In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 22-589V

NINETTE HANNA HOLBROOK, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: November 19, 2025

Daniel Alholm, Alholm Law, P.C., Chicago, IL, for Petitioner.

Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On May 31, 2022, Ninette Hanna Holbrook filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] ("Vaccine Act"). ECF No. 1 ("Petition"). Petitioner alleges that following her receipt of an influenza ("flu") vaccine on September 30, 2019, she suffered a left shoulder injury related to vaccine administration ("SIRVA"). Petition at ¶ 4. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

For the foregoing reasons, I find that Petitioner has provided insufficient proof of severity of injury, as required for all Vaccine Act claims. Petitioner's motion for a ruling on

[1] Because this decision 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).

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the record in his favor is therefore **denied**, and the case dismissed.

I. Relevant Procedural History

On August 18, 2022, the Petition was assigned to the SPU, since it alleged a SIRVA Table claim. ECF No. 9. On February 6, 2023, an initial status conference was held. Petitioner then filed additional evidence and medical records. Respondent represented that he was not interested in settlement discussions and filed a Rule 4(c) Report on October 26, 2023. ECF No. 22 ("Rule 4(c) Report").

In his Rule 4(c) Report, Respondent opposed the Table SIRVA claim on two grounds. First, Respondent argued that Petitioner had not satisfied the severity requirement because she waited ten months after vaccination to seek medical care for her alleged shoulder pain. Rule 4(c) Report at 8. Second, Respondent argued that Petitioner could not establish that her pain was limited to the arm in which the vaccine was given, because she also reported neck and back pain in certain instances when discussing her left shoulder with treaters. *Id.* at 8-9.

On December 19, 2023, a status conference was held, and this matter was subsequently placed on a briefing schedule. ECF No. 23. Petitioner filed additional evidence and a motion for a ruling on the record on February 20, 2024. ECF No. 26 ("Pet'r Mot."). On April 22, 2024, Respondent filed a response to Petitioner's motion for a ruling on the record. ECF No. 27 ("Resp't Opp'n"). On May 6, 2024, Petitioner filed a reply in support of his motion for a ruling on the record. ECF No. 28 ("Pet'r Reply"). 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.

A. Petitioner's Pre-Vaccination Medical Status and September 2019 Vaccination

Petitioner's earliest medical records date from 2009, when she was seen at the Orlando Orthopaedic Center for lower back pain. Ex. 4 at 68-71. In 2014, Petitioner began to complain of unexplained pain in her chest/thoracic area and her arms and hands. *See id.* at 61-65. Petitioner received a mammogram, ultrasound, breast MRI, and x-rays as a result. *See id.* at 64.

Petitioner then returned to the Orlando Orthopaedic Center for this issue. At an appointment on November 14, 2014, Petitioner indicated that she was experiencing pain and weakness in several parts of her body, including her back, left shoulder, left elbow, left hand, left fingers, left knee, and both feet. *See id.* at 63, 65. The treating physician, Dr. Steven Weber, noted a "reproducible tenderness to the left chest wall midaxillary line" that had been ongoing for several months. *Id.* at 66. Dr. Weber also stated that within the past two weeks, Petitioner had developed upper left extremity pain. *Id.* Dr. Weber found these symptoms to be concerning, but Petitioner was pregnant at the time and unable to undergo necessary imaging. He recommended finding out if it was feasible for Petitioner to have an MRI or else wait to have a further workup. It is unclear if Petitioner followed up after this appointment with Dr. Weber. Her subsequent records address orthopedic treatment for osteoarthritis in both knees and upper back pain. *See id.* at 50-52.

In March 2019, Petitioner established care with a new primary care provider ("PCP"). Ex. 3 at 56. Petitioner complained of chronic constipation, a "weird smell in her throat," and a pulled muscle in her left thigh. *Id.* At another PCP appointment, Petitioner stated that this throat discomfort and odor had been ongoing since November 2018. *Id.* at 52. In June and July 2019, Petitioner had PCP appointments regarding pain and swelling her left leg (diagnosed as trochanteric bursitis), constipation, and pain in her fingers and toes. *See id.* at 41, 48.

