In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1416V

Filed: September 22, 2022

JULIE NICHOLSON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Influenza ("flu") Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA"); Dismissal Decision

Isiah R. Kalinowski, Maglio Christopher & Toale, Seattle, WA, for Petitioner
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On October 3, 2017, Petitioner Julie Nicholson filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program") alleging that she suffered from a Shoulder Injury Related to Vaccine Administration ("SIRVA") as a result of the influenza ("flu") vaccine she received on October 3, 2016. Pet. at 2, ECF No. 1.

[1] This Decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Decision will be available to the public in its present form. *Id.*

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

Upon review of the evidence in this case, I find that Petitioner has failed to preponderantly demonstrate that the vaccine she received caused her condition. The petition is accordingly dismissed.

I. Procedural History

Petitioner filed her petition on October 3, 2017. Pet. at 1. She filed medical records in support of her claim on October 5, 2017 (Exs. 1-10), and an affidavit on December 26, 2017. ECF Nos. 7, 8, 11. Respondent then filed his Rule 4 Report on October 2, 2018, recommending that entitlement be denied. Resp't's Rep. at 1; ECF No. 22.

Petitioner filed a second affidavit (Ex. 12) and additional medical records on February 7, 2019 (Ex. 13). ECF No. 25.

I held a status conference February 28, 2019, where I asked the parties whether a ruling addressing the issue of onset of Petitioner's symptoms would help to move the case forward. Respondent indicated that it would not, since Respondent believed there were several issues besides onset with Petitioner's case. ECF No. 26 at 1. I asked Petitioner's counsel if any additional objective evidence existed that may assist in pinpointing the date of onset. Specifically, I asked whether Petitioner had confirmed that there was no record of the phone call she allegedly made to her doctor the day after her flu vaccination. Petitioner's counsel stated that he would search for a record of that phone call, or any additional evidence that may clarify the date of onset. *Id.* at 2. ECF No. 26.

Petitioner filed a third affidavit (Ex. 14) and additional medical records on April 15, 2019 (Exs. 15-18).

Petitioner filed an expert report from Dr. Naveed Natanzi (Ex. 20) along with supporting medical literature on February 20, 2020. Exs. 21-41. Respondent filed a responsive expert report from Dr. Geoffrey Abrams (Ex. A) and supporting medical literature on July 17, 2020 (Ex. A, Tabs 1 – 13, Ex. B). Petitioner filed a second expert report on September 15, 2020 (Ex. 43). Respondent filed a second responsive expert report on April 30, 2021, along with supporting medical literature.

On May 25, 2021, I held a second status conference. ECF No. 55. I informed the parties that I believed that Petitioner was unlikely to succeed in her claim, given 1) timing, 2) prior left shoulder pain, and 3) alternative causation. *Id.* at 1. Each of these issues standing alone would make it difficult for Petitioner to prevail in this case, but when taken together, they effectively eliminate any path for Petitioner to receive compensation. *Id.* Accordingly, I ordered Mr. Kalinowski to file a status report indicating whether Petitioner would like to file a motion to dismiss or a motion for a ruling on the record.

On June 30, 2021, Petitioner filed a motion for a ruling on the record. Pet'r's Mot., ECF No 57. Respondent filed his response on September 7, 2021. Resp't's Resp. ECF No. 59. On September 8, 2021, my law clerk reached out to Petitioner's counsel via email to inquire if

Petitioner intended to file a reply brief. Counsel responded that Petitioner did not. *See* Informal Communication (Remark) of September 13, 2021.

On September 21, 2021, the parties filed a joint status report indicating that the record was complete for a ruling on the record. ECF No. 60. This matter is now ripe for an adjudication.

II. Relevant Medical Records

A. Petitioner's Pre-Vaccination History

Petitioner was born on October 16, 1960. Ex. 1 at 1. She was diagnosed with multiple sclerosis in 1999. Ex. 2 at 167.

Petitioner had previously received flu vaccinations on November 13, 2014 and October 13, 2015. Ex. 1 at 4. She received a Tdap vaccine on November 18, 2015. *Id.*

On September 26, 2012, Petitioner visited Dr. Michael Will at Lynchburg General Hospital for several complaints, including "pain about her left arm, also some pain about the chest." Ex. 2 at 198. X-rays taken on September 28, 2012 showed no damage to the left arm. Ex. 5 at 43. A doppler ultrasound of her left upper arm was likewise negative. *Id.* Dr. Will stated that he suspected the chest pain was "more GI in origin." Ex. 2 at 200. Dr. Will emphasized that Petitioner needed to be consistently taking her insulin, as her diabetes was uncontrolled and poorly managed. *Id.*

On September 28, 2012, while still in the hospital, Petitioner was seen by Dr. Nathan Williams. Ex. 4 at 419. Dr. Williams noted that Petitioner was "complaining bitterly of her left arm and shoulder hurting, which she said is the reason she came in." *Id.* at 420. Dr. Williams noted that her "range of motion is a little bit limited by pain." *Id.* His notes state that the left arm pain "sounds musculoskeletal." *Id.* Dr. Williams ordered an x-ray of Petitioner's left shoulder. Ex. 2 at 192. During the x-ray, Petitioner stated that she had been feeling "pain x 3 wks, no injury." *Id.* Petitioner was also noted to be suffering from "left arm pain and swelling." *Id.* X-rays found no evidence of an acute fracture or glenohumeral dislocation. *Id.* Petitioner was diagnosed with a cervical strain after a CT scan of the C-Spine showed degenerative changes. Ex. 4 at 420.

On November 21, 2012, Petitioner "tripped on a rug while leaving Petsmart and fell forwards to the ground." Ex. 4 at 208. Petitioner complained of "lower back, left and right arm pain, left and right knee pain, hip pain, and shoulder area/neck pain" after she was loaded into the medic unit. *Id.* Petitioner had good PMS [pulse, motor, sensory] in all extremities, an abrasion to her left knee, and some swelling/bruising to her right knee. *Id.* Petitioner's pain was characterized as moderate but aching. *Id.* at 217. X-rays of her left hand showed "a ring around the thumb that apparently could not be removed. No fracture or other bony abnormality [was] seen. *Id.* at 222. Petitioner was eventually diagnosed with a cervical strain and discharged home. *Id.* at 230.

On February 22, 2013, Petitioner was seen by Dr. Michael Okin for management of diabetes. Ex. 2 at 99. Petitioner's diabetes was eventually characterized as uncontrolled, as she did not take her insulin consistently. *Id.* at 101.

On July 16, 2013, Petitioner visited Dr. Okin in the emergency room for a follow up regarding her back pain. Ex. 2 at 96. Her glucose value was noted to be 521 at this visit. *Id.*

On March 17, 2015, Petitioner was seen at Centra Lynchburg General Hospital for neck, back, left shoulder, left hip, and right wrist pain following a motor vehicle accident. Ex. 4 at 158. Petitioner complained of left shoulder pain radiating to her neck. *Id.* at 154. X-Rays were ordered of Petitioner's pelvis and right hip. No fracture or misalignment was found. *Id.* at 158, 161. Petitioner was discharged home the same day with pain medication and was instructed not to drive. *Id.* at 163.

On April 3, 2015, Petitioner presented to Dr. Michael Okin for a follow up of pain "all over" following a motor vehicle accident on March 17, 2015. Ex. 2 at 63. Petitioner complained of "total body aches and pains including her low back without radiation. She ha[d] knee pain as well as upper back pain." *Id.* Upon examination, Dr. Okin noted "back pain, joint pain, myalgia and swelling of extremities.", as well as a headache. *Id.* Petitioner was given an x-ray and was noted to have "mild degenerative disc disease." *Id.* at 134.

On May 4, 2015, Petitioner presented to Rehab Associates of Central Virginia. Ex. 2 at 169. She presented with complaints of lower back pain related to her motor vehicle accident occurring on March 17, 2015. *Id.* Petitioner was suffering from "increased pain, decreased ROM, and decreased BLE strength." *Id.* She was noted to suffer from "functional deficits of prolonged standing, walking, squatting, bending, and lifting." Petitioner was noted to have "extreme" difficulty lifting or carrying groceries. Ex. 5 at 13.

On June 9, 2015, Petitioner presented again to Rehab Associates of Central Virginia. Ex. 5 at 13. Petitioner presented "with rounded shoulder posture and noted having to change positions frequently and holding L arm throughout entire evaluation." *Id.* Physical Therapist Matthew Nolen documented that Petitioner presented with "tenderness to touch to the PSIS [posterior superior iliac spine] and to the Lumbar paraspinals. [Petitioner] presents tenderness to touch to the piriformis on [both] sides, more [left] than [right]." *Id.* at 17. Petitioner attended a total of nine physical therapy appointments between May 4, 2015 and June 9, 2015.[3] *Id.* at 16. On the same day, Petitioner was discharged from physical therapy. Mr. Nolen's notes indicate that Petitioner demonstrated a "13 percent improvement" over the course of her physical therapy. *Id.*

On December 11, 2015, Petitioner visited the emergency department with complaints of right foot pain for four days. Ex. 4 at 7. Petitioner reported redness, drainage, and chills. *Id.* Petitioner was diagnosed with a diabetic foot ulcer and was discharged home with care instructions. *Id.* at 22.

On January 4, 2016, Petitioner was seen for an MRI of her right knee and her left ribs. Ex. 5 at 2, 3. In the provider notes, Dr. Michael Rowland stated that Petitioner had "right patellar and elbow pain, left sided rib pain." Ex. 5 at 2. Petitioner's rib exam showed no displaced rib fractures. *Id.* at 3.

