

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1076V

UNPUBLISHED

MARILYNNE LESHER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 2, 2020

Special Processing Unit (SPU);
Findings of Fact; Onset; Prior
Condition; Causation in Fact;
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Lawrence R. Cohan, Anapol Weiss, Philadelphia, PA, for Petitioner.

Christine Mary Becer, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT¹

On August 8, 2017, Marilynne Leshner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a full-thickness rotator cuff tear in her left shoulder caused in fact by an influenza (“flu”) vaccine she received on November 11, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

Based on the record as a whole and for the reasons discussed below, I find Petitioner likely suffered a left shoulder injury caused by the November 2016 vaccination. Furthermore, I find by preponderant evidence that Petitioner is entitled to compensation under the Vaccine Act.

I. Relevant Procedural History

Shortly after initiating the case, Ms. Leshner filed the required medical records. Exhibits 1-5, ECF No. 7; Statement of Completion, ECF No. 8. Following the initial status conference, Petitioner filed her affidavit regarding the requirements of Section 11(c). Exhibit 6, ECF No. 10. Respondent was ordered to provide his tentative position on the merits of Petitioner's claim. Order, issued Sept. 29, 2017, ECF No. 9.

On April 4, 2018, Respondent filed a status report indicating he "intend[ed] to continue to defend this case and [wa]s not interested in reviewing a settlement demand at this time." ECF No. 18. In his Rule 4(c) report, he argued that Petitioner's injury did not meet several of the requirements for a Table shoulder injury related to vaccine administration ("SIRVA"). Rule 4(c) Report, filed June 4, 2018, at 8-9, ECF No. 21. Regarding causation, he stressed that several of Petitioner's treating physicians expressed a belief that her shoulder injury was not vaccine caused. *Id.* at 8-9. He also noted that Petitioner had not filed an expert report supporting her claim. *Id.* at 9.

On November 26, 2018, Petitioner filed a detailed affidavit regarding her left shoulder injury, additional medical records including the vaccine consent form, and an expert report, curriculum vitae ("CV"), and medical literature from Samir Mehta, M.D. Exhibits 7-18, ECF Nos. 29-32. On April 19, 2019, Respondent filed an expert report, CV, and medical literature from David Ring, M.D., Ph.D. Exhibits A-E, ECF No. 36.

Thereafter, this case was accepted for a test mediation program being implemented by then-Chief Special Master Dorsey.³ The parties participated in a neutral evaluation on December 16, 2019. See Status Report, filed Dec. 23, 2019, ECF No. 41 (joint status report from the parties). Following the mediation, Petitioner filed a handwritten

³ In 2019, 25 cases were selected by the parties to participate in a "Pilot-100" or "P-100" program designed to facilitate the settlement of these cases. Under the P-100 program, these cases were scheduled for neutral evaluation before a third-party neutral consistent with the U.S. Court of Federal Claims Procedure for Alternative Dispute Resolution. See Rules for the Court of Federal Clams ("RCFC") app. H. The P-100 program was overseen by then Chief Special Master Dorsey and me, after I was appointed Chief Special Master on October 1, 2019. The P-100 program was terminated in January 2020.

note from one of her orthopedists, Michael J. Mehnert, M.D., representing his belief that Petitioner's left shoulder injury had been caused by the flu vaccine she received. Exhibit 19, ECF No. 40. On January 24, 2020, the parties filed a joint status report indicating the mediation had failed and "Respondent has indicated [he] will continue to defend the matter."

After reviewing all evidence in this case, I determined the record was fully developed and appropriate for a ruling on the written record as it currently stands.⁴

II. Relevant Factual History

Pre-Vaccination History

Petitioner's medical records from her primary care provider ("PCP"), Julia Tiernan, M.D., show that prior to vaccination, Petitioner suffered usual illnesses such as high blood pressure and cholesterol, upper respiratory and gastrointestinal illnesses, irritable bowel syndrome, occasional vertigo, and an episode of double vision and fatigue. Exhibit 2 at 86-95. She underwent gallbladder surgery in September 2013. *Id.* at 39-83, 101-102.