On September 30, 2019, Petitioner (then 39 years old) received the flu vaccine at her PCP's office.[3] Ex. 2 at 1; Ex. 3 at 39. Petitioner has filed screenshots of a text message conversation with her brother, Dr. Nicolas Hanna, dated the evening of September 30, 2019, discussing this vaccination. Ex. 10 at 1. Dr. Hanna is a double board-certified cardiologist practicing in Tulsa, Oklahoma. Ex. 13 at 1. In these text messages, Petitioner stated that "my arm is killing and my back is achy, no bueno." Ex. 10 at 1. Petitioner also asked how to "make [her] arm not hurt so much," to which Dr. Hanna suggested ice and compression. *Id.*

Petitioner did not receive any medical care thereafter for ten months.

B. Petitioner Does Not Seek Treatment Until July 2020 for Left Shoulder Pain

On July 27, 2020, Petitioner had an appointment with Dr. Christopher Warrell at the Orlando Orthopaedic Center. Ex. 17 at 2. Petitioner was seen for "bilateral shoulders," but her primary complaint was left shoulder pain. *Id.* Dr. Warrell indicated that Petitioner

[3] The vaccine consent form used by Petitioner's PCP office did not document the site of vaccination. *See* Ex. 3 at 39. Respondent does not appear to contest Petitioner's statements that she received the vaccine in her left arm. *See generally* Rule 4(c) Report.

had pain "in the left shoulder for approximately 10 months" and that this pain "began insidiously." *Id.* Petitioner "initially felt that the pain was secondary to a flu shot that she received around the same time." *Id.* However, Dr. Warrell noted that "[m]ore recently, over the past few weeks, she has had similar discomfort in the right shoulder." *Id.*

Dr. Warrell examined Petitioner's shoulders and found a "mildly positive" Hawkins test bilaterally. Ex. 17 at 3. He also ordered x-rays, which did not show any abnormalities. *Id.* Dr. Warrell discussed treatment options, including conservative management, formal physical therapy ("PT"), and steroid injections. *Id.* Petitioner decided to proceed with self-directed therapeutic exercises only. *Id.*

Following this appointment, there was another gap in treatment of three months. On October 22, 2020, Petitioner followed up with Dr. Warrell, reporting that her symptoms had not improved. *Id.* at 5. Dr. Warrell listed the diagnosis as "bilateral shoulder subacromial impingement/bursitis" and stated that she had bilateral shoulder pain, with the left greater than the right. *Id.* Dr. Warrell suggested that Petitioner try more regular use of anti-inflammatories while continuing to perform home exercises. *Id.* at 6. Petitioner declined an MRI or steroid injection. *Id.*

On November 25, 2020, Petitioner emailed her brother with a link to a website about post-vaccination shoulder injuries and commented, "I think this is what happened to me[.]" Ex. 11 at 1. Petitioner stated that she was "going on over a year of pain that gets worse weekly/monthly" and that she intended to go back to the orthopedist to see what other treatment was available.[4] *Id.* Dr. Hanna suggested a steroid injection. *Id.* In text messages on the same day, Petitioner asked if a steroid injection would also help a possible "ligament or tendon issue." Ex. 10 at 5.

Petitioner and Dr. Hanna exchanged further text messages on December 4, 2020, in which Petitioner asked what kind of doctor she should see to diagnose an issue with "tendons/ligaments/tissue damage." *Id.* at 5. Dr. Hanna recommended physical medicine and rehabilitation or a physiatrist. *Id.* Petitioner also commented that although she did not want a doctor who just dispensed pain medicine, she "wouldn't mind a huge shot of pain medicine in [her] arm right now." *Id.* at 3-4.

[4] Petitioner stated that she had tried physical therapy and a prednisone pack and neither had helped. Ex. 11 at 1. However, there are no records of Petitioner receiving such treatment before November 25, 2020.

