 (ECF No. 37). My ruling herein would not change if I were to find that Petitioner's PCP intended to refer to her left arm.

Petitioner saw orthopedist Dr. Christopher Stroud on August 3, 2020 for left shoulder pain. Ex. 8 at 6. She explained that she received a flu vaccine in November, and “[s]hortly after that, she noted some heaviness and a dull aching sensation in the shoulder and upper arm.” *Id.* Her symptoms had continued since then. *Id.* On examination, she had some limitations in internal rotation but otherwise full range of motion in her shoulder. *Id.* at 7. She had positive results on the Speed’s test and negative results on the O’Brien’s maneuver. *Id.* Left shoulder x-rays were unremarkable. *Id.* at 8. Dr. Stroud’s impression was left shoulder pain following flu vaccination, and he recommended heat, Voltaren gel, and stretches. *Id.* He also recommended Neurontin for nighttime use. *Id.*

Petitioner returned to Dr. Buchanan for left shoulder pain on August 25, 2020, stating that the onset of her pain was “months ago.” Ex. 3 at 4. Her range of motion was better, but the pain was the same. *Id.* Dr. Buchanan’s impression was that she was 30-40% improved, and he noted that she was participating in PT and seeing Dr. Stroud. *Id.* at 5.

Petitioner attended a total of 16 PT visits before being discharged on August 26, 2020. Ex. 5 at 56. At discharge, her shoulder was stronger, and she was able to move it better, but she still had pain, especially at night. *Id.* Her pain level was zero out of ten at best and eight out of ten at worst. *Id.* She continued to have reduced active range of motion, with slight improvement in some planes of motion from her initial evaluation. *Id.* at 57. Because her range of motion had not improved and she was still in pain, she was discharged from PT and advised to return to her physician. *Id.* at 59.

Petitioner returned to Dr. Stroud on September 11, 2020, reporting that she was not much better, with pain at night that came and went. Ex. 8 at 9. She had tried Neurontin without success. *Id.* On examination, her shoulder was not tender and had full range of motion, with pain at the mid range. *Id.* at 10. He described her left shoulder as “irritable” with a positive impingement sign and excellent strength. *Id.* He assessed her with shoulder inflammation secondary to vaccine administration, and ordered a left shoulder ultrasound to evaluate the bursa. *Id.* He also prescribed a steroid Dosepak and Meloxicam. *Id.* If she was not better in five weeks, he would consider a subacromial steroid injection. *Id.*

Petitioner saw Dr. Stroud for left shoulder adhesive capsulitis on October 16, 2020. Ex. 8 at 11. She reported that her symptoms had been ongoing since November 2019, and her pain was slightly improved. *Id.* However, she continued to have pain at night, or when holding groceries. *Id.* Meloxicam and the steroid Dosepak helped. *Id.* On examination, she had full range of motion “except for some scapular recruitment.” *Id.* at 12. He recommended PT and again prescribed Meloxicam and a steroid Dosepak. *Id.*

Petitioner underwent a second PT evaluation on October 21, 2020. Ex. 6 at 16. Although the medical record indicates that she reported the onset of her symptoms both

on October 19, 2020, and “on November 30th⁴ when she got a flu shot.” (*Id.*), on the intake form Petitioner wrote that her symptoms began on November 30, 2019. *Id.* at 28. Petitioner reported that her shoulder had been “really painful and she has been losing ROM since the injection.” *Id.* at 16. She had gone to PT for about two months in the summer without relief. *Id.* On examination, her left shoulder active and passive range of motion were both reduced compared to her right shoulder. *Id.* at 17. Petitioner attended four more PT visits through November 2, 2020. *Id.* at 8.

Petitioner saw Dr. Stroud for left shoulder pain on November 30, 2020. Ex. 15 at 6. Meloxicam had helped somewhat, but the steroid Dosepak did not help and PT was hurting her. *Id.* Dr. Stroud administered a steroid injection in her left shoulder and recommended another course of PT, along with heat and stretches. *Id.* at 7.