[3] The medical record does not appear to contain physical therapy records from any visit aside from May 4, 2015, or June 9, 2015.

On January 21, 2016, Petitioner visited Dr. Kimberly Combs for chest pain. Petitioner described the injury as occurring on January 12, 2016, where she "fell and hit chest, both knees and right elbow." Ex. 2 at 37. Petitioner was diagnosed with "decreased range of motion of the left chest wall, difficulty taking a deep breath, hurts with palpitation, large bruise over the left breast, painful to take a deep breath in, somewhat panting." *Id.* at 40. On February 23, 2016, Petitioner received an injection to help relieve the pain in her right elbow. *Id.* at 36.

On September 2, 2016, Petitioner presented to Dr. Combs with complaints of myalgia and warts on her right hand. Ex. 2 at 24. Dr. Combs' notes state that "the onset of myalgia has been gradual and has been occurring for years (Worse this time [of] year, Has MS). *Id.* Petitioner's pain was described as a "moderate dull aching" located over the entire body. *Id.* Dr. Combs noted that the symptoms have been associated with arthralgia. *Id.*

On September 9, 2016, Petitioner presented to nurse practitioner Shauntell Kline for back pain. Ex. 2 at 19. Petitioner's pain was described as "being located in the upper back (left side)". *Id.* It was characterized as "stabbing" and did not radiate. Petitioner's symptoms were noted to be aggravated by exertion. *Id.* Petitioner also complained of leg cramping at this visit. *Id.* The onset of leg cramping was approximately one week prior. *Id.* Ms. Kline's notes indicate that "there is involvement of the left lower extremity, right lower extremity, left calf, right calf, left foot and right foot." *Id.* Upon examination, Ms. Kline noted that the "left side of back in lower rib area [was] tender to touch" and Petitioner had "normal and symmetric movement" of all her extremities. *Id.* at 22.

On October 3, 2016, Petitioner presented to Dr. Combs for a recheck of her back pain. Ex. 2 at 14. Petitioner's pain was described as "being located in the upper back (left side)". *Id.* It was characterized as "stabbing" and did not radiate. *Id.* Dr. Combs noted that the pain had begun approximately one month prior. *Id.* Upon examination, Petitioner was noted to have "joint pain, joint swelling, joint stiffness and muscle spasm." *Id.* at 16. Dr. Combs noted that Petitioner was diagnosed with fibromyalgia and prescribed Lyrica. *Id.* at 16. Petitioner received her flu vaccination at this visit. *Id.* at 17.

B. Petitioner's Post-Vaccination History

On November 3, 2016, Petitioner presented to Dr. Peter Konieczny at CMG Neurology for a follow up of her multiple sclerosis. Ex. 6 at 18. Petitioner complained that "I hurt, my muscles hurt, feel like spiders are crawling on me, little tingly things." *Id.* Dr. Konieczny's notes indicate that Petitioner had not seen a neurologist since 2011 because she "didn't feel [as if she] needed to." *Id.* Petitioner complained of "fatigue, muscle pain, and paresthesias which have been problematic now for 2-3 months." *Id.* Upon performing a neurologic exam, Dr. Konieczny noted that Petitioner's shoulder shrug was "5/5 strength." *Id.* at 18. A musculoskeletal exam revealed that "strength and tone in all major muscle groups WNL for age and [d]emonstrates symmetrical movements." *Id.* Dr. Konieczny stated that "I'm not enti[r]ely sure how her symptoms of diffuse pain and paresthesias are related to MS, if in any way. Repeat MRIs are warranted." *Id.* at 19. Petitioner was prescribed physical therapy.

On November 16, 2016, Petitioner was seen for an MRI of her cervical spine. Ex. 6 at 23. The MRI revealed several degenerative findings, which Dr. Konieczny characterized as "mild diffuse atrophy." *Id.* at 24.

On November 22, 2016, Petitioner presented to Dr. Kimberly Combs with complaints of arm pain "occurring in a persistent pattern for 1 month." Ex. 2 at 10. Petitioner described the pain as "moderate." Dr. Combs noted that "since 10/3/16 flu shot she has had left arm/shoulder pain." *Id.* An examination revealed that Petitioner's pain radiated "from the le[ft] shoulder down into forearm." *Id.* at 13. Petitioner was also noted to be suffering from depression at this visit. *Id.*

On December 14, 2016, Petitioner was seen at OrthoVirginia by Dr. Ian Smithson. Ex. 7 at 56. Under "history of present illness", Dr. Smithson's notes indicate that

> for the past 2 months, [Petitioner] has had shooting pain radiate from her anterior shoulder down her forearm. She believes the flu shot stemmed her pain that she received on 10/3/16. Pain interrupts her sleep because she likes to sleep on her left side. Pain is also aggravated with driving and lifting items. Denies symptoms of numbness and tingling. Does not have radicular pain in hand.

Id. Dr. Smithson noted that Petitioner suffered from both fibromyalgia and MS. *Id.* Upon examination, Petitioner had no swelling, ecchymosis, erythema, or induration. *Id.* at 57. Her shoulder was tender to "palpitation at [the] anterior shoulder," and her range of motion exam revealed she had a loss of internal and external rotation. *Id.* Dr. Smithson explained to Petitioner that he did not believe her symptoms were related to her flu shot, but instead were consistent with adhesive capsulitis. *Id.* at 56. Dr. Smithson noted that Petitioner was seeking information "because she has been consulting a lawyer regarding flu shot being administered incorrectly. She was advised for home exercise program and steroid injection. Did not wish to proceed with steroid injection. She admitted she will not do at home exercise program but did request more information regarding adhesive capsulitis." *Id.* Petitioner was prescribed physical therapy. *Id.*

On January 13, 2017, Petitioner was seen by physical therapist Kristine Lee. Ex. 7 at 60. Ms. Lee's notes indicated that Petitioner "developed left shoulder pain [anterior] [s]houlder which goes down arm and stiffness since getting fl[u] shot 10/3/2016…Patient feels like the pain has gotten worse since she saw the [d]octor. Pain is 7-8/10 today during therapy with movement." *Id.* Petitioner's current level of function was noted as "basically reports keeps the left arm at side with walking." *Id.*

Petitioner saw Ms. Lee for physical therapy again on January 17, 2017. Ex. 7 at 62. Petitioner noted that her arm felt better "after the heat." *Id.* Following the session, Petitioner was able to let her arm "hang at side after PROM." *Id.* Ms. Lee noted that Petitioner "still walks with it adducted to side with elbow flexion." *Id.*

Petitioner had another physical therapy session on January 20, 2017. Ex. 7 at 64. Petitioner noted that "my left shoulder feels so much better after heat that I can use the arm a little. Otherwise I have to keep it at my side." *Id.* Ms. Lee noted that "Patient did better with PROM left shoulder ER today, but still quite painful with elevation." *Id.* at 65. On January 23, 2017, Ms. Lee noted

that Petitioner was "still with pain with PROM shoulder and axilla. Needed verbal cues for correct technique with [swiss ball] roll outs which she also does at home." *Id.* at 67. On January 27, 2017, Ms. Lee noted that Petitioner "continues to have pain with PROM and AROM left shoulder. Still braces left arm at side with walking." *Id.* at 72.

On January 31, 2017, Petitioner again presented for physical therapy with Ms. Lee. Ex. 7 at 73. Ms. Lee's notes indicate that "Patient states she can't pick up a coffee cup with Left UE. The only thing that has improved since starting therapy is that she can raise [her] arm to the side a little to put deodorant on. [She is] keeping [her] arm at [her] side all the time otherwise." *Id.* Ms. Lee's assessment was that "Petitioner has not made progress with AROM Left shoulder since SOC. Actually has less IR and ER. Still diffusely tender around scapula. Significant pain with all PROM. Elbow extension has improved." *Id.* at 74.

On February 3, 2017, Petitioner had her last physical therapy appointment with Ms. Lee. Petitioner stated that her left shoulder was "feeling about the same" and that it was "still very sore and she couldn't use her arm for anything." Ex. 7 at 75. Ms. Lee's notes from February 3, 2017 indicate that she was treating Petitioner for "adhesive capsulitis of the left shoulder." *Id.*

On April 21, 2017, Petitioner presented to Dr. Smithson for evaluation of left shoulder pain. Ex. 8 at 6. Petitioner's history indicates that "for the past 5 months, she has had shooting pain radiate from her anterior shoulder down her forearm. She believes the flu [shot] she received on 10/3/16, incited the pain." *Id.* Dr. Smithson noted that Petitioner's range of motion had "worsened because she has been apprehensive in working through her pain." *Id.* at 9.

On June 9, 2017, Petitioner suffered a fall while carrying boxes from her living room to her car. Ex. 10 at 13. Petitioner landed on her right hip and was unable to bear weight on her right leg. *Id.* Petitioner was eventually diagnosed with fractures in her pelvis and was mostly confined to a wheelchair. *Id.* at 11.

On August 30, 2017, Petitioner visited Dr. John Prahinski for pain in her right shoulder and right pelvis. Ex. 10 at 5. Petitioner was described as being "mostly in the wheelchair" and using a "walker in the house to get around to the refrigerator." *Id.* Dr. Prahinski noted that Petitioner had sustained a fall in early June which resulted in a sacral ala fracture and right pubic rami fractures. *Id.* Dr. Prahinski diagnosed Petitioner with glenohumeral arthritis of the right shoulder, and "unspecified chronicity" of right shoulder pain. *Id.* at 6. Petitioner made no mention of left shoulder pain at this visit. Petitioner received a glenohumeral injection to her right shoulder on September 7, 2017 to relieve her symptoms. *Id.* at 2.