C. Petitioner Receives a Cortisone Injection and Acupuncture for Left Shoulder Symptoms in Late 2020 to Early 2021

On December 5, 2020, Dr. Michael McCleary at the Orlando Orthopaedic Center requested an MRI of Petitioner's left shoulder.[5] Ex. 17 at 7. The suggested diagnosis was "rotator cuff tear, bursitis." *Id.* Petitioner underwent the MRI on December 18, 2020, which showed "mild to moderate supraspinatus tendinosis with focal interstitial tear at the anterior footprint," a "small amount of signal within the base of the superior labrum" that could reflect a "focal nondetached tear," and "mild subacromial and subdeltoid bursitis." Ex. 4 at 39. The MRI report also noted "[w]eakness. Limited range of motion x1 year. Status post flu shot." *Id.* at 38.

Petitioner had an appointment with Dr. McCleary on December 22, 2020, to discuss these findings. Ex. 17 at 10. Petitioner complained of continued soreness in her left shoulder and a tightness in her deltoid region. *Id.* At this point, it does not appear that Petitioner was still complaining of right shoulder pain. Petitioner rated the pain as 1/10 and reported having taken oral steroids with minimal improvement. *Id.* Dr. McCleary administered a cortisone injection into the subacromial space. *Id.* at 11.

On January 28, 2021, Petitioner filled out a patient information form for acupuncture physician Amanda Bouque. Ex. 5 at 37-38. Petitioner's first documented appointment with Dr. Bouque occurred on February 8, 2021. *Id.* at 39. Petitioner's chief complaint was a loss of taste and smell post-COVID exposure, but she also discussed other health issues, including her left shoulder. *Id.* at 39-40. Petitioner reported shoulder pain "since" the flu vaccine on "11/19." *Id.* at 39. At her next appointment with Dr. Bouque on February 16, 2021, Petitioner stated that her shoulder had felt better, presumably after the cortisone injection, for "just a day or two." *Id.* at 40.

D. Petitioner Treats Other Health Issues For Another Seven Months

After her acupuncture appointments in February 2021, Petitioner's medical care shifted away from her left shoulder symptoms. On April 19, 2021, Petitioner began regular sessions with Nasly Lopez, a doctor of chiropractic. Ex. 8 at 7. Petitioner's initial complaints were neck pain and a loss of smell and taste following COVID-19. *Id.* Petitioner then had sixteen additional appointments with Dr. Lopez from May to August 2021 for neck and back pain, without any mention of her left shoulder.[6] *See id.* at 8-23. Petitioner

[5] There are no records documenting any contact with Petitioner that spurred this MRI order.

[6] On June 3, 2021, Petitioner attended massage therapy. Ex. 7 at 6. The notes for this session mentioned neck, back, and shoulder pain, although which shoulder was not specified. *See id.* The massage therapist performed active release therapy of her bilateral shoulders. *Id.*

also saw Dr. Bouque many times through the end of 2021, but the treatment does not appear to have been focused on her left shoulder.[7] *Id.* at 40-45.

On June 11, 2021, Petitioner had an appointment with a nurse practitioner ("NP") at her PCP's office to discuss neck pain. Ex. 3 at 33. Petitioner reported that she woke up the day before feeling like she had pulled a muscle or pinched a nerve in her neck. *Id.* Petitioner also complained about a post-COVID-19 infection loss of smell and taste that involved episodes "in which she could smell only cigarette smoke." *Id.* The NP prescribed a muscle relaxer for Petitioner's neck pain and ivermectin for "smell and taste sensation disturbance."[8] *Id.* at 34. Petitioner did not discuss her left shoulder.

Petitioner returned to her PCP on June 29, 2021.[9] *Id.* at 28. Petitioner stated that her neck pain had resolved, but requested more ivermectin for distortions in taste and smell "based on research and discussions with others who have had similar problems." *Id.* The physician discussed the off-label use of ivermectin and the potential for side effects, but Petitioner wished to proceed. *Id.* Petitioner also did not mention her left shoulder at this appointment.