Petitioner attended a third PT evaluation on December 28, 2020. Ex. 14 at 7. She reported left shoulder pain that began a year earlier in November 2019 after receiving a flu vaccine. *Id.* She had attended two rounds of PT, but had to stop “due to insurance purposes.” *Id.* She had received a steroid injection a month earlier (November 30, 2020) that helped some. *Id.* A left shoulder ultrasound had revealed bursitis. *Id.* She reported a pain level of two out of ten, that ranged from zero at best to ten at worst. *Id.* On examination, her left shoulder active and passive range of motion were reduced, as was her left shoulder strength. *Id.* at 8.

Petitioner returned to Dr. Stroud the following month (January 28, 2021). Ex. 15 at 3. Dr. Stroud noted that this had been “an ongoing issue since November 2019,” that Petitioner stated began following a flu vaccination. *Id.* Mobic and Voltaren gel helped slightly, and she had a 30% improvement with a glenohumeral steroid injection done in November 2020. *Id.* Petitioner chose to proceed with another steroid injection. *Id.* at 4.

2. Witness Statements

Petitioner has filed five declarations in support of her claim. Exs. 1, 17, 18, 21, 23. Petitioner states that after receiving the flu vaccination:

I recognized almost immediately that something was wrong in my left arm. I described it “like when a dentist’s needle goes into your gum to anesthetize the gum for a procedure which caused me to see stars briefly.” This was not a normal feeling of getting an immunization.

Ex. 1 at ¶ 5.

Because she works in the healthcare field, she has had flu shots annually for over 20 years, and this vaccination did not feel the same as usual. Ex. 1 at ¶ 5. Nevertheless,

⁴ Although the record does not specify the year, given the timing I interpret the record as referring to November 30, 2019.

she has felt soreness for up to about two weeks after a flu vaccination, so she waited for the pain to subside. *Id.* at ¶ 6.

Petitioner states that she felt “weakness and awkwardness” in doing daily tasks such as folding clothes, carrying groceries, reaching to pick up items, or lifting her grandchild, although she does not explain when these problems began. Ex. 1 at ¶ 7. She used to go to the gym regularly, but states that “[s]ince receiving the November 30, 2019 Flu vaccination” she can no longer lift weights or use her arm for the elliptical machine. *Id.* at ¶ 8. She has difficulties with getting dressed, driving, and sleep. *Id.* at ¶¶ 9, 10, 14.

As for the December 19, 2019 appointment that was silent on problems with her left arm or shoulder, she explains that she made this appointment due to feeling “off” physically for weeks, with strange heart palpitations and high blood pressure swings. Ex. 17 at ¶ 4. She had also been experiencing hip pain for several years, probably starting around 2015, that she had been meaning to address but had put off. *Id.* at ¶ 6. She reported her hip pain to Dr. Buchanan at the December 2019 appointment, explaining that it “*likely* took precedence over any concern I had regarding my sore left shoulder presuming it would resolve on its own.” *Id.* (emphasis added).

Petitioner adds that she also reported to Dr. Buchanan during the December 2019 visit that she had lost her right big toenail a couple of months earlier, but this also was not noted in the record – suggesting that the record is incomplete as to matters other than her left shoulder pain. Ex. 17 at ¶ 7. She is “confident that I mentioned my left arm’s ‘achiness’ and ‘soreness’ during this December 19, 2019 visit, but apparently this never made it into my medical records either.” *Id.* She explains that she is so confident about this because when a Tdap vaccine was recommended she agreed, but instructed the nurse to administer it in her “good” arm – her right arm – since her left arm was still sore from the flu vaccination the month prior. *Id.*; Ex. 23 at ¶ 2.

Petitioner states that her December 2019 appointment with Dr. Buchanan was the first time she had seen him, and she had not had a PCP for the previous two years. Ex. 23 at ¶ 1. This visit was mainly to check her blood pressure due to headaches. *Id.* She was also “being prescribed Gabapentin and Tramadol for my painful right hip that had been bothering me for quite some time,”⁵ and in retrospect she suspects that these medicines masked the true extent of her shoulder injury. *Id.* She adds that the medical documentation for that visit was entered by Dr. Buchanan’s scribe rather than the doctor himself, and that there was no documented evaluation of her musculoskeletal system in the exam section of the note. *Id.* at ¶ 3. She adds that she did report her sore left arm

⁵ In a different declaration, Petitioner states that she had been prescribed Tramadol for right foot pain and Gabapentin for pain from trigeminal neuralgia. Ex. 17 at ¶¶ 16, 20. Although this inconsistency is troubling, I find it does not matter for purposes of this ruling.

during her January 3, 2020 mammogram, explaining that she told the technician to “go easy on my left side, because I had a sore arm.” *Id.* at ¶ 4.