On October 17, 2017, Petitioner visited Dr. Prahinski for a follow up on pain in her pelvis and right shoulder. Ex. 13 at 5. Petitioner stated that her shoulder pain had improved significantly with a glenohumeral injection. *Id.* at 6. Petitioner's left shoulder was not mentioned at this visit, and left shoulder pain was not listed in Petitioner's problem list. *Id.* at 9-10.

On February 16, 2018, Petitioner visited Dr. Omar Elkhamra for pelvis pain. Ex. 13 at 11. Petitioner complained of right sided pelvis pain and left ankle pain "for the past few months with no inciting injury." *Id.* Petitioner made no mention of either left or right shoulder pain at this visit.

On August 17, 2018, Petitioner visited Dr. Ian Smithson for chronic left shoulder pain. Ex. 13 at 18. Petitioner reported that she believed that the flu vaccine she received on October 3, 2016 incited her pain. *Id.* Petitioner reported persistent pain of her left shoulder, "localized over the anterolateral aspect of the shoulder with limited motion." *Id.* Petitioner was given a glenohumeral injection in her left shoulder. *Id.* X-rays of the left shoulder demonstrated a "type 1 acromion with moderate genohumeral joint space narrowing without fracture, dislocation, or subluxation." *Id.* at 26.

III. Affidavits

A. Petitioner's First Affidavit

Petitioner submitted her first affidavit on December 26, 2017. Ex. 11. Petitioner stated that "she mentioned to the vaccine administrator that it seemed she was injecting the vaccination too high, but she assured me that it was in the correct location. I felt pain within two hours from the vaccination." *Id.* at 1. Petitioner further stated that "The next day I had trouble moving my left arm. I remember taking note that it was impossible for me to use my left arm to turn my steering wheel when driving. Soon I could hardly move my left arm because of this injury." *Id.*

Petitioner also averred that she was unable to book a doctor's appointment until approximately one month after her vaccination. Ex. 11 at 2. At the primary care provider's office, Petitioner's doctor referred her to an orthopedist for additional evaluation and treatment. *Id.* The orthopedist speculated that Petitioner might be developing fibromyalgia and prescribed Lyrica as treatment. *Id.*

B. Petitioner's Second Affidavit

On February 7, 2019, Petitioner submitted a second affidavit in response to Respondent's Report. Ex. 12. Petitioner stated that "the place on my shoulder where [the nurse] injected the vaccine immediately hurt." *Id.* at 1. She further stated that the next day she "called the doctor's office where [she] had received the vaccination to complain that my left arm hurt ever since the vaccination was administered, but was told the pain was normal, that my muscle was just sore from the needle prick and [would] get better." *Id.*

Petitioner then stated that she noticed "more pain on the morning of 4 October 2016" which she assumed was a sore muscle from the vaccination, but the pain "got worse as that day wore on and into the next day, 5 October." Ex. 12 at 2. Petitioner stated that by October 5, 2016, she had trouble "even moving [her] shoulder." *Id.* Petitioner stated that "within 24 hours of the vaccination I knew something was definitely wrong because I could not hold so much as a coffee cup with my left hand" and that "within a few days from the vaccination…it was hard to drive because of the difficulty in turning the steering wheel with my affected arm." She further stated that she could not sleep on her left side without it hurting her. *Id.*

Petitioner stated she was unable to book a doctor's appointment until nearly two months after she had received the vaccination. Ex. 12 at 2. In the interim, she was seen by a neurologist

for her MS. Petitioner stated that she did not mention her shoulder pain at this visit because "the problem with my shoulder was not related to my MS." *Id.* Petitioner stated she was eventually diagnosed with "frozen shoulder" by an orthopedist and referred to physical therapy, which did not "substantially improve [her] situation." *Id.* at 2-3.

Petitioner further denied suffering chronic problems in her neck, stating that she suffers from "lower back pain at times." Ex. 12 at 3. Petitioner stated that on June 9, 2015, she was "noted to have 'moderate limitation' with tasks such as 'lifting or carrying items like groceries' but that does not mean I was unable to lift or carry groceries." *Id.* Petitioner noted that she "had been in a car wreck two months earlier, which caused a lot of pain and limitations." *Id.*

Petitioner also denied that her reports of pain in 2015 and 2016 were related to her left shoulder. Ex. 12 at 3. Petitioner stated that she had never suffered from an injury to her shoulder that would cause her ongoing pain or limitation to her range of motion, an injury or systemic condition that would cause adhesive capsulitis, or that chronic problems in her back and neck caused adhesive capsulitis in her shoulder. *Id.*

C. Petitioner's Third Affidavit

On March 1, 2019, I issued an order instructing Petitioner to file any additional objective evidence which may assist me in pinpointing the date of onset of Petitioner's shoulder injury. ECF No. 26.

In response, Petitioner filed a third affidavit on April 14, 2019. Ex. 14. Petitioner denied ever engaging in email correspondence with her doctors, or filing a VAERS report regarding her injury. *Id.* at 1. Petitioner denied undergoing chiropractic treatments, non-traditional treatments, or psychological treatment. *Id.* Petitioner also stated she had been unemployed since she suffered her injury. *Id.* at 2.

Petitioner also stated that she did not maintain a written journal, a calendar, or agenda at the time of her injury. Ex. 14 at 1. She did not exercise at the time of her injury. *Id.* She did not maintain telephone billing records and "did not believe telephone records would prove or disprove the facts at issue herein." *Id.* Petitioner also stated that her "financial records would not contain useful information regarding the purchase of items that would help resolve the factual disputes in this case." *Id.* Finally, Petitioner averred that she did not post on social media regarding her injury at any point. *Id.*

D. Petitioner's Fourth Affidavit

Petitioner filed a fourth affidavit on February 20, 2020. Ex. 19, ECF No. 36. Petitioner stated that she was standing while the vaccine was administered, and that her left arm was "lying at rest, roughly parallel" with her torso. *Id.* at 1.

IV. Expert Qualifications and Reports

A. Petitioner's Expert: Naveed Natanzi, DO

Petitioner submitted two expert reports from Naveed Natanzi, DO. Ex. 20 (hereinafter "First Natanzi Rep."), Ex. 43 (hereinafter "Second Natanzi Rep.").

Dr. Natanzi is board certified by the American Academy of Physical Medicine and Rehabilitation and is board-eligible by the American Board of Pain Management. Ex. 21 at 1 (hereinafter "Natanzi CV"). Dr. Natanzi received a Bachelor of Arts in Biological Studies at the University of California, Santa Barbara in 2007, and attended medical school at Western University of Health Sciences, where he received a Doctor of Osteopathy in June 2012. *Id.* at 2. Dr. Natanzi completed an internship at Downey Regional Medical Center from 2012-2013, then completed his residency in physical medicine and rehabilitation at the University of California, Irvine from 2013-2016. *Id.* at 1. Dr. Natanzi completed a fellowship at the Bodor Clinic in Napa, California from January 2017-August 2017. *Id.*

From 2017-2018, Dr. Natanzi worked at the Pasadena Rehab Institute as an attending physician specializing in interventional pain management. Natanzi CV at 1. In November 2017, Dr. Natanzi founded the Regenerative Sports and Spine Institute, and since April 2018, Dr. Natanzi has been a staff physician at the VA Long Beach Healthcare System. *Id.* Dr. Natanzi has served as a witness in several SIRVA cases in the Program since 2017. *Id.; see e.g.*, *Taylor v. Sec'y of Health & Hum. Servs.*, 2020 U.S. Claims LEXIS 2298 (Fed. Cl. Spec. Mstr. Oct. 20, 2020). He has authored seven publications and has conducted a large double-blind research study. *Id.* at 3.

B. Respondent's Expert: Dr. Geoffrey Abrams

Respondent filed two expert reports from Dr. Geoffrey D. Abrams. Ex A (hereinafter "First Abrams Rep."), Ex. C (hereinafter "Second Abrams Rep.").

Dr. Abrams received a Bachelor of Arts in Human Biology with a concentration in Neuroscience from Stanford University in 2000. Ex. B at 1 (hereinafter "Abrams CV"). He received his medical degree from the University of California, San Diego in 2007. *Id.* He completed a surgical internship at Stanford University in 2008. *Id.* Dr. Abrams completed his residency at Stanford University Hospital and Clinics in 2012, and a fellowship at Rush University Medical Center in 2013. *Id.*

Dr. Abrams is board certified in Orthopedic Surgery, with a subspeciality in Orthopedic Sports Medicine. Abrams CV at 2. He is licensed to practice medicine in Illinois and California and is a California Fluoroscopy Supervisor and Operator. *Id.* He holds academic appointments at the Stanford University School of Medicine and the Veterans Administration Hospital of Palo Alto. *Id.* at 1.

Dr. Abrams has published seventy-two peer-reviewed publications as well as a number of peer-reviewed short communications. Abrams CV at 2-22. He serves as the head team physician for several of Stanford University's varsity teams and is an assistant team physician for the Golden

State Warriors and the San Francisco 49ers. He has given numerous lectures on the topic of orthopedics. *Id*. at 22-28.

C. Dr. Natanzi's First Expert Report

Petitioner filed Dr. Natanzi's first expert report on February 20, 2020. Dr. Natanzi stated his theory of the case as follows: (1) an inadvertent overpenetration of the vaccine needle resulted in (2) bursal rotator cuff and/or capsular penetration, which caused (3) immediate pain, limited range of motion and discomfort. Petitioner's vaccine then (4) interacted with naturally-occurring antibodies from a prior vaccination, which resulted in an exaggerated, robust, and prolonged inflammatory response resulting in (5) adhesive capsulitis and rotator cuff mediated pain.[4] First Natanzi Rep. at 11.