The only evidence of prior shoulder pain can be found in the medical record from an October 21, 2013 visit to Petitioner's PCP. Exhibit 2 at 99-100. At this follow-up appointment for treatment of her high blood pressure, Petitioner complained of diarrhea and left shoulder pain for two weeks. *Id.* at 99. It was noted that she had received a flu vaccine in her left deltoid six weeks earlier. *Id.* Dr. McTiernan assessed Petitioner as having a mild rotator cuff strain and possible viral gastroenteritis illness. *Id.* at 99-100. She renewed Petitioner's high blood pressure medication and instructed her to consume increased fluids. Petitioner declined physical therapy ("PT"), but Dr. McTiernan indicated she should undergo PT if her left shoulder pain worsened. *Id.* X-rays were taken which showed mild osteoporosis. *Id.* at 112. There is no evidence that Petitioner pursued any further treatment, and it appears Petitioner's left shoulder pain had resolved by her next visit to her PCP on July 30, 2014. *Id.* at 97-98.

At a follow-up appointment for high blood pressure the next year, on August 25, 2014, Petitioner noted that her vertigo had resolved but that she suffered from neck pain

⁴ Pursuant to Vaccine Rule 8, "[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." As the Federal Circuit recently explained, a special master may rule on the record after if he "determine[s] that the record is comprehensive and fully developed." *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020).

which gave her headaches. Exhibit 2 at 95-96. X-rays were taken which showed no fracture but some evidence of cervical spondylosis.⁵ Exhibit 2 at 117. There is no mention of neck pain at Petitioner's next visit to her PCP, on July 23, 2015, when she was treated for dizziness and vomiting. *Id.* at 93-94.

Receipt of Flu Vaccine in 2016

Petitioner was administered the flu vaccine alleged as causal at Walgreens Pharmacy on November 11, 2016. Exhibit 1 at 4. The actual vaccine record indicates it was administered intramuscularly, but it is not noted in which arm the vaccination was given. *Id.* Petitioner has, however, filed the consent form which shows she received the vaccination in her left deltoid. Exhibit 14 at 2.

Petitioner sought treatment for her left shoulder/upper arm pain from her PCP, Dr. McTiernan, approximately six weeks later, on December 23, 2016. Exhibit 2 at 84-85. She reported that she "got flu shot on November 1⁶ [and] [e]ver since then she has had soreness and pain in her left shoulder/upper arm." Exhibit 2 at 84. She described the soreness and pain as getting better than worse in the last week. Reporting that she was unable to lift her arm overhead, Petitioner indicated she had taken Aleve which had not helped. "She denied any injury or overuse [of her] arm." *Id.* Dr. McTiernan indicated Petitioner should begin PT and should take Aleve for her pain. She added that she would order an MRI if Petitioner's pain had not resolved in four to six weeks. *Id.* Dr. McTiernan opined that she did "not believe [Petitioner's] shoulder pain [wa]s directly related to the flu shot." *Id.* at 85.

At her initial PT evaluation conducted on December 28, 2016, Petitioner portrayed the onset of her left shoulder pain as sudden and insidious after receiving a flu shot in early November. Exhibit 3 at 9. Reporting an initial lump and soreness which worsened after two weeks, Petitioner described her current pain was constant and aggravated by certain activities. Her prior function was characterized as "full and unrestricted." *Id.* Upon examination, Petitioner exhibited tenderness along the bicipital groove and decreased strength and range of motion ("ROM"). *Id.* at 11.

⁵ Cervical spondylosis is a "degenerative joint disease affecting the cervical vertebrae, intervertebral disks, and surrounding ligaments and connective tissue, sometimes with pain or paresthesia radiating along the upper limbs as a result of pressure on the nerve roots." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 1754 (32th ed. 2012).

⁶ Either Petitioner provided the incorrect date of her vaccination or it was mistakenly recorded as occurring on November 1, 2016. As shown in the vaccine record, Petitioner received the vaccine on November 11, 2016. Exhibit 1 at 4.