As to the January 20, 2020 exam, although the record describes it as an annual physical and well-female exam with routine gynecological exam, Petitioner’s recollection is that the visit was mostly focused on her routine gynecological exam and not a “full-blown physical where the doctor evaluates a patient from head to toe.” Ex. 17 at ¶ 17. She does not recall Dr. Buchanan asking her questions about her musculoskeletal system. *Id.* She states, “*I think* I believed my arm soreness was going to go away any day.” *Id.* (emphasis added). She explains that the “trigeminal neuralgia that I was experiencing was such an overbearing heavy feeling and caused such tiredness and overall malaise, that I think I lumped it all together and just didn’t stress what else was still bothering me regarding my left shoulder.” *Id.* She adds, “[*l*]ikely, the pain in my left shoulder was still being numbed/masked somewhat by the pain medication” she was taking. *Id.* (emphasis added). She adds that the record’s notation that she did not report decreased range of motion, joint pain, joint swelling, or myalgia, and that an examination found full range of motion and normal joints and muscles is “not entirely accurate” because she had significant hip pain at the time, with decreased range of motion in her hip. Ex. 23 at ¶ 5. At this visit, she does not recall feeling significant reduction in her left shoulder range of motion. *Id.*

Petitioner adds that the March 6, 2020 visit was only a lab draw with a medical assistant. Ex. 17 at ¶ 18; Ex. 23 at ¶ 6.

At Petitioner’s April 16, 2020 telemedicine visit, Dr. Buchanan reviewed her lab results. Ex. 17 at ¶ 20. Petitioner recalls “complaining about the odd symptoms related to my chest and upper armpit area and that I was still experiencing severe itchiness and some sharp pains.” *Id.* She also reported right foot pain, which had been bothering her for years and for which she had been prescribed Tramadol, and she “presume[d] this medication also had the added benefit of helping alleviate my left shoulder pain.” *Id.* Due to the “limitations and awkwardness” of a telemedicine visit, and that her toe took precedence because it limited her mobility, she presumes that Dr. Buchanan “mistook my armpit complaints with the rest of my complaints related to my left shoulder.” *Id.* She adds that he only noted her toe complaints and neglected to record the remaining complaints she raised. *Id.*

Petitioner asserts that Respondent’s suggestion that she did not mention shoulder pain at the April 16th telehealth visit is “misleading, as this was a very short telemedicine appointment” to review lab results in the early days of the COVID-19 Pandemic. Ex. 23 at ¶ 7. She recalls mentioning pain in her chest area, and adds that because it was a virtual visit, she was “too embarrassed to really go into detail” about pain around her nipples and itchiness in her chest. *Id.* But the pain in her chest was “from the same muscles one moves when they move their shoulder and is exactly the pain I feel when I

cross my body with my left arm or wash my face.” *Id.* She adds that she was still taking Gabapentin and Tramadol, likely masking her left arm pain and making it “hard to differentiate the pain in my upper left arm/shoulder that was slowly getting worse.” *Id.* Although Petitioner *suggests* that she reported left shoulder pain at this appointment, she does not actually say that she did. Exs. 1, 17, 23.

Petitioner adds that at Dr. Buchanan’s suggestion, she had previously begun tracking her blood pressure using the health portal. Ex. 23 at ¶ 8. On examining her journal, she notes that she “experienced a lot of pain in the area of my chest and breast, and the muscle groups affected with arm movement, and associated with movement of one’s shoulder, shoulder joint, and shoulder muscles. To me, it’s all connected, and it all started with the flu vaccination I received on November 30, 2019 at Sam’s Club.” *Id.* at ¶ 9. She adds that Respondent’s suggestion that she first reported left shoulder pain on June 23, 2020 “is misleading.” Ex. 23 at ¶ 10. She states:

I had been telling medical professionals all along that I was feeling soreness/achiness/pain that later turned to limited mobility in my left side that started when I received my flu vaccination of November 30, 2019. It was only at this point that I went to see Dr. Buchanan specifically for this pain because it had not gone away and seemed to be actually getting worse with time.