E. Petitioner Resumes Treatment of Her Left Shoulder in Fall 2021

On August 26, 2021, Petitioner underwent a thermogram administered by a different chiropractor, Dr. William Palmer.[10] Ex. 5 at 5-15. Dr. Palmer's report listed Petitioner's concerns as "consistent breast pain since 2014" that hurt more on the left side, a "flu shot injury in the left shoulder where she was given it," left hip bursitis, and painful swelling on her left thigh. With regard to her upper extremities, the thermogram

[7] On February 23, 2021, Petitioner purchased a package of services from Dr. Bouque, including acupuncture, nutrition, fire cupping, ear seeds, "energy work," and supplements. Ex. 5 at 46-47.

[8] Ivermectin is an antiparasitic medication. *See Ivermectin*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=26466 (last visited November 13, 2025).

[9] Petitioner also saw her PCP on August 13, 2021 for sinusitis. Ex. 3 at 19. She also did not mention her left shoulder at this appointment.

[10] Thermography is "a technique wherein an infrared camera is used to photographically portray the surface temperatures of the body, based on the self-emanating infrared radiation; sometimes employed as a means of diagnosing underlying pathologic processes, such as breast tumors." *Thermography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=49629 (last visited Nov. 13, 2025). The thermography report contained the following warning: "This Report is intended for use by trained health providers to assist in evaluation, diagnosis, and treatment. It is not intended for use by individuals for self-evaluation or self-diagnosis. This Report does not provide a diagnosis of illness, disease or other condition. Clinical Thermology is a screening procedure subject to both false negative and false positive results. It is most reliable when a stable baseline is obtained followed by regular repetitive screening for changes. Results must be interpreted in the context of historic and current clinical information." Ex. 5 at 9.

found "areas of hyperthermia on both shoulders/deltoid regions (L>R)" that "may be linked to myofascial/joint related inflammation and/or to the reported flu shot injury." *Id.* at 8.

On September 13, 2021, Petitioner had an appointment with Dr. Lopez. Ex. 8 at 24. Unlike her previous appointments, Petitioner now complained of left shoulder pain in addition to neck pain and thoracic pain. *Id.* Dr. Lopez wrote that Petitioner "explained that she had been feeling pain near the injection site of her flu vaccine from September 2019." *Id.* Petitioner had nine additional appointments with Dr. Lopez in September 2021 to December 2021 that addressed left shoulder pain. *See id.* at 26-42.

Petitioner had a PCP appointment on September 16, 2021. Ex. 3 at 8. Petitioner requested medication for the ongoing loss of smell and taste, an orthopedic referral for left hip and left shoulder pain, and testing for small intestine bacteria overgrowth. *Id.* at 8-10. Petitioner described her left hip and left shoulder pain as getting worse despite acupuncture. *Id.* at 9. Petitioner's doctor provided the requested referral.[11] *Id.* at 11.

On September 23 and 30, 2021, and October 22, 2021, Petitioner was seen by myofascial release massage therapist Kathy Conyers. Ex. 6 at 5-8. Petitioner requested whole body treatment, but also mentioned that she had found a doctor in California that had a treatment for what was wrong with her shoulder. *Id.* at 5. On another page of Ms. Conyer's records, she noted that Petitioner was part of a website group for post-injection pain and was "invited for seminar [with] DOC in NAPA valley who uses [ultrasound] to find area of injury: remove." *Id.* at 6. Ms. Conyers also wrote that Petitioner had a "flu shot injury" two years ago or "October 2019" and experienced "debilitating pain" and decreased range of motion ("ROM"). *Id.* at 8.

Petitioner underwent an ultrasound on her left shoulder on November 4, 2021. Ex. 4 at 35. The procedure notes stated that Petitioner had a history of "[p]ain since flu vaccine 2019." *Id.* The ultrasound did not reveal any abnormalities. *Id.*

On December 22, 2021, Petitioner had a telehealth appointment with Dr. Nicholas Gularte, who worked with Dr. Marko Bodor, a recognized interventional spine and sports medicine physician.[12] Ex. 9 at 8. Dr. Gularte wrote that Petitioner's chief complaint was "[l]eft shoulder pain status post flu vaccine" and took a detailed history of this issue.