Petitioner attended eight more PT sessions during the remainder of December 2016 and into January 2017. Exhibit 3 at 14-29. Throughout this time, she showed good progress (e.g., *id.* at 19) but some regression at specific appointments (e.g., *id.* at 22). At her last visit on January 23, 2017, it was noted that Petitioner had shown “objective improvements in shoulder ROM and strength” but no significant change in the level of her pain. *Id.* at 29. Observing that Petitioner had an MRI scheduled, the therapist suggested she consult with an orthopedist regarding her pain. Petitioner’s PT was placed on hold. *Id.*

On January 26, 2017, Petitioner underwent an MRI of her left shoulder. Exhibit 4 at 31. Approximately one week later, on February 2, 2017, she was seen by an orthopedic surgeon, Shyam Brahmabbatt, M.D. at the Rothman Institute.⁷ Exhibit 4 at 20-22. She again reported that her symptoms began in early November 2016 shortly after receiving the flu vaccine. *Id.* at 20. Having received no relief from NSAIDs or PT, Petitioner described her pain as throbbing, present even at rest, and “most severe on the anterolateral aspect of her shoulder.” *Id.* “She also admit[ed] to some cervical spine discomfort with radiation down her arm at times. *Id.*

Dr. Brahmabbatt observed evidence of joint arthritis on both the x-rays performed in December 2016 and MRI performed in 2017. Exhibit 4 at 20-21. The MRI also revealed “evidence of a large tear of the supraspinatus tendon, . . . [a] tear of the infraspinatus tendon, [i]ntramuscular cysts, . . . [and] subchondral bursitis.” *Id.* at 21; *accord. id.* at 31 (results of the MRI). The MRI report indicated “[t]here [wa]s mild excess fluid within the subacromial/subdeltoid bursa.” *Id.* at 31. Given the atrophy seen with the chronic tears, Dr. Brahmabbatt informed Petitioner “that the rotator cuff tear [wa]s chronic and not due to her recent vaccination.” *Id.* at 21. He recommended a cortisone injection, additional PT, and possible surgery if Petitioner’s symptoms persisted. After obtaining Petitioner’s consent, he administered a cortisone injection. *Id.*

Petitioner was seen again by Dr. Brahmabbatt on March 6, 2017. Exhibit 4 at 18-19. She reported that she had obtained a few weeks of relief from the cortisone injection but that her pain had returned. *Id.* at 18. While mentioning Petitioner’s rotator cuff tear, Dr. Brahmabbatt noted that “her pain started in November of 2016 when she had received a flu shot and since then she has had throbbing laterally.” *Id.* Because the majority of Petitioner’s pain was laterally based, Dr. Brahmabbatt wondered “if she [had] sustained

⁷ On the Rothman Orthopaedics website, Dr. Brahmabbatt is listed as “board certified in Orthopaedic Surgery . . . specializing in arthroscopic surgery of the shoulder, knee, and hip as well as knee and shoulder replacement surgery.” See <https://rothmanortho.com/physicians/shyam-brahmabbatt-md> (last visited on June 26, 2020).

a neuropraxia of her axillary nerve due to the flu shot.” *Id.* He referred Petitioner to a colleague for a discussion of nonsurgical options. *Id.*

On March 21, 2017, Petitioner was seen by Edward Rosero, D.O. at the Rothman Institute⁸ for her left shoulder pain. Exhibit 4 at 15-16. During his examination, Dr. Rosero noticed tenderness of Petitioner’s left deltoid muscle and “some mild lower cervical facet tenderness on the left side.” *Id.* at 15. Her cervical spine ROM was noted to be pain free. *Id.* Dr. Rosero ordered an EMG and cervical MRI. *Id.* at 16.

Approximately one week later, on March 30, 2017, Petitioner was seen by Dr. Mehnert at the Rothman Institute.⁹ Exhibit 4 at 12-14. At this visit, Petitioner again recounted immediate pain after receiving the flu vaccine which she indicates was giving too high on her shoulder. *Id.* at 12. Describing her prior treatment which had proved ineffective, she rated her current level of pain as severe. Petitioner stated “[s]he ha[d] no history of any prior cervical spinal injuries or prior neck injections.” *Id.* Dr. Mehnert characterized the EMG performed during the visit as “a normal study.” *Id.*; *see also id.* at 23-25, 29-30 (EMG documentation and results). While observing that the EMG revealed “borderline changes in the left median nerve compatible with a median sensory motor neuropathy at the wrist,” he opined Petitioner “had no symptoms to suggest a true carpal tunnel syndrome.” *Id.* at 12; *see also id.* at 29-30 (EMG results). He furthermore opined there was “no clear electrodiagnostic evidence of cervical radiculopathy or brachial plexopathy.” *Id.* at 12. He instructed Petitioner to undergo the cervical MRI ordered by Dr. Rosero and to see him for a follow-up visit thereafter. *Id.* at 13.