Ex. 23 at ¶ 10.

Petitioner also submitted a declaration from her husband, John Orban. Ex. 21. Mr. Orban states that his wife had left shoulder surgery in October 2021 “for a frozen shoulder that she has been suffering from ever since shortly after she got a flu shot in November 2019.” *Id.* at ¶ 2. He recalls that “during the Winter of 2019 she began becoming frustrated with a nagging pain in her left shoulder that seemed to start shortly after the flu injection.” *Id.* at ¶ 4. She kept waiting for the soreness to go away and tried to exercise thinking it would help. *Id.* at ¶ 6. He recalls that “in the early months of 2020,” Petitioner was worried that exercising may be preventing her shoulder from healing, so she cut back on her exercise regime and stopped lifting weights. *Id.* at ¶ 8. Starting in March 2020 she stayed home completely, as she had been furloughed at work and had no need to go out. *Id.* at ¶ 9.

Petitioner submitted a witness statement from Farrah Naeem. Ex. 18. Ms. Naeem explains that she and Petitioner were both laid off from positions with the same employer in March 2020. *Id.* They had become friends and continued to exchange text messages about Petitioner’s shoulder condition. *Id.* Ms. Naeem states that she is “aware that Liza Orban had an issue with her upper arm in late December 2019 and early 2020.” *Id.* At work, Ms. Naeem “tried to help with suggestions on exercises that could help her regain her motion and strengthen her arm again.” *Id.* These conversations occurred when she

would accidentally hurt herself at work and say that her arm was still sore from the flu vaccination. *Id.*

C. The Parties' Arguments

Petitioner argues that she “has consistently reported her symptoms began on November 30, 2019 right after receiving the flu injection.” Petitioner’s Motion for Findings of Fact on Issue of Onset, filed May 10, 2023, at *7 (ECF No. 36) (“Mot.”). She maintains the July 21, 2020 visit notes “are erroneous” because they note onset as being “weeks ago” – apparently in contrast to the notes of the prior and subsequent visits, which report onset as having been “months ago.” Mot. at *7. She adds that her July 6, 2020 PT evaluation reflects November 30, 2019 as the onset date. *Id.* Thus, “[t]here is no evidence in the record that contradicts Petitioner’s version of events – that she experienced the onset of symptoms consistent with SIRVA immediately after vaccination, on November 30, 2019” (*id.* at *8) – despite the July 21st record stating that onset was *weeks* earlier, which would mean June or July 2020 (not to mention the absence of reports of shoulder pain for over six months post-vaccination).

Regarding the extended treatment delay, Petitioner argues that once she began treatment, “she always consistently attributed her shoulder symptoms to the flu vaccine she received on November 30, 2019.” Mot. at *9. Her decision to wait to obtain treatment “was reasonable because she thought the symptoms would go away and wanted . . . in person visits during the Covid pandemic.”⁶ *Id.*

Petitioner cites two cases in support of her claim, *Shelton v. Sec’y of Health and Human Servs.*, No. 19-279V, 2021 WL 2550093 (Fed. Cl. Spec. Mstr. May 21, 2021), and *Winkle v. Sec’y of Health & Human Servs.*, No. 20-485V, 2021 WL 2808993 (Fed. Cl. Spec. Mstr. June 3, 2021). Mot. at *9-10. Petitioner acknowledges that the treatment delay in both of these cases was slightly shorter (five months), but asserts that her nearly seven-month delay is “about the same amount of time.” *Id.* at *10. *Shelton* and *Winkle*, she maintains, demonstrate that “medical records reflecting consistent attribution of shoulder symptoms to vaccine administration are crucial,” noting that her records show that she consistently stated that her symptoms began when the vaccine was administered. *Id.* at *11. Further, Petitioner gave “reasonable explanations for why the medical records do not reflect concerns about her shoulder sooner.” *Id.* at *11. The December 2019 was her first primary care visit in two years, and her shoulder was not the focus of the visit; at that time, she also expected the pain to go away. *Id.* Petitioner

⁶ This sentence is missing a verb between the words “to” and “in.” Presumably, Petitioner meant to state that she wished to *avoid* in person visits during the COVID-19 Pandemic.