[11] In the Petition, Petitioner alleged that she saw a physical therapist at Orlando Orthopaedic Center eight times from September 17, 2021 through November 2, 2021. Petition at ¶ 7. However, the only records filed for these sessions are billing records that do not include any treatment notes. It is therefore unknown what area(s) of Petitioner's body were treated.

[12] Dr. Bodor's office was in Napa, California, and thus he appears to be the doctor referenced in Ms. Conyers' notes. *See* Ex. 9 at 8. Both Petitioner and Respondent describe this visit as being with Dr. Bodor himself, but the notes are signed "Nicholas P. Gularte, D.O., M.S. for Marko Bodor, M.D." *See id.* at 9.

Petitioner told Dr. Gularte that she "experienced pain immediately" following the vaccination and the pain "persisted since that time and she has experienced progressive worsening of the pain." *Id.* Petitioner also described difficulties raising and lifting her arm, particularly when getting dressed. *Id.* Dr. Gularte diagnosed "[l]eft shoulder pain likely related to flu vaccine" and "[p]ossible rotator cuff tendinopathy" also due to the flu vaccine.[13] *Id.* at 9.

Petitioner then travelled to Napa, California for treatment. On March 3, 2022, Petitioner had an office visit with Dr. Gularte. *Id.* at 5. After reviewing her December 18, 2020 MRI, Dr. Gularte diagnosed Petitioner with "[l]eft shoulder pain likely due to shoulder injury related to vaccine administration" and "left supraspinatus tendinopathy." *Id.* Dr. Gularte used an ultrasound to locate "two distinct lesions" in Petitioner's infraspinatus tendon and humeral head "with cortical irregularity that correspond to pain generators in her left shoulder." *Id.* Dr. Gularte then performed an ultrasound-guided injection of lidocaine into these areas. *Id.* at 5-6.

The next day, March 4, 2022, Dr. Bodor performed an ultrasound-guided aspiration and debridement of the left infraspinatus and teres minor tendons and adjacent bone. *Id.* at 9-10. Dr. Bodor noted a diagnosis of "[v]accination-related shoulder dysfunction (shoulder injury related to vaccine administration)." *Id.* at 9. After the procedure, Petitioner stated that she had no pain raising her arm and had full ROM. *Id.* at 10.

F. Petitioner's Final Left Shoulder Treatment

After she had returned home, Petitioner saw Dr. Lisa Valastro at New Regeneration Orthopedics on April 25, 2022. Ex. 16 at 12. Dr. Valastro stated that Petitioner had experienced "left shoulder pain following influenza vaccination on 9/30/2019," and was "hoping in this visit to determine a precise area of tendon that was causing her pain." *Id.* at 18, 19. Petitioner described a "stabbing, shooting, aching, sharp, tight/stiff" sensation that was associated with weakness but "no radiation." *Id.* Dr. Valastro diagnosed "SIRVA," "bone marrow edema at the supraspinatus and infraspinatus insertions," and "large cortical defects in the humeral head beneath the infraspinatus and teres minor." *Id.* at 19.

At this appointment, Dr. Valastro administered anesthetic injections into the left infraspinatus and teres minor tendons and glenohumeral joint. *Id.* at 19. Dr. Valastro also recommended shockwave therapy and Petitioner participated in her first session.[14] *Id.* at

[13] Dr. Gularte also noted that Petitioner "has been working and communicating with Attorney Daniel Alholm." Ex. 9 at 8.

[14] "Extracorporeal shock wave therapy (ESWT) is the transcutaneous application of high-energy acoustic

12-13, 19. Petitioner acknowledged that this treatment was "well-studied for several orthopedic conditions such as tennis elbow, golfer's elbow, and plantar fasciitis," but experimental for her conditions. *Id.* at 12. Petitioner received two more shockwave therapy sessions in May 2022 and June 2022. *Id.* at 8-10. At the June session, Petitioner reported that she had started to notice improvement. *Id.* at 8.