Dr. Natanzi stated that "at the time of vaccination, [Petitioner's] left arm was in a resting, non-abducted position by her side. Both Ms. Nicholson and the injector were standing. The exact injection location on her left deltoid muscle was not recorded." *Id.* at 8.

Dr. Natanzi acknowledged that Petitioner's medical providers do not correlate her symptoms with her vaccination. First Natanzi Rep. at 8. He explained this by stating that "most people are unaware that a vaccination can cause significant shoulder dysfunction, and they often do not inherently associate adverse symptoms with a vaccination. This lack of knowledge and understanding of SIRVA oftentimes results in discrediting vaccines as sources of post-vaccination shoulder pain." *Id.*

Based on Dr. Natanzi's review of the medical records, he believed that Petitioner's shoulder pain began "immediately post vaccination and that this presentation meets the temporal relationship requirements (onset of pain within 48 hours) of a SIRVA injury." First Natanzi Rep. at 9. Dr. Natanzi's belief stems from the fact that there is no "alternative etiology for the acute development of shoulder pain in the peri-vaccination time period." *Id.*

Dr. Natanzi opined that Petitioner's adhesive capsulitis was due to the fact that her flu vaccination was improperly administered. First Natanzi Rep. at 9. Dr. Natanzi stated that the "risk of adverse reactions and overpenetration is least when both the patient and administering provider are seated and the arm is fully exposed, abducted, and flexed to 60 degrees with the hand resting on the ipsilateral hip." *Id.* Dr. Natanzi compared this optimal position with Petitioner's vaccination, stating that both Petitioner and the injector were standing, the vaccine was administered higher than normal (per Petitioner's first affidavit), and Petitioner's arm was non-abducted at the time of vaccination. *Id.* Dr. Natanzi stated that this sub-optimal vaccination procedure made it "increasingly likely" that inadvertent overpenetration of the needle caused a SIRVA injury in Petitioner. *Id.*

[4] Dr. Natanzi also opined that Petitioner's August 30, 2017 right shoulder injury was "at least in part" the result of overcompensation, "given [Petitioner's] left shoulder dysfunction since vaccination." First Natanzi Rep. at 10. Because I have found that Petitioner's left shoulder pain was not caused by her flu vaccine, I similarly conclude that her right shoulder dysfunction was not attributable to vaccination.

Dr. Natanzi then proceeded to rule out other causes of Petitioner's shoulder pain. He noted that in September 2012, Petitioner was seen in the emergency department for chest pain, nausea, vomiting, and left shoulder pain. First Natanzi Rep. at 9. While in the hospital, Petitioner was found to suffer from "mild shoulder restriction with some bicipital tenderness" and "atraumatic left shoulder pain." *Id.* Dr. Natanzi noted that following this emergency room visit, Petitioner's medical records did not mention left shoulder pain "for a few years." *Id.* at 10. Dr. Natanzi therefore attributed Petitioner's shoulder pain to her "fear of having a heart attack and not a structural shoulder injury." *Id.*

Dr. Natanzi then addressed Petitioner's March 2015 motor vehicle accident. First Natanzi Rep. at 10. Dr. Natanzi noted that the ambulance records indicated that Petitioner experienced "left shoulder pain that radiated to her neck" but that hospital records from the same day describe Petitioner with hip, neck, and wrist pain, with no mention of shoulder pain; he further noted that the medical records from April 3, 2015 describe "multiple joint complaints" but make no mention of shoulder-specific complaints. *Id.* Dr. Natanzi acknowledged that Petitioner's physical therapy notes from June 9, 2015, stated that Petitioner "was holding her left arm and had difficulty carrying groceries" but he noted that "there is not a description of why [Petitioner] was having this difficulty." *Id.* Furthermore, Dr. Natanzi noted that none of Petitioner's other physical therapy records from this time period mention shoulder pain, "which further lends likelihood to the theory that there was no significant shoulder injury in the post-motor vehicle accident period."[5] *Id.* Finally, Dr. Natanzi stated that if Petitioner's shoulder was a "true pain generator and limiting factor, [Petitioner] would have made mention of it as she did with regard to her left shoulder post-vaccination." *Id.*

Given Dr. Natanzi's interpretation of the medical records, he opined that "as a result of the motor vehicle accident, [Petitioner] experienced multiple joint strains and whiplash, which may or may not have involved the shoulder joint" and that Petitioner "did not experience a significant shoulder injury and that her symptoms were likely related to a strain which is common in the context of motor vehicle collisions." First Natanzi Rep. at 10. Dr. Natanzi stated that Petitioner's post-motor vehicle collision symptoms were "markedly different in intensity, frequency, and quality in comparison to her post-vaccination symptoms." *Id.*

Finally, Dr. Natanzi discussed Petitioner's fibromyalgia diagnosis. First Natanzi Rep. at 11. Dr. Natanzi stated that he is not convinced that Petitioner suffered from fibromyalgia, but even if she did, fibromyalgia symptoms are typically "diffuse and present throughout the body" whereas the symptoms experienced by Petitioner in the shoulder were "focal and isolated." *Id.* As a result, Dr. Natanzi opined that the presence or absence of fibromyalgia has "no bearing" on the fact that Petitioner was injured by her vaccination. *Id.*

[5] The medical records from Rehab Associates from Central Virginia do not contain any notes from the visits between May 4, 2015 and June 9, 2015. However, notes from May 4, 2015 indicate that Petitioner had "extreme difficulty" "lifting or carrying items like groceries." Ex. 2 at 164. By June 9, 2015, the records indicate that Petitioner had a "moderate limitation" "lifting or carrying items like groceries." *Id.* at 163-64.

D. Dr. Abrams' First Expert Report

Respondent filed an expert report from Dr. Abrams on July 17, 2020, responding to Petitioner's expert report. First Abrams Rep.

Dr. Abrams stated that there were "a number of factors" which would preclude ascribing Petitioner's left shoulder pain to her vaccination, including: (1) "a history of severe and uncontrolled diabetes, which is a well-known cause of adhesive capsulitis and shoulder pain"; (2) "the literature reporting on adhesive capsulitis following vaccine administration almost exclusively describes healthy patients"; (3) "the lack of any objective evidence (imaging) of a SIRVA-related injury"; (4) "A diagnosis of arthritis of the left shoulder, also a well-known source of waxing and waning shoulder pain"; (5) "numerous medical events and accidents associated with left shoulder pain prior to the index vaccination"; and (6) "No report of shoulder pain until almost two months after vaccination, including no mention of any shoulder pain during a visit with a neurologist approximately one month following the vaccination in question." First Abrams Rep. at 5.

Dr. Abrams opined that, without an MRI of Petitioner's shoulder, it was impossible to tell if Petitioner suffered a SIRVA injury, as an MRI would show symptoms of a SIRVA such as inflammation in the subacromial space. First Abrams Rep. at 7. He also noted that Petitioner did not report any ongoing left shoulder pain from April 2017 to August 17, 2018, which led him to believe that Petitioner "did not have ongoing pain at that time." *Id.* at 9. Dr. Abrams opined that this lack of ongoing pain, coupled with radiographs in August 2018 showing "moderate osteoarthritis of the shoulder", strongly suggested a non-SIRVA related cause of shoulder pain. *Id.*

Dr. Abrams stated that "There is a significant and profound effect on the petitioner's diagnosis of uncontrolled diabetes (and subsequent predisposition to inflammation and shoulder pathology) on the overall pain, function, and structure of her shoulder." He opined that because Petitioner's A1c values and blood sugar values were significantly elevated from May 2011 "up to and including the day of vaccination", Petitioner was suffering from hyperglycemia. First Abrams Rep. at 6. Dr. Abrams stated that "diabetes is the single greatest risk factor" for the development of adhesive capsulitis. *Id.*

Dr. Abrams then explained the method by which hyperglycemia causes adhesive capsulitis, stating that "hyperglycemia permanently alters tissue macromolecules through accelerated advanced glycation end-products (AGEs) formation." First Abrams Rep. at 7. Dr. Abrams noted that these AGEs have been found in cases of frozen shoulder, and that clinically, the changes caused by AGE formation can "change the biological properties of the shoulder joint capsule to decrease its elasticity (makes the shoulder stiff) and increase intrinsic inflammation (make it painful). *Id.* Dr. Abrams conceded that case reports exist of adhesive capsulitis following vaccine administration but stated that these injuries occur almost entirely in patients who are otherwise healthy prior to vaccine administration and none of the reported cases include patients with a "diagnosis of uncontrolled diabetes and prior shoulder pain." *Id.*

Dr. Abrams also differentiated between an injury to the subacromial space, and an injury to the joint capsule of an injured person's arm, stating that adhesive capsulitis is an "inflammatory

condition" of the joint capsule. First Abrams Rep. at 6. Dr. Abrams stated that the American Academy of Orthopedic Surgeons holds the position that "vaccine administration to the shoulder cannot cause or contribute to common shoulder pathologies such as…adhesive capsulitis." *Id.*

Dr. Abrams then discussed other alternative causes of Petitioner's shoulder pain. Dr. Abrams stated that Petitioner suffered from left shoulder arthritis, pointing to a radiograph from December 2016 which revealed "joint space narrowing of the glenohumeral…joint (osteoarthritis)." First Abrams Rep. at 8 (omitting internal quotations). He opined that "some of the petitioner's symptoms match th[ose] experienced by patients with mild to moderate arthritis of the shoulder. Vaccines are not known to cause arthritis of the shoulder and therefore have no etiologic factor in this condition." *Id.*