adds that the “report failed to make any entries about Petitioner’s musculoskeletal even though this visit was an annual physical,” citing *Kirby*, 997 F.3d at 1383.⁷ *Id.*

Petitioner adds that she is “certain that she told the technician to go easy on her left arm” at the January 3, 2020 visit. Mot. at *12. And she describes the January 20, 2020 appointment as a “very brief meeting . . . about the issues she had already reported” – despite the fact that it was documented as a comprehensive physical examination. *Id.*

With respect to the April 16, 2020 visit, she explains that she was “simply too embarrassed to talk about her shoulder symptoms.” Mot. at *12. It was a virtual visit, and she was embarrassed to go into detail about the pain around her nipples and itchiness from clothes. *Id.* Thus, her “reticence to undress in front of a video camera” is understandable. *Id.* She adds that the June 23, 2020 appointment was the first time she saw Dr. Buchanan specifically for her shoulder pain – because it had not gone away and seemed to be getting worse with time. *Id.* at *13.

Respondent argues that Petitioner has not preponderantly established that the onset of her shoulder pain occurred within 48 hours of vaccination. Respondent’s Response, filed June 22, 2023, at *5 (ECF No. 37) (“Resp.”). Petitioner’s witness statements alone are “inadequate to overcome the presumed accuracy and reliability of contemporaneous medical records, which show petitioner’s alleged SIRVA did not begin” within 48 hours of vaccination. Resp. at *6. And “[n]one of the contemporaneous medical records support an immediate post-vaccination onset of shoulder pain and several of petitioner’s records are inconsistent with her claim.” *Id.* Further, Respondent points out that Petitioner explained that because she has received the flu vaccine annually for over 20 years and immediately recognized that something was wrong with her arm, yet still did not report shoulder concerns for seven months despite multiple intervening visits with her primary care physician, Dr. Buchanan – the treater to whom she ultimately reported her shoulder pain months later. *Id.* at *6.

Respondent also points out that Petitioner requested her healthcare information from Dr. Buchanan on December 21, 2019, two days after the December 2019 visit – but never sought to correct that that Dr. Buchanan allegedly omitted her report of shoulder pain from the record. Resp. at *7. And Petitioner allegedly began recording problems with chest pain and her periods in April 2020 – but none of these notes refer to left shoulder pain. Resp. at *7. Petitioner’s reliance on *Shelton* and *Winkle* is misplaced, Respondent contends, because the petitioners in those cases had shorter delays in seeking care, with little or no intervening medical encounters. *Id.*

⁷ It appears that Petitioner is referring to the January 20, 2020 visit, which was the annual physical. Ex. 3 at 13.

Otherwise, Respondent maintains, Petitioner's attempts to discredit contemporaneous medical records with declarations prepared years after vaccination for purposes of litigation "are self-serving and not adequate to overcome the reliability of contemporaneous medical records." Resp. at *7. And although Petitioner asserts that pain medication she was taking for other conditions could have masked her degree of pain, Petitioner has also attested that she "saw stars briefly" during vaccination and experienced sharp pain, "blast[s] of soreness" and "a feverish feeling" – and *did* complain of pain in her hip and right foot during this time period. *Id.* at *7-8 (*citing* Ex. 1 at 1-2). If the pain medication she was taking during that time were insufficient to manage her lesser hip and foot pain, Respondent argues, then it is unlikely those medications would have "numbed the true extent" of her alleged left shoulder pain. *Id.* at *8.

Respondent finally contends that Petitioner's argument that she did not report shoulder symptoms during her April 2020 telehealth appointment due to embarrassment is unsupported. Resp. at *8. Petitioner had already discussed her chest pain and soreness, and documented this in her health portal. *Id.* Moreover, when Petitioner did finally report shoulder pain, she described it as shoulder and left arm pain that radiated into her neck – not chest pain or itchiness. *Id.* Respondent further points out that Petitioner asserts that she did discuss her left arm pain at prior appointments, despite record omission of those reports – but in contradiction to her assertion that she was not comfortable doing so. *Id.* And Petitioner would not have needed to undress for a shoulder examination to be done. *Id.*