However, at a follow-up telehealth appointment with Dr. Valastro on August 10, 2022, Petitioner stated that the improvement had "since gone away" and that she had not had any pain relief from the most recent treatment. *Id.* at 7. Dr. Valastro encouraged Petitioner to keep doing home exercises. Dr. Valastro also recommended new MRI imaging in order to "pinpoint the current pain generator in her shoulder in order to properly move forward with treatment." *Id.*

Petitioner did not file records for any further treatment.

G. Witness Evidence

Petitioner filed her first affidavit, dated May 5, 2022, shortly after the claim's initiation. *See* Ex. 2 at 1-2. This affidavit is quite brief and contains few factual details. Primarily, Petitioner testified that she experienced pain in her shoulder immediately after the vaccination, and that she consulted with her brother about her condition before seeking formal treatment. *Id.* at 1. Notably, Petitioner did not include any statement that her pain had continued for six months post-vaccination. *See id.*

Following the status conference held on February 3, 2023, Petitioner filed a new declaration on May 3, 2023. Ex. 12 at 1. Also included in this filing were declarations of her brother, husband, and mother.[15]

In Petitioner's second declaration, she now stated that she had experienced pain "every day since September 30, 2019." Ex. 12 at 1. Petitioner explained that between September 30, 2019, and July 27, 2020 (the date of her initial orthopedist appointment), she spoke with her brother at least four times to discuss her left shoulder pain. *Id.* Petitioner also researched her condition on the Internet. *Id.* According to Petitioner, she

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waves to break down tissue or to promote healing and repair." *See The evolving use of extracorporeal shock wave therapy in managing musculoskeletal and neurological diagnoses*, Mayo Clinic, https://www.mayoclinic.org/medical-professionals/physical-medicine-rehabilitation/news/the-evolving-use-of-extracorporeal-shock-wave-therapy-in-managing-musculoskeletal-and-neurological-diagnoses/mac-20527246 (last visited November 13, 2025).

[15] Petitioner's May 5, 2022 affidavit was notarized. *See* Ex. 2 at 1. However, her later statement, as well as that of her brother, husband, and mother, were not. These later statements indicate that they were signed under penalty of perjury, but do not reference 28 U.S.C. § 1746.

was hesitant to seek medical care after the COVID-19 Pandemic began in March 2020, but by July 2020 she "decided that [she] was in too much pain to put it off any longer," and made the appointment with Orlando Orthopaedic Center. *Id.*

Dr. Hanna's declaration similarly stated that "[b]etween September 30, 2019, and July 27, 2020, on a minimum of four occasions, my sister and I discussed that she was experiencing left shoulder pain following her receipt of an influenza vaccine in her left arm." Ex. 13 at 1. Dr. Hanna disclaimed any ability to provide medical testimony, stating that he never examined Petitioner and had "no medical opinions regarding the cause of her shoulder pain and her care and treatment." *Id.*

Petitioner's husband, Dave Holbrook, provided his views on Petitioner's condition. *See* Ex. 14 at 1. Mr. Holbrook asserted that he observed Petitioner having pain since September 30, 2019. *Id.* Between September 30, 2019 and July 27, 2020, he saw Petitioner researching and trying out different methods to address her pain. *Id.* He also saw her condition progressively worsen and stated that she had difficulty performing tasks like brushing her hair. *Id.* at 2. Mr. Holbrook attributed Petitioner's delay in seeking treatment to having other health issues that required her attention, putting the needs of her children and others first, the COVID-19 Pandemic, the fact that she was in "constant consultation" with her brother, and her attempts to find a remedy on her own. *Id.* at 1-2.

Petitioner's mother, Phoebe Hanna, also submitted a declaration. Ms. Hanna saw Petitioner almost every day between September 30, 2019 and July 27, 2020 and was aware during that time that Petitioner "was suffering a left shoulder injury related to vaccine administration." Ex. 15 at 1. Ms. Hanna observed that Petitioner did not have full use of her left arm and also observed Petitioner applying ice and therapeutic patches to her left shoulder and regularly taking Tylenol. *Id.* Ms. Hanna also had to assist Petitioner in daily activities or caring for her children due to her shoulder pain. *Id*.