Dr. Abrams also noted that Petitioner had suffered from numerous medical events and accidents, some of which involved her left shoulder, any one of which could have led to her shoulder pain. First Abrams Rep. at 8. This included Petitioner's September 2012 admission to the hospital for "nausea, vomiting, and chest pain" which included "reported left shoulder pain" and Petitioner's March 17, 2015 motor vehicle accident in which she complained of left shoulder pain. *Id.*

Dr. Abrams then addressed Dr. Natanzi's assertion that Petitioner's right shoulder pain was caused by overcompensation due to her alleged left SIRVA injury. First Abrams Rep. at 9. Dr. Abrams disputed this assertion, noting that Petitioner "first reported right shoulder pain…on August 25, 2017, and stated that her pain had been present for over one month. Petitioner herself stated it was "possibly from [a] recent fall back in June." *Id.* Dr. Abrams further noted that on August 30, 2017, Petitioner saw Dr. Prahinski and made no mention of left shoulder pain or a need to compensate for her left shoulder at this visit. *Id.* Dr. Abrams concluded that Petitioner's right shoulder pain was likely due to her use of a wheelchair and walker following a fractured hip in June 2017, as wheelchairs and walkers place considerable stress on the shoulders. *Id.*

Dr. Abrams concluded his report by stating that Petitioner did not meet the criteria for a SIRVA injury because (1) Petitioner had a history of pain and dysfunction of the affected shoulder; (2) Petitioner's pain did not occur within 48 hours of vaccination; and (3) Petitioner's uncontrolled diabetes was a much more logical explanation for Petitioner's symptoms. First Abrams Rep. at 10.

E. Dr. Natanzi's Second Expert Report

Petitioner submitted a rebuttal report from Dr. Natanzi on September 15, 2020. Second Natanzi Rep.

Dr. Natanzi began his report by noting that both he and Dr. Abrams agree that Petitioner suffers from adhesive capsulitis but disagree as to the etiology of Petitioner's condition. Second Natanzi Rep. at 1. He also noted that Petitioner "never experienced a sustained shoulder injury prior to her vaccination in October 2016." *Id.* at 3. He supported this statement by noting that pre-vaccination, Petitioner logged "sparse, infrequent, and inconsistent complaints" regarding her left shoulder, but post-vaccination, Petitioner's complaints of shoulder pain were "sustained." *Id.*

Dr. Natanzi conceded that those patients who suffer from "uncontrolled [diabetes mellitus] have an increased chance of developing adhesive capsulitis." Second Natanzi Rep. at 1. Citing Chan, Dr. Natanzi stated that "for each unit that the HbA1c level was greater than 7, the risk of developing [adhesive capsulitis] increased 2.7%." *Id.* Using this formula, Dr. Natanzi calculated that the chance of Petitioner developing spontaneous adhesive capsulitis was anywhere from 20-46%. *Id.* He therefore concluded that "mathematically, even in light of [Petitioner's] uncontrolled [diabetes mellitus], it is more likely than not that [diabetes mellitus mediated adhesive capsulitis] does not develop." *Id.*

Dr. Natanzi disagreed with Dr. Abrams' assertion that Petitioner did not develop pain within 48 hours of her vaccination, stating that Petitioner developed pain "within hours after her vaccination". First Natanzi Rep. at 1. To support this point, Dr. Natanzi referred to Petitioner's first affidavit, in which she discussed feeling pain immediately after her shot; he also noted the medical record from November 22, 2016, in which Petitioner stated to Dr. Combs that she had pain in her shoulder for approximately one month. *Id.*, *see also* Ex. 2 at 10. Dr. Natanzi concluded that, based upon this timeline, Petitioner's injury was "more in line with a SIRVA mediated injury rather than a spontaneously occurring underlying disease". *Id.*

Dr. Natanzi then addressed Dr. Abrams' assertion that reports of SIRVA-mediated adhesive capsulitis "are in generally healthy patients." Second Natanzi Rep. at 2. He opined that "this statement is not supported by the literature" (noting one patient who was described to have underlying hypertension and chronic obstructive pulmonary disease) and that Dr. Abrams' assertion had no relevance. *Id.* Dr. Natanzi opined that if adhesive capsulitis "can happen to a healthy person without medical conditions it is even more likely to happen to someone with multiple medical conditions." *Id.*

Finally, Dr. Natanzi addressed Dr. Abrams' alternative diagnosis of osteoarthritis. Second Natanzi Rep. at 2. Dr Natanzi noted that both osteoarthritis and SIRVA "present with shoulder pain and limited range of motion; therefore, they can be challenging to distinguish based on physical exam alone. As with [adhesive capsulitis], the clinical history/context is key in differentiating whether or not osteoarthritis could be a source of [Petitioner's] pain." *Id.* Dr. Natanzi stated that osteoarthritis is a "degenerative issue with a development of pain that is characteristically slow, gradual, indolent, waxing and waning, and oftentimes progressive" as opposed to a SIRVA injury, which is "acute, sudden, and immediate." *Id.* He therefore concluded that, because Petitioner's symptoms were "acute and severe", the clinical picture was "much more in line with an acute process which is exactly what SIRVA is." *Id.*

Dr. Natanzi concluded his report by stating that "if one were to accept it as fact that Petitioner's pain began immediately (within hours) after her vaccination as she describes in her affidavit and as described by multiple medical providers" and "given the temporal relationship of symptoms to the accident coupled with physical exam findings of limited range of motion and pain – a SIRVA injury is the only reasonable diagnosis." Second Natanzi Rep. at 2.

F. Dr. Abrams' Second Expert Report

Respondent submitted a rebuttal expert report from Dr. Abrams on April 30, 2021. Second Abrams Rep.

Dr. Abrams disagreed with Dr. Natanzi's characterization of Petitioner's risk for shoulder pain due to her uncontrolled diabetes. Second Abrams Rep. at 1. Dr. Abrams noted that in a group of participants with type 2 diabetes, 63% had shoulder pain or a shoulder disability. *Id.*, *citing* Shah.

Dr. Abrams also disagreed with Dr. Natanzi's interpretation of the Chan article. Dr. Natanzi stated that "for each unit that the HbA1c level was greater than 7, the risk of developing [adhesive capsulitis] increased 2.7%." Second Abrams Rep. at 1*; citing* Second Natanzi Rep. at 1. Dr. Abrams stated that Dr. Natanzi failed "to recognize [that] the risk for developing adhesive capsulitis is cumulative over time, and if one reads from the article itself…the article states that "(f)or each unit of time (emphasis added) that HbA1c was greater than 7, there was a 3% increase in the risk of adhesive capsulitis." *Id*, *citing* Chan (emphasis in original). Dr. Abrams noted that Petitioner's blood sugar (HbA1c) was significantly elevated for at least six years prior to her vaccination. Second Abrams Rep. at 1. Dr. Abrams opined that "because of this history of elevated blood glucose over such a long time period, her risk of developing adhesive capsulitis was much greater than 20-46%, as the petitioner's expert states." *Id.*

Dr. Abrams disagreed with Dr. Natanzi that adhesive capsulitis can occur in patients with underlying conditions. Second Abrams Rep. at 2. Dr. Abrams noted that, although Dr. Natanzi pointed to a single report of "suspected SIRVA in a patient with hypertension and chronic pulmonary disease", these are conditions that have no known association with shoulder pain or pathology, "unlike diabetes, cervical pathology, [or] fibromyalgia." *Id.* Dr. Abrams therefore opined that "in patients with conditions like diabetes, or other medical diagnoses known to cause shoulder pathology, this would be a significant confounder and calls into question the accuracy of a SIRVA diagnosis." *Id.*

Dr. Abrams also disagreed with Dr. Natanzi's characterization of shoulder pain related to arthritis. Second Abrams Rep. at 2. Dr. Natanzi stated that pain linked to shoulder arthritis is "slow and gradual" rather than acute. Second Natanzi Rep. at 2. Dr. Abrams disagreed with this assertion, stating that shoulder arthritis often presents with acute complaints, and "the most common presentation for a person with shoulder arthritis is a statement that 'it just started hurting one day' and they do not recognize an inciting event." *Id.*

Dr. Abrams then turned to Petitioner's history of cervical spine disease/arthritis. Second Abrams Rep. at 3. He noted that a CT scan in November 2012 showed "multilevel degenerative changes" in her cervical spine and on an MRI taken "just after the vaccination in question, she was found to have C4/5 severe left foraminal narrowing and degenerative changes." *Id.*, *citing* Ex. 4 at 217, Ex. 6 at 23. Dr. Abrams stated that cervical disease has "well known overlap with shoulder pain, and in many cases, can be the cause of perceived shoulder pain." *Id.*

Dr. Abrams disagreed with Dr. Natanzi that Petitioner's shoulder pain began "within hours" of her vaccination. Second Abrams Rep. at 3. In support of his assertion, Dr. Abrams stated that (1) Petitioner "did not report shoulder pain until almost two months after the vaccination"; (2) that she "had spoken to legal counsel prior to this first report of shoulder pain"; (3) her medical visit with her neurologist on November 3, 2016 yielded no "documentation of any shoulder pain or weakness/pain on physical exam"; (4) Petitioner described her pain to Dr. Combs on November 22, 2016 as "radiating pain"; and (5) In September 2016, Petitioner was diagnosed with fibromyalgia, "a chronic pain condition and…another potential reason for musculoskeletal pain." *Id.*

Dr. Abrams concluded his report by restating his opinion that Petitioner's shoulder pain was likely not present when she was seen by her neurologist on November 3, 2016 and started at some point after that date. Second Abrams Rep. at 4.

V. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

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. § 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. § 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)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement, a petitioner must establish that he 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 he received. § 11(c)(1)(C).

The most recent version of the Table identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). Pursuant to the Table, SIRVA is defined 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.

If, however, a petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused her injury to receive Program compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A).

The Federal Circuit has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury' to establish that the vaccine was a substantial factor in bringing about the injury." *Shyface*, 165 F.3d at 1352-53 (*quoting Grant v. Sec'y of Health & Hum. Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). The Federal Circuit added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required to show by preponderant evidence that the vaccination brought about her injury by providing:

> (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.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id*. at 1280.

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States*

v. U.S. Gypsum Co., 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude

evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

A. Table Claim

In the instant case, Petitioner alleges that she suffered a SIRVA Table injury following her influenza vaccination on October 3, 2016. In order to prevail on her claim, Petitioner must show each of the following by a preponderance of the evidence:

(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.

For the reasons discussed below, I do not find that Petitioner has presented preponderant evidence that she meets the criteria for a Table injury.

1. Petitioner's History of Prior Left Shoulder Pain does not Explain her Post-Vaccination Pain

Although Petitioner had a history of left shoulder pain in the years prior to her October 3, 2016 flu vaccination, there is not preponderant evidence that this prior pain explains her post-vaccination symptoms.

On September 26, 2012, Petitioner was admitted to the hospital complaining of nausea, vomiting, and chest pain. Ex. 2 at 190. During her hospital stay, Petitioner also complained of left shoulder pain that she stated had been ongoing for three weeks with no known injury. *Id.* at 190, 192. She had a left shoulder x-ray, which was negative. *Id.* Left shoulder pain was included as one of her discharge diagnoses. *Id.* at 191.

On March 17, 2015, Petitioner visited the ER after she was involved in a motor vehicle accident. Ex. 4 at 159. Upon presentation, Petitioner complained of neck, back, right wrist, left shoulder, and left hip pain. *Id.* She had digital x-rays performed of her pelvis and right wrist only, suggesting that she was not experiencing sufficient left shoulder pain such that her doctor felt an x-ray was appropriate. *Id.* at 161.

On June 15, 2015, Petitioner presented to physical therapy for lower back pain caused by her MVA in March, 2015. Ex. 2 at 163. The PT Matthew Nolen added the following note to the record: "Pt is a female with BMI of 26.6, presenting with rounded shoulder posture and noted

having to change positions frequently and holding L arm throughout entire evaluation." *Id.* at 164. The record does not elucidate why Petitioner was holding her left arm.

Although Petitioner's medical records document that she was experiencing back pain in 2015 and 2016, none of these records suggest that Petitioner's prior shoulder pain recurred. *See e.g.*, Ex. 2 at 19 (medical visit on September 9, 2016 where Petitioner complained of back pain). In fact, on October 3, 2016, the day she received the allegedly causal flu vaccine, Petitioner presented for a re-check of her back pain. *Id.* at 14-18. Dr. Combs performed a comprehensive physical exam and did not document that Petitioner was experiencing left shoulder pain. *See id.* This medical visit, conducted on the day Petitioner received the vaccine at issue in this case, suggests that any shoulder pain Petitioner had experienced in the past was not affecting her as of the date of vaccination. Accordingly, Petitioner has presented preponderant evidence in support of the first Table injury criterion.

2. Onset of Petitioner's Shoulder Pain was between November 4, 2016 and November 22, 2016, more than 48 Hours after Vaccination

Petitioner received her flu vaccine on October 3, 2016. She described experiencing intense pain in her shoulder within one day of vaccination. Petitioner averred,

> Within 24 hours of the vaccination I knew something was definitely wrong because I could not hold so much as a coffee cup with my left hand. Within a few days from the vaccination, I could not maneuver to put on a brassiere, and it was hard to drive because of the difficulty in turning the steering wheel with my affected arm.

Ex. 12 at 2.

Petitioner claims that she called her PCP's office the next day to report the pain she was experiencing. Petitioner stated, "I called that doctor's office where I had received the vaccination to complain that my left arm hurt ever since the vaccination was administered, but was told the pain was normal, that my muscle was just sore from the needle prick and [would] get better."[6] Ex. 12 at 1.

Petitioner requested copies of the office telephone records from her PCP, presumably to corroborate her account of calling the office on October 4, 2016. Ex. 18 at 3. The request returned the following:

> ☒ **Other: NO PATIENT TELEPHONE MESSAGES FOUND FOR D.O.S. REQUESTED (OCTOBER-DECEMBER 2016).**

Id. at 7.

[6] Petitioner did not mention this phone call in her first affidavit. Instead, she averred that she "waited a week to see if the symptoms would resolve on their own, as residual pain from vaccinations usually do. When the pain and limitation in movement did not resolve, I called my doctor's office to schedule an appointment." Ex. 11 at 2.

During a status conference on February 28, 2019, I asked Petitioner to attempt to find any additional objective evidence that could assist her in pinpointing the date of onset of her shoulder pain. *See* Scheduling Order dated March 1, 2019. ECF No. 26. Specifically, I asked Petitioner to look for personal phone records which would document any call she may have made to her PCP. *Id.* Petitioner filed her third affidavit on April 15, 2019, although the document was executed on February 25, 2019, three days before the status conference where I asked for the information. *See* Ex. 14 at 3. In her third affidavit, Petitioner averred as follows: "I have not maintained telephone billing records that contain listings of numbers dialed, and I do not believe telephone records would prove or disprove the facts at issue herein." *Id.* at 1. Thus, there is no evidence in the record which corroborates Petitioner's statement that she called her PCP the day after vaccination to complain of left arm pain.

Petitioner's first medical visit after vaccination was with Dr. Konieczny, her neurologist, on November 3, 2016. The purpose of the visit was to re-establish care for her MS. Ex. 6 at 17-19. During this visit, Petitioner indicated that she had not been to a neurologist in five years. *Id.* at 17. She complained of fatigue, muscle pain, and paresthesias that had been going on for two to three months. *Id.* She stated, "I hurt, my muscles hurt, feel like spiders are crawling on me, little tingly things." *Id.* There is no indication that Petitioner told Dr. Konieczny she was experiencing left shoulder pain.

The Review of Systems section documents that Petitioner was experiencing tingling, but was negative for any other complaint. Ex. 6 at 17.

Upon performing a neurologic exam, Dr. Konieczny noted that Petitioner's shoulder shrug was "5/5 strength." Ex. 6 at 18. Dr. Konieczny further documented "Give way weakness of both deltoids, biceps, iliopsoas".[7] *Id.* Petitioner was able to complete the finger-nose-finger testing without any documented issues. *Id.*

A musculoskeletal exam revealed "strength and tone in all major muscle groups WNL for age." Ex. 6 at 18. Dr. Konieczny described that Petitioner was experiencing "diffuse pain and paresthesias", and did not note any pain specific to her left shoulder. *Id.*

Dr. Abrams persuasively opined as follows:

[7] The iliopsoas musculotendinous unit (IPMU) is comprised of the major and minor psoas muscles and the iliacus muscle. The IPMU is commonly referred to as the iliopsoas muscle. "The iliopsoas musculotendinous unit (IPMU) is the primary flexor of the thigh with the ability to add and extra-rotate the coxofemoral joint. … The muscles can act separately. The iliacus muscle stabilizes the pelvis and allows a correct hip flexion during the run; the psoas major muscle stabilizes the lumbar spine during the sitting position and the thigh flexion in a supine position or when standing. The psoas major acts as a stabilizer of the femoral head in the hip acetabulum in the first 15 degrees of movement. The psoas minor muscle participates in the flexion of the trunk and can stretch the iliac fascia." NIH, National Library of Medicine, *Anatomy, Bony Pelvis and Lower Limb, Iliopsoas Muscle*, www.ncbi.nlm.nih.gov/books/NBK531508/ (last accessed Sept. 6, 2022).

> The petitioner did not report any left shoulder pain when she saw [] Dr. Konieczny on November 3, 201[6]. That was just one month after the index event, and there is no mention of any left arm symptoms. Dr. Konieczny evaluated petitioner for any signs of MS after a long break in care for that condition, and his record shows that he tested every extremity, including the petitioner's upper extremity, for which she reported no pain with exam maneuvers.

First Abrams Rep. at 10. This failure to mention left shoulder pain was despite the fact that, as stated in her affidavit, Petitioner was experiencing so much pain that she could not hold a coffee cup with her left hand. Ex. 12 at 2.

Petitioner conceded that she did not mention shoulder pain to Dr. Konieczny at the November 3, 2016 visit. *See* Ex. 12 at 2.[8] She averred that the reason for this omission was "because the problem with my shoulder was not related to my MS." Ex. 12 at 2. However, Petitioner not only failed to *mention* shoulder pain to Dr. Konieczny, but she also did not exhibit any pain during the comprehensive physical exam performed by her neurologist. The fact that Petitioner did not mention left shoulder pain during this visit with her neurologist or exhibit any left shoulder pain during the physical exam he performed is a significant fact which suggests that she was not experiencing left shoulder pain at the time she presented to Dr. Konieczny.