Petitioner replies that Respondent misunderstands what Petitioner meant in her declaration about the December 2019 appointment. Petitioner's Reply, filed June 28, 2023, at *1-2 (ECF No. 38) ("Reply"). Petitioner clarifies that she does not state or imply that Dr. Buchanan failed to record left shoulder issues that she reported; instead, Petitioner "implied that she made these statements to the nurse administering the TDAP vaccine, not Dr. Buchanan." Reply at *2. Petitioner reiterates that the December 2019 appointment was "for a myriad of medical issues that had long predated the vaccine." *Id.* She presumed that her left shoulder issues would resolve on their own, like in previous years. *Id.* Because she only mentioned it to the nurse administering the Tdap vaccine, "it should not come as a surprise that it was not documented." *Id.* at *3. She adds that her declaration shows that "she has previously delayed treatment for painful conditions, so her delay in getting her shoulder treated was not unprecedented." *Id.*

Petitioner further takes issue with Respondent's suggestion that a more painful condition generally requires more extensive treatment than a less painful one, and asserts that the extent of the treatment she received for her hip and right foot, as well as her left shoulder, "has no bearing on the pain associated." Reply at *3.

In addition, Petitioner argues that "it is not inconsistent for a patient to feel embarrassed and reticent to share with a doctor over a virtual-video appointment (which

was fairly new technology for most patients who may be more reticent to disrobe while ‘on camera’)” and more comfortable reporting the issue in writing in a health portal. Reply at *4. And “pain associated with her left shoulder can change over time Just because Petitioner did not later report chest pain in connection to her shoulder pain, it does not follow that Petitioner did not think her shoulder pain was connected to her chest issues.” *Id.*

Petitioner ultimately maintains that she has filed multiple witness declarations credibly explaining how she did report left shoulder issues to her doctor, and has provided reasonable explanations for why this may not have been set forth in some records. Reply at *4. Petitioner thus argues that she has “presented sufficient corroborative evidence to support a finding of fact that she experienced the onset of symptoms of SIRVA” within 48 hours of vaccination or, in the alternative, that her shoulder injury was caused in fact the flu vaccination. Reply at *5.

D. Factual Finding on Onset

One fact stands out above all else in this onset debate: Petitioner did not seek care for shoulder pain until *nearly seven months* after vaccination. In the interim, she saw her PCP – the same doctor to whom she ultimately reported her shoulder pain later – for care *three times* (in addition to other medical encounters where reporting shoulder pain may not be expected, such as a lab draw and mammogram). Thus, she unquestionably had the *opportunity* to report shoulder pain, and it is reasonable to expect she might have if it were in fact as severe as alleged.

Most significantly, Petitioner saw her PCP for a comprehensive physical examination 51 days – nearly two months – after vaccination, but reported no joint pain or decreased range of motion, and on examination was found to have full range of motion in all joints. Ex. 3 at 14. Although Petitioner characterizes this appointment as being more focused on gynecological care, that is not what the record itself states. Furthermore, she saw her PCP two additional times in the first five months after vaccination, but did not seek care for shoulder pain at either of these appointments. While her declarations provide *some* explanation for why she did not seek shoulder treatment at these appointments, on key factual issues they rely more on inference rather than clear statements, and are not otherwise detailed or persuasive. Moreover, it is difficult to reconcile her statement that the November 2019 vaccination was immediately different than previous vaccinations with her failure to seek medical attention thereafter for nearly seven months, particularly with multiple opportunities to do so.

When Petitioner finally sought care for shoulder pain, she did mention her flu vaccination, stating that she “[t]hinks that the flu vacc[ine] that was given to her at Sam’s Club was given too high.” Ex. 3 at 8. But even then she did not directly relate her shoulder injury to vaccination, identifying the onset of her shoulder pain as “months ago” – which

could mean any number of months, and does not suggest that the onset of her pain was within 48 hours of vaccination.

Admittedly, Petitioner did report that her symptoms began on November 30, 2019 “sudden[ly] following the flu shot” at her PT evaluation on July 6, 2020. Ex. 5 at 3. However, on her medical history form she reported an injury date of “Nov/Dec 2019.” *Id.* at 62. Thereafter, her medical records are somewhat inconsistent, indicating that she reported that her shoulder began “weeks ago”⁸ (Ex. 3 at 6), “[s]hortly after” a November flu vaccine (Ex. 8 at 6), “months ago” (Ex. 3 at 4), since November 2019 (Ex. 8 at 11), on October 19, 2020 and November 30, 2019 (Ex. 6 at 16, 28), in November 2019 (Ex. 14 at 7), and “since November 2019” (Ex. 15 at 3).