Analysis

I. Six-Month Severity Requirement

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered an injury falling within the Vaccine Injury Table, or (2) that he suffered an injury that was actually caused by his vaccine. *See* Sections 13(a)(1)(A) and 11(c)(1). Regardless of how a claim is framed or arises, however, all petitioners must demonstrate that the injured person has "suffered the residual effects or complications of his illness, disability, injury, or condition for more than six months after the administration

of the vaccine."[16] Section 11(c)(1)(D)(i). Cases may appropriately be dismissed for failure to substantiate the severity requirement. *See, e.g.*, *Hinnefeld v. Sec'y of Health & Hum. Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that a petitioner's Guillain-Barré Syndrome resolved less than two months after onset).

Petitioners carry the burden of establishing the matters required in the petition, including the severity requirement, by a preponderance of the evidence. Section 13(a)(1)(A); *see Song v. Sec'y of Health & Hum. Servs.*, 31 Fed. Cl. 61, 65-66 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 2014). Congress has stated that the severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied,* 132 S.Ct. 1908 (2012); *Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

The Act prohibits finding that a petitioner has met this burden "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a). Medical records must be considered, *see* Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, the Federal Circuit has recently "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 & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The factual matters required to prove elements of a Vaccine Act claim, including severity, may be established by a *mix* of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing Section 12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

II. Petitioner Has Not Established Severity with Preponderant Evidence

In this case, to meet the statutory six-month severity requirement Ms. Holbrook must preponderantly demonstrate that she suffered the "residual effects or complications" of her claimed injury beyond March 30, 2020 (assuming an onset of September 30, 2019). *See* Section 11(c)(1)(D)(i). Respondent's challenge centers on Petitioner's lack of *any*

[16] Petitioner does not allege, nor would the evidence support, either alternative for establishing the severity requirement: that the alleged injury resulted in death, or "inpatient hospitalization and surgical intervention." Section 11(c)(1)(D)(ii), (iii).

formal treatment for her left shoulder for *nearly ten months* post-vaccination. Rule 4(c) Report at 7-8; Resp't Opp'n at 5-7. Petitioner's argument in reaction conflates severity and onset, relying on proof supporting the conclusion that she began to experience pain within 48 hours of vaccination. *See* Pet'r Mot. at 9-14. As it stands, I do not doubt based on the record that Petitioner can establish 48-hour onset consistent with this Table element, as evidenced by her September 30, 2019 text message to her brother.

But Petitioner has failed to sufficiently connect this pain to her later complaints and treatment, and/or to provide a persuasive explanation for her lengthy treatment gap. In so finding, I give significant weight to the fact that Petitioner's first orthopedic appointments were for *bilateral* shoulder pain. Dr. Warrell's notes from the July 27, 2020 appointment do not suggest a single, ongoing vaccine-related injury. Although Petitioner endorsed pain in her left shoulder for approximately ten months that she "initially" felt was related to the flu vaccine, the pain "began insidiously," and she had recently developed a "similar discomfort in the right shoulder." *See* Ex. 17 at 2. At her next appointment, on October 22, 2020, again after a notable gap in treatment (and now well-beyond the six month period), Dr. Warrell still addressed Petitioner's symptoms as a bilateral shoulder issue. *Id.* at 5-6. Petitioner is thus incorrect that she never provided any medical history that was inconsistent with a persistent concern since vaccination 10-plus months prior.[17] *See* Pet'r Mot. at 14.

Petitioner further argues that she consistently described her left shoulder pain as manifesting "after" the September 30, 2019 vaccination. *See id.* at 12, 14. For support, Petitioner lists instances in which her treaters set forth in records that her pain originated from the flu vaccine -- specifically the December 18, 2020 MRI report; the September 13, 2021 appointment with Dr. Lopez; the November 4, 2021 ultrasound report; the December 22, 2021 appointment with Dr. Gularte; and the April 25, 2022 appointment with Dr. Valastro. *Id.* at 13. However, this evidence is more supportive of a favorable onset finding than proof of severity. Petitioner's subjective attribution of all left shoulder issues to the flu vaccine over a three year period does not answer the question of whether she *likely* experienced pain during at least the first six months after vaccination, as required by statute, and for which there are no contemporaneous records. Given the extensive treatment gaps and periods of focus on other health issues, I give less weight to these later records.