Petitioner did not mention left shoulder pain until her next medical appointment, which was on November 22, 2016.[9] Petitioner presented to Dr. Kimberly Combs complaining of moderate left arm/shoulder pain which began after her 10/3/16 flu vaccine. Ex. 2 at 10. An examination revealed that Petitioner's pain radiated "from the le[ft] shoulder down into forearm." *Id.* at 13. Dr. Combs referred Petitioner to an orthopedist. *Id.*

On December 14, 2016, Petitioner was seen at OrthoVirginia by Dr. Ian Smithson. Ex. 7 at 56. Under "history of present illness", Dr. Smithson's notes indicate that "[f]or the past 2 months, [Petitioner] has had shooting pain radiate from her anterior shoulder down her forearm. She believes the flu shot stemmed her pain that she received on 10/3/16." *Id.*

Petitioner's shoulder was tender to "palpitation at [the] anterior shoulder," and her range of motion exam revealed she had a loss of internal and external rotation. Ex. 7 at 57. Dr. Smithson explained to Petitioner that he did not believe her symptoms were related to her flu shot. *Id.* at 56. He assessed her with adhesive capsulitis of the left shoulder. *Id.* Dr. Smithson further noted that Petitioner was seeking information "because she has been consulting a lawyer regarding flu shot being administered incorrectly." *Id.*

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[8] In her brief, Petitioner also conceded that the notes from this visit "are admittedly inconsistent with Petitioner's account of constant and debilitating pain with reduced range of motion in her left shoulder." Pet'r's Mot. at 8.

[9] On November 16, 2016, Petitioner was seen for an MRI of her cervical spine. She did not mention left shoulder pain at this appointment either. Ex. 6 at 23.

Petitioner returned to Dr. Konieczny on January 5, 2017. Ex. 6 at 20. The purpose of this visit was to discuss the results of her MRI, which revealed "at least 15 white matter lesions of both cerebral hemispheres without enhancement and no intrinsic cord signal changes… The brain MRI was judged to be stable from prior in 2011." *Id.* Accordingly, like the last visit with Dr. Konieczny, Petitioner visited her neurologist to discuss issues surrounding her MS. However, unlike her prior visit with Dr. Konieczny, in the review of systems section from the January 5, 2017 appointment, Dr. Konieczny documented:

> **Musculoskeletal** Present- **Arm or Leg Pain** and **Arm Weakness.** Not Present- Muscle Pain and Weakness.

Id. There is no indication from this record that Petitioner's arm or leg pain and arm weakness involved her MS. This fact further reduces the persuasiveness of her explanation that she did not mention shoulder pain to Dr. Konieczny on November 3 because she was seeing him for MS.

In general, contemporaneous medical records are presumed to be accurate and complete. *Cucuras v. Sec'y of Health & Hum. Servs.,* 933 F.2d 1525, 1528 (Fed. Cir. 1993). In assessing when Petitioner developed pain in her left shoulder/arm, I have credited the medical records from November 3, 2016 over those from November 22, 2016.

By the time Petitioner presented to her December 14, 2016 medical appointment with Dr. Smithson, she was actively pursuing her vaccine claim. This point further reduces the value of this record, as it was created in anticipation of litigation.[10] *See, e.g., Sheets v. Sec'y of Health & Hum. Servs.,* No. 16-1173V, 2019 WL 2296212 at *19 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (finding that later-in-time statements whether made to treaters or prepared for purposes of litigation do not suffice to contradict contemporaneous records); *Goodgame v. Sec'y of Health & Hum. Servs.*, No. 17-339V, 2019 WL 4165275 at *4 (Fed. Cl. Spec. Mstr. Jul. 30, 2019) (giving little weight to medical records prepared after a doctor's visit that petitioner attended "at the recommendation of her lawyer.").

I have also considered the *Kirby* case in arriving at my factual determination in the case at bar. In *Kirby,* a portion of the petitioner's medical records were silent regarding the persistence of her symptoms. The Federal Circuit held that medical records are not presumptively accurate and complete as to all [of a] patient's physical conditions. *Kirby v. Sec'y of Health & Hum. Servs,* 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). The Circuit held that a reasonable fact finder *could find* that petitioner's testimony of ongoing pain did not conflict with the records which were silent about either the existence or the nonexistence of such symptoms. *Id.* at 1383. The Circuit noted that the silence in the *Kirby* records could be explained by the fact that petitioner had "reached maximum medical improvement and thus exhausted all available treatment." *Id.* This final point is certainly a difference between the petitioner in *Kirby* and the petitioner in this case. Petitioner had never sought treatment for left arm pain that she associated with vaccination.

Based on the particular facts of this case, I find that Petitioner's silence about left arm/shoulder pain on November 3, 2016 raises substantial question about whether such pain

[10] I find the medical records documenting Petitioner's later medical visits to be unpersuasive for the same reason. *See e.g.*, Ex. 7 at 60. Ex. 8 at 6. Ex. 13 at 18.

existed at that time. Petitioner first mentioned shoulder pain to a medical provider on November 22, 2016, approximately 50 days after vaccination.

Ultimately, for the reasons discussed in this decision, I find there is not preponderant evidence to support the onset of shoulder pain within 48 hours of vaccination. Instead, preponderant evidence supports that Petitioner developed shoulder pain sometime between November 4 and November 21, 2016, between 32 and 49 days after her October 3, 2016 flu vaccine.

3. Pain and Reduced Range of Motion are not Limited to the Left Shoulder

Petitioner has not presented preponderant evidence that her "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered" as required by the QAI for SIRVA. 42 C.F.R. § 100.3(c)(10).

The medical records consistently document that Petitioner's pain radiated from her shoulder down her arm. *See* Ex. 2 at 13 (medical visit from November 22, 2016 documenting that Petitioner's pain radiated "from the le[ft] shoulder down into [the] forearm."); Ex. 7 at 56 (appointment with orthopedist who noted Petitioner "has had shooting pain radiate from her anterior shoulder down her forearm."); Ex. 7 at 60 (physical therapy appointment which documented that Petitioner "developed left shoulder pain … which goes down arm."); Ex. 8 at 6 (appointment with orthopedist who documented "for the past 5 months, [Petitioner] has had shooting pain radiate from her anterior shoulder down her forearm."). Because Petitioner's pain is not limited to her shoulder, she does not meet this element required to establish a Table injury.

4. Petitioner has Other Conditions that Explain her Symptoms

I have conducted a thorough analysis of Petitioner's other conditions in my discussion of the second *Althen* prong. Ultimately, I find there is no reason to conclude that Petitioner's shoulder pain is separate and distinct from these other conditions.

Although Petitioner has presented preponderant evidence that she had no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain her signs and symptoms of left shoulder pain, she has not preponderantly demonstrated that her pain began within 48 hours of vaccine administration, that her reduced range of motion is limited to her left shoulder, or that she has no other condition or abnormality that would explain her symptoms. Accordingly, she has not established the elements of a Table Injury.

B. Causation in Fact

Even though Petitioner has not demonstrated that she suffered from a Table Injury, she may still be entitled to compensation if she can establish each element of the three part *Althen* test.

1. *Althen* Prong One

Under *Althen's* first prong, the causation theory must relate to the alleged injury. Petitioner

must provide a "reputable" medical or scientific explanation, demonstrating that the vaccines received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). It must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

There is little question that a vaccine (to include the flu vaccine) can cause a SIRVA. The Vaccine Injury Table indicates that a SIRVA can be presumed to be caused by the flu vaccine if certain criteria are met. The Court of Federal Claims has noted that the existence of a Table injury can help a petitioner to meet *Althen*'s first prong. *See Doe 21 v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 178, 199 (2009), *rev'd on other grounds,* 527 Fed. Appx. 875 (Fed. Cir. 2013) (determining that a petitioner fulfilled *Althen* prong one, in part, because "the Table recognizes that a vaccine containing pertussis can cause encephalopathy[ ]"). Additionally, the Court of Federal Claims indicated that "a medical theory causally connecting" a given vaccine and a given injury that has been "well recognized by the Office of Special Masters[ ]" can support a petitioner's fulfillment of the first prong. *See id.* Special masters have previously taken judicial notice that the Table links SIRVA to certain vaccines and have also found that "there is a well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program." *See, e.g., Porcello v. Sec'y of Health & Hum. Servs.,* No. 17-1255V, 2020 WL 4725507 at *6 (Fed. Cl. Spec. Mstr. June 22, 2020).

Dr. Natanzi opined that the overpenetration of the vaccine needle into the upper portion of the deltoid can cause an inflammatory response leading to adhesive capsulitis. First Natanzi Rep. at 11. This opinion is supported by the medical literature filed in this case. *See e.g.*, Cross et al., *Don't aim too high: Avoiding shoulder injury related to vaccine administration*, 45 AFP 5, 303-06 (2016) (filed as Ex. 24); Bodor & Montalvo, *Vaccination-related shoulder dysfunction*, 25 VACCINE, 585-87 (2007) (filed as Ex. 25); Degreef & Debeer, *Post-vaccination Frozen Shoulder Syndrome. Report of 3 Cases*, 112 ACTA CHIR BELG, 447-49 (2012) (filed as Ex. 28). I find this theory to be sound and reliable. Accordingly, Petitioner has presented preponderant evidence in support of the first *Althen* prong.

2. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano*, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong.