In her declarations, Petitioner asserts that the flu vaccination caused her to “see stars briefly,” and was different from previous vaccinations. Ex. 1 at ¶ 5. She “recognized almost immediately that something was wrong in [her] left arm.” *Id.* And she states that “[s]ince receiving the November 30, 2019 Flu vaccination” she can no longer lift weights or use her arm for the elliptical machine. *Id.* at ¶ 8. However, she does not state that she had pain within 48 hours of vaccination. Petitioner has not provided consistent, clear, cogent and compelling testimonial evidence sufficient to overcome the presumptive accuracy of the medical records. *Sanchez*, 2013 WL 880825, at *3.

Other witness statements are no more helpful to resolving the onset issue in Petitioner’s favor. Petitioner’s husband, for example, recalls that she had a frozen shoulder “that she has been suffering from ever since *shortly after* she got a flu shot in November 2019” (Ex. 21 at ¶ 2 (emphasis added)) and was frustrated with left shoulder pain “during the Winter of 2019.” Ex. 21 at ¶ 2. However, he does not specify in more detail *when* Petitioner’s shoulder pain began, or provide details about how he was able to recall this information nearly two years later.⁹ And Ms. Naeem states only that she was aware of an issue with Petitioner’s upper arm “in late December 2019 and early 2020” (Ex. 18) – which does not support a finding of onset within 48 hours.

I find that the most compelling evidence in this case are the medical records closest in time to vaccination. And these records contain no mention of any problems with Petitioner’s left shoulder until nearly seven months after vaccination. Most persuasive is the record of Petitioner’s January, 20, 2020 comprehensive physical examination containing no musculoskeletal findings on examination and stating that Petitioner did not report joint pain or decreased range of motion. I find that later medical records and the

⁸ Petitioner attempts to dismiss the record stating that her pain began weeks earlier as “erroneous.” Mot. at *7. Petitioner’s logic in this regard is circular, suggesting that this record is erroneous because it is inconsistent with earlier and later records – and then, assuming this record can now be ignored, asserting that she consistently reported onset on November 30, 2019. *Id.*

⁹ Mr. Orban’s declaration was signed on November 22, 2021. Ex. 21.

witness statement evidence filed in this case are not sufficient to overcome the January 20th record. Based on this record, along with the remaining record evidence, a preponderance of the evidence supports a finding that the onset of Petitioner's shoulder pain occurred after January 20, 2020 – which is at least 51 days after vaccination.

Other records do not support the interpretation proposed by Petitioner. Thus, although Petitioner suggests that she reported left shoulder pain during the April 16, 2020 telemedicine visit, she never actually states that she did – despite filing three declarations totaling 24 pages on her own behalf. Exs. 1, 17, 23. Instead, she implies that she reported problems with her chest, armpit, and shoulder, and that Dr. Buchanan neglected to record her shoulder complaints. But when she did report her shoulder pain two months later, she did not report related chest and armpit concerns. And she does not allege that she sought *treatment* for shoulder pain during the April 16th visit.

In addition, the two cases Petitioner relies on, *Winkle* and *Shelton*, are too different to help Petitioner. In both, the petitioner's delay in seeking care was approximately five months – nearly two months shorter. More significantly, the *Winkle* petitioner had *no* intervening medical treatment, and the *Shelton* petitioner's only intervening medical treatment was a single emergency visit for an asthma attack. *Winkle*, 2021 WL 2808993, at *4; *Shelton*, 2021 WL 2550093, at *4-5. In contrast, Ms. Orban had multiple intervening medical appointments, including three with her PCP, and, importantly, a comprehensive physical examination that is silent on her left shoulder and states that she reported no joint pain and no problems were found on musculoskeletal examination.