After the cervical MRI, conducted on April 5, 2017 (Exhibit 4 at 27-28 (cervical MRI results)), Petitioner attended a follow-up visit with Dr. Mehnert on April 21, 2017 (*id.* at 7-8). Regarding the cervical MRI, Dr. Mehnert indicated there was “little in the way of left foraminal stenosis in the cervical spine or any significant cord compression.” *Id.* at 7. Because the MRI revealed a mass compatible with a neoplasm, he ordered a thoracic MRI. He described the apparent thoracic spine mass lesion as “a separate issue.” *Id.*

Regarding her left shoulder pain, which Petitioner rated at a level of 10 out of 10, Dr. Mehnert stated that he “d[id] not see any clear evidence of cervical radiculopathy

⁸ On the Rothman Orthopaedics website, Dr. Rosero is listed as “[d]ouble [b]oard certified by the American Board of Physical Medicine and Rehabilitation, specializ[ing] in non-operative sports medicine with emphasis on treatment of sports injuries, joint pain, low back pain, neck pain and sports related concussion.” See <https://rothmanortho.com/physicians/edward-rosero-do> (last visited on June 26, 2020).

⁹ On the Rothman Orthopaedics website, Dr. Mehnert is listed as a board-certified physical medicine and rehabilitation specialist . . . [with] a subspecialty certification in Sports Medicine. See <https://rothmanortho.com/physicians/michael-j-mehnert-md> (last visited on June 26, 2020).

causing her symptoms.” Exhibit 4 at 7. While noting the degenerative changes shown on the earlier left shoulder MRI, he opined that some of the unusual characteristics of Petitioner’s pain caused him to believe Petitioner’s shoulder injury “may in fact be related to a vaccine reaction.” *Id.* He prescribed an “ultrasound-guided left shoulder bursa injection” to treat Petitioner’s left shoulder pain. *Id.*

Petitioner underwent a thoracic MRI on May 3, 2017. Exhibit 11 at 4. An ultrasound-guided injection was performed by Lindsey Szymaszek, D.O.¹⁰ on May 23, 2017. Exhibit 4 at 4-5.

Approximately one week later, on May 30, 2017, Petitioner returned for a follow-up appointment with Dr. Mehnert. Exhibit 4 at 33-34. At this visit, she reported that her level of pain had been reduced to 4-5 out of 10 and her ROM had improved. *Id.* at 33. Dr. Mehnert opined that Petitioner appeared to have “[l]eft shoulder bursitis and [a] possible component of synovitis,^[11] [and] [s]he does not seem to have a frank radiculopathy.” Exhibit 4 at 33. Recognizing that Petitioner “[wa]s making progress albeit slowly,” Dr. Mehnert instructed her to follow-up with him or Dr. Szymaszek in two to three months. *Id.*

On June 15, 2017, Petitioner was seen by a neurosurgeon, Steven J. Barrer, M.D., at Abington Jefferson Health. Exhibit 10 at 8. At this visit, Dr. Barrer indicated Petitioner had an asymptomatic, slow growing, and most likely benign meningioma in the thoracic spine which was discovered incidentally during the work-up for her left shoulder pain. Noting that the mass was unrelated to Petitioner’s shoulder pain, he recorded that Petitioner “ha[d] no back pain, no arm pain or numbness, no leg numbness, [and] no difficulty with her gait or sphincter problems.” *Id.* Given Petitioner’s age, he recommended against surgery but indicated Petitioner should be scanned at four months then six months thereafter to determine the rate of growth. *Id.* A second thoracic MRI, performed on October 4, 2017, showed “mild associated mass effect upon the cord, [n]o other lesions, . . . [and] no other areas of abnormal enhancement.” *Id.* at 31. The MRI also “show[ed] no canal stenosis or neural foramen narrowing.” *Id.*

When Petitioner returned for a follow-up visit with Dr. Mehnert on August 7, 2017, she reported “excellent relief” after the ultrasound-guided injection in late May 2017 but some “recurrent pain.” Exhibit 7 at 7. It was noted that she exhibited good ROM and some

¹⁰ It appears Dr. Szymaszek now practices medicine at PSF Primary Care Health Care Services which is part of Centura Health. On the Centura Health website, she is listed as “a board-certified sports and family medicine physician.” See <https://www.centura.org/provider-search/lindsey-szymaszek-do> (last visited on June 26, 2020).