The evidence in this case suggests that Petitioner's shoulder pain was likely caused by

either her uncontrolled diabetes or osteoarthritis of the left shoulder.[11] The existence of these other medical conditions reduces the persuasiveness of Petitioner's showing that the vaccine "did cause" her condition. *See K.L. v. Sec'y of Health & Hum. Servs.,* 134 Fed. Cl. 579, 598 (Fed. Cl. 2017) ("regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case") (internal citations omitted).

a. *Diabetes Mellitus*

It is uncontested that Petitioner has a significant medical history of uncontrolled diabetes. As Dr. Abrams noted in his report, Petitioner's A1c[12] and blood sugar values in the years prior to vaccination were severely elevated and included the following: A1c of 15.0% on September 26, 2012 (Ex. 2 at 205); blood glucose of 521 on July 15, 2013 (Ex. 2 at 96); A1c of 10.65% on March 27, 2014 (Ex. 2 at 140); A1c of 10.6% on May 8, 2015 (Ex. 2 at 130); A1c of 10.6% on October 3, 2016 (Ex. 2 at 113). A normal A1c range is 4.50-5.70. Ex. 2 at 140.

As Dr. Abrams noted in his first expert report, "There is a significant and profound effect of the petitioner's diagnosis of uncontrolled diabetes (and subsequent predisposition to inflammation and shoulder pathology) on the overall pain, function, and structure of her shoulder." First Abrams Rep. at 6. This position is supported by the medical literature.

Diabetes is the "single greatest risk factor" for the development of adhesive capsulitis. First Abrams Rep. at 6; citing Jason Ramirez, *Adhesive Capsulitis: Diagnosis and Management*, 99 AM FAM PHYSICIAN 5, 297-300 (2019) (filed as Ex. A, Tab 1) (hereinafter "Ramirez"); Redler & Dennis, *Treatment of Adhesive Capsulitis of the Shoulder*, 27 J AM ACAD ORTHOP SURG, e544-54 (2019) (filed as Ex. A, Tab 2). The Ramirez article described a 2016 study, which concluded that patients with diabetes "were five times more likely than the control group to have adhesive capsulitis." Ramirez at 297. Additionally, Shah et al., noted that 63% of a group of participants with type 2 diabetes had shoulder pain or disability. Shah et al., *Upper extremity impairments, pain and disability in patients with diabetes mellitus,* 101 PHYSIOTHERAPY 2, 147-54 (2015) (filed as Ex. C, Tab 1).

Dr. Abrams described the biological process at play. He opined that "hyperglycemia permanently alters tissue macromolecules through accelerated advanced glycation end-products (AGEs) formation." First Abrams Rep. at 7; citing Michael Brownlee, *Glycation Products and the Pathogenesis of Diabetic Complications*, 15 DIABETES CARE 12, 1835-43 (1992) (filed as Ex. A,

[11] I have not assessed whether Respondent has established alternate causation by preponderant evidence, and instead have considered this evidence in so much as it reduces the strength of Petitioner's *Althen* prong two showing.

[12] "The A1C test is a blood test that provides information about your average levels of blood glucose, also called blood sugar, over the past 3 months. The A1C test can be used to diagnose type 2 diabetes and prediabetes. The A1C test is also the primary test used for diabetes management." *The A1C Test & Diabetes*, NIH, National Institute of Diabetes and Digestive and Kidney Diseases, www.niddk.nih.gov/health-information/diagnostic-tests/a1c-test (last accessed Sept. 8, 2022).

Tab 6); Brownlee et al., *Advanced Glycosylation End Products in Tissue and the Biochemical Basis of Diabetic Complications*, 318 N ENGL J MED. 20, 1315-21 (1988) (filed as Ex. A, Tab 7). Dr. Abrams noted that AGEs have been found in cases of adhesive capsulitis. First Abrams Rep. at 7; citing Hwang et al., *Advanced glycation end products in idiopathic frozen shoulders*, 25 J SHOULDER ELBOW SURG. 6, 981-88 (2016) (filed as Ex. A, Tab 4). "Clinically, these factors change the biological properties of the shoulder joint capsule to decrease its elasticity." First Abrams Rep. at 7; citing Wu et al., *Elasticity of the Coracohumeral Ligament in Patients with Adhesive Capsulitis of the Shoulder*, 278 RADIOLOGY 2, 458-64 (2016) (filed as Ex. A, Tab 8).

In fact, Dr. Natanzi accepted this point in his expert report. He stated: "It is undeniable that Ms. Nicholson has a history of uncontrolled DM. It is also equally undeniable that those with DM and especially uncontrolled DM have an increased chance of developing adhesive capsulitis (AC)." Second Natanzi Rep. at 1.[13] He went on to note that the Chan article stated that "for each unit that the HbA1c level was greater than 7, the risk of developing AC increased 2.7%."[14] *Id.* He then concluded as follows:

> Ms. Nicholson's HbA1c in October 2016 was around 10.6%. Using this general formula, the chance of Ms. Nicholson spontaneously developing AC related to DM is approximately 20 – 46%. As such, mathematically, even in light of her uncontrolled DM it is more likely than not that DM mediated AC does not develop. In other words, just because on[e] may have DM or even uncontrolled DM - it may increase your chance but does not guarantee development of DM mediated AC.

Id. As noted, Dr. Abrams disagreed and opined that because the risk of developing adhesive capsulitis is cumulative over time, Petitioner's risk was higher than 20-46%. Second Abrams Rep. at 1-2.

Ultimately, it is clear that patients with uncontrolled diabetes have an increased risk of developing adhesive capsulitis, and that Petitioner's diabetes was uncontrolled for years before she developed adhesive capsulitis. As such, a preponderance of the evidence demonstrates that

[13] Petitioner also acknowledged this point in her brief. She stated: "Petitioner concedes that the prior history of diabetes, and the worsening of symptoms from diabetes in the 18 months leading up to vaccination, clearly do present a strong risk factor for Petitioner's shoulder injury." Pet'r's Mot. at 27. Petitioner argues, however, that this clinical picture "created a situation ripe for immune dysregulation" and that the vaccine Petitioner received was a substantial causal factor in her development of a shoulder injury. *Id.* However, this position is not persuasive. Petitioner has not presented any evidence that this happened in her case. In fact, my findings that her pain began between 32 and 49 days after vaccination strongly suggests that this theory is inapplicable to the specific facts of Petitioner's case.

[14] Petitioner never filed this article into the record, so I am unable to assess the merit of Dr. Natanzi's position. I do note that Dr. Abrams disagreed with this interpretation of the Chan article. *See* Second Abrams Rep. at 1-2.

Petitioner's uncontrolled diabetes is a likely explanation for her development of adhesive capsulitis.

b. *Osteoarthritis*

Dr. Abrams noted that "[s]houlder arthritis in another leading cause of shoulder pain in the general population." First Abrams Rep. at 8; citing Millet et al., *Shoulder Osteoarthritis: Diagnosis and Management*, 78 AM FAM PHYSICIAN 5, 605-11 (2008) (filed as Ex. A, Tab 10). Dr. Natanzi acknowledged that "OA and SIRVA both present with shoulder pain and limited range of motion; therefore, they can be challenging to distinguish based on physical exam alone." Second Natanzi Rep. at 2.

However, Petitioner did not only have a physical exam. Petitioner had an x-ray of her left shoulder on December 14, 2016 which demonstrated "[j]oint space narrowing of glenohumeral and AC joint." Ex. 7 at 56-57. Dr. Abrams opined that these x-ray results demonstrate that Petitioner has arthritis of the left shoulder, which he described as "a well known source of waxing and waning shoulder pain." First Abrams Rep. at 5. Accordingly, Petitioner's osteoarthritis of the left shoulder is also a condition that explains her shoulder pain.

c. *Treating Physicians*

I further note that none of Petitioner's treating doctors linked her vaccination with her shoulder pain. In fact, Dr. Smithson, Petitioner's treating orthopedist, noted the following during Petitioner's December 14, 2016 medical appointment: "I advised Ms. Nicholson that I do not believe her symptoms are related to her flu shot." Ex. 7 at 56.

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). The fact that Dr. Smithson disavowed any connection between Petitioner's flu vaccine and her shoulder injury is persuasive evidence that the vaccine did not play any role in her condition.

For these reasons, Petitioner has failed to establish the second *Althen* prong by preponderant evidence.

3. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

As discussed in the analysis of her Table claim, I find that Petitioner developed shoulder pain sometime between November 4 and November 21, 2016, between 32 and 49 days after her October 3, 2016 flu vaccine. Petitioner has presented no persuasive evidence which suggests a shoulder injury caused by vaccination can develop this long after vaccine administration. In fact, her medical literature indicates onset of shoulder pain generally occurs within approximately two days of vaccination. Significantly, Petitioner's expert did not provide an opinion explaining how shoulder pain could develop 32-49 days after vaccination.

Other special masters have considered this issue and have determined that a timeline between vaccination and onset of pain such as the one in the present case does not constitute a medically acceptable temporal interval. *See*, *Clavio v. Sec'y of Health & Hum. Servs.*, No. 17-1179V, 2022 WL 1078175 (Fed. Cl. Spec. Mstr. Feb. 16, 2022) (finding that 59 days between vaccination and onset of shoulder pain fails to satisfy the third *Althen* prong); *Mack v. Sec'y of Health & Hum. Servs*., No. 15-149V, 2016 WL 5746367 at *8 (Fed. Cl. Spec. Mstr. July 14, 2016) (finding that a 42 day onset between vaccination and onset of shoulder pain is not a medically acceptable timeframe to infer causation in a SIRVA case). *C.C. v. Sec'y of Health & Hum. Servs*., No. 17-708V, 2021 WL 2182817 at *20, 23 (Fed. Cl. Spec. Mstr. Mar. 31, 2021) (concluding that a one week onset in a SIRVA case was not medically appropriate given the theory of causation).

For these reasons, I find that Petitioner has not presented preponderant evidence in support of the third *Althen* prong.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, medical literature, the affidavits, as well as the experts' opinions, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[15]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[15] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.