Petitioner's case is more like *Nicholson v. Sec'y of Health & Human Servs.*, No. 17-1416V, 2022 WL 14437541 (Fed. Cl. Spec. Mstr. Sept. 22, 2022). In *Nicholson*, the petitioner saw a neurologist one month after vaccination, and on examination her shoulder shrug was full strength, and she had strength and tone within normal limits in all major muscle groups. *Id.* at *4. Nineteen days later, the petitioner saw another doctor complaining of arm pain since her October 3, 2016 flu vaccination. *Id.* Although Petitioner asserted that she felt intense pain within one day of vaccination, the special master found that the petitioner's silence about left arm or shoulder pain at the previous neurology appointment "raises substantial question about whether such pain existed at that time." *Id.* at *19, 22. The special master then ruled that preponderant evidence supported a finding that the petitioner "developed shoulder pain sometime between" the neurology appointment and the later appointment where she reported shoulder pain. *Id.* at *22.

Here too, a preponderance of the evidence supports a finding that Petitioner was *not* experiencing left shoulder pain at the time of her January 20, 2020 comprehensive physical examination. From this, it follows that the onset of her left shoulder pain most likely occurred sometime *after* the January 20th appointment. *Nicholson*, 2022 WL 14437541, at *22; *see also N.B. v. Sec'y of Health & Human Servs.*, No. 20-151V, 2023 WL 183458, at *4, 7-8 (Fed. Cl. Spec. Mstr. July 19, 2022), (finding onset was not within

48 hours when the petitioner did not report shoulder pain until four months after vaccination despite multiple intervening appointments – including one with her PCP, from whom she ultimately sought care for her shoulder problem – that were silent on shoulder pain); *Shoemaker v. Sec’y of Health & Human Servs.*, No. 20-625V, 2022 WL 2288698 (Fed. Cl. Spec. Mstr. Jan. 18, 2022), *mot. for rev. denied*, 150 Fed. Cl. 307 (2022) (dismissing claim where the petitioner alleged immediate shoulder pain but did not seek care until almost ten months after vaccination); *Porcello v. Sec’y of Health & Human Servs.*, No. 17-1255V, 2020 WL 4725507, at *1-2, 9-10 (Fed. Cl. Spec. Mstr. June 22, 2020), *mot. for rev. denied*, 152 Fed. Cl. 469 (2020) (dismissing claim where the petitioner did not report arm pain until nearly four months after vaccination, despite intervening examination finding normal range of motion).

The record *does* support a finding that Petitioner experienced a left shoulder injury, but not that the onset of Petitioner’s shoulder pain occurred within 48 hours of vaccination. Her Table SIRVA claim must therefore be dismissed.

III. Order to Show Cause

The Petition asserts an alternative claim that Petitioner’s shoulder injury was caused in fact by the flu vaccination. In order to prevail on a causation in fact claim, Petitioner must establish the *Althen* factors. See *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (setting out a three part test for causation in fact claims, requiring that a petitioner establish (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 a proximate temporal relationship between vaccination and injury).

In this case, based on the record evidence and my ruling herein that the onset of Petitioner’s shoulder pain occurred at least 51 days after vaccination, it does not appear that Petitioner can meet the third prong, which requires a showing of a proximate temporal relationship between the vaccination and injury. Thus, it appears that Petitioner cannot prevail on a causation in fact claim on the current record. Nevertheless, I allow Petitioner a final opportunity to provide additional evidence on this issue.

Conclusion

This claim cannot proceed unless Petitioner offers sufficient evidence demonstrating that the onset of her injury occurred within a time that could satisfy the *Althen* standard. I will afford her the chance to file such evidence that may exist but is not

yet part of the record, or to provide other argument (perhaps based on prior Program determinations) that such a lengthy post-vaccination onset could still support a SIRVA.

It is important that Petitioner take seriously the chance I am providing her to substantiate her claim. It is a petitioner's obligation to follow court orders and to provide the evidence to support her claim. Failure to follow court orders, as well as failure to file the medical records and other evidence to support her claim, may result in dismissal of Petitioner's claim. *Tsekouras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 439 (1992), *aff'd*, 991 F.2d 810 (Fed. Cir. 1993) (per curiam); *Sapharas v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b).

Accordingly:

Petitioner is therefore hereby ORDERED to Show Cause why this case should not be dismissed for insufficient evidence by Monday, July 29, 2024.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master