[17] Petitioner also argues that "there is nothing in the record that provides an alternative explanation for [her] left shoulder injury." Pet'r Mot. at 14. I note, however, although Respondent does not challenge the first or fourth SIRVA elements, Petitioner had previously complained of back and breast/chest pain that seemingly involved her left upper extremity. In any event, the gap *itself* – coupled with the treatment records from the time after – allows for the possibility of an alternative injury.

Petitioner's other explanations for the ten month delay do not assist her in overcoming this crucial lack of evidence. As Respondent notes, the COVID-19 Pandemic did not cause closures until mid-March 2020, by which point almost the entire six-month period had passed. *See* Resp't Opp'n at 6. There are no medical records for the months of October 2019 through February 2020 establishing efforts to treat shoulder pain.

Further, although Petitioner suggests that she was in constant consultation with her brother regarding her symptoms, none of their text messages or emails date from the six-month period. *See* Pet'r Mot. at 11-12. As to the contention that Petitioner did not seek medical care for ten months because she had young children or because she was researching her symptoms on her own, this *could* in some cases be an acceptable bridge for a treatment gap. It is not uncommon for SIRVA petitioners to attempt to self-treat or delay seeking care due to work or family obligations. Here, however, the later records document a variety of left shoulder treatment but do not supply the missing information about the first six months after vaccination.

Petitioner also relies on her own testimony that her shoulder pain persisted for more than six months. *See id.* at 10. But that the Vaccine Act prevents me from finding a petitioner entitled to compensation based upon the petitioner's claims alone. *See* Section 13(a). Rather, corroboration of statements about such matters is reasonably sought – but missing in this case. Additionally, Petitioner's first affidavit did not even address severity, and this issue was only corrected during litigation. Petitioner cannot meet the sixth-month severity requirement based on her personal statements, some of which came long after the relevant timeframe.

I also find that the statements of Petitioner's family members are entitled to less weight. Petitioner's husband and mother were well-placed to observe the effects of an alleged injury, but their declarations were written three years after the fact, and also lack in detail. Both Ms. Hanna and Mr. Holbrook make generic statements about the condition of Petitioner's left shoulder during the entire ten month period, from September 30, 2019 through July 27, 2020, but ignore that at the first orthopedic appointment Petitioner reported *bilateral* shoulder pain. *See* Ex. 14 at 1-2; Ex. 15 at 1-2. Without some further anchoring as to time or more specific recollections, these declarations are not sufficiently corroborative.

In light of Petitioner's lengthy delay in seeking out formal treatment, her initial invocation of bilateral shoulder pain as her principal complaint, the extended gaps once she did begin treatment, and the lack of contemporaneous support for the more recent declaration statements, I conclude that Petitioner has not met the sixth-month severity

requirement.[18] In her motion, Petitioner requested the opportunity to pursue a causation-in-fact claim in the event of a ruling that her Table claim cannot proceed. *See* Pet'r Mot. at 14. However, a failure to meet the statutory six-month severity requirement is fatal to both forms of claim.

Conclusion

Petitioner has presented insufficient proof to establish the six-month severity requirement. Section 11(c)(1)(D). Therefore, she is ineligible to pursue compensation. Petitioner's motion for ruling on the record (ECF No. 26) is **DENIED.** In the absence of a timely-filed motion for review (*see* Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this Decision.[19]

IT IS SO ORDERED.

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

[18] Respondent also argues that Petitioner's pain was not limited to the shoulder in which she received the vaccine, contrary to the Table SIRVA QAI. Rule 4(c) Report at 8-9; Resp't Opp'n at 7. The evidence cited by Respondent is not supportive and does not indicate that Petitioner ever presented her left shoulder pain as radiating or being linked to other areas of pain. However, it is unnecessary to discuss this issue further because I rule against Petitioner on severity.

[19] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.