¹¹ Synovitis is “inflammation of a synovium; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within a synovial sac.” DORLAND’S at 1856.

pain with movement. Characterizing Petitioner's condition again as persisting and ongoing bursitis, Dr. Mehnert instructed her to return in another month for a second ultrasound-guided injection. He explained that he preferred to administer these injections at least three months apart. *Id.* Dr. Szymaszek administered a second ultrasound-guided injection on September 5, 2017. *Id.* 4-5.

At her next appointment on January 9, 2018, Dr. Szymaszek noted that after her last injection, Petitioner had obtained "close to complete resolution of [her] discomfort until about 4 weeks ago." Exhibit 9 at 4. After examining Petitioner, Dr. Szymaszek reported tenderness over the lateral shoulder, a positive Hawkins test, and negative cross body test. *Id.* She described Petitioner's condition as "established left shoulder pain and underlying impingement syndrome associated with a complete rotator cuff tear" and administered a third ultrasound-guided injection. *Id.* at 5.

On February 1, 2018, Petitioner was seen by her PCP for a follow-up appointment to discuss recent bloodwork. Exhibit 10 at 50. Updates regarding her asymptomatic spinal mass and left shoulder pain were included in the history section. While reporting that "it aches when she uses her arm" (*id.*), Petitioner declined any pain medication (*id.* at 51). It was noted in this record that, in the past, pain medication had not helped and "PT made [her symptoms] worse." *Id.* at 50.

There is nothing in the record as it currently stands to show Petitioner has since required further treatment of her left shoulder pain. In late April 2018, she visited the emergency room at Lansdale Hospital twice with complaints of leg pain and headaches. Exhibit 10 at 30, 34-46 (April 26, 2018 visit for leg pain); 32-33 (April 30, 2018 visit for headaches). Petitioner visited her PCP on May 2, 2018 for a follow-up appointment regarding her leg pain, headaches, nasal congestion, and hormone therapy replacement. *Id.* at 47-48.

On December 20, 2019, Petitioner filed a handwritten note from Dr. Mehnert purported to be his note regarding Petitioner's diagnosis. Exhibit 19, ECF No. 40. The note states "Intraarticular Vaccination or Vaccine Injection." *Id.* at 2 (original with all letters capitalized).

III. Findings of Fact

Petitioner's medical records contain preponderant evidence supporting factual findings on several issues relevant to the determination of entitlement in this case. As the Federal Circuit has stated, contemporaneous medical records are presumed to be

accurate. *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). The Circuit Court explained that

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id. Petitioner’s contemporaneously created medical records reveal the following: 1) that the onset of her pain likely occurred immediately upon vaccination; 2) that she previously complained of left shoulder pain which resolved without treatment on one occasion, but three years prior to vaccination; 3) that she has an spinal mass, unrelated to her left shoulder condition which appears to be asymptomatic, slow growing, and benign; and 4) that she suffered from an age-related rotator cuff tear which appears to have developed prior to vaccination.

A. Onset of Petitioner’s Pain

Respondent argues that Petitioner has not established that the onset of her pain occurred within 48 hours of vaccination because she did not seek medical treatment until more than 40 days after vaccination. Rule 4(c) Report at 8. In addition, when Petitioner did first seek care (on December 23, 2016), she generally indicated her pain had occurred “following” vaccination but did not specify an onset within 48 hours. *Id.* at 9. Indeed, Respondent notes that as of this appointment Petitioner stated that her “pain had abated and had only worsened within the last week.” *Id.*

It is common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own, and not otherwise realizing the potential significance of immediate post-vaccination pain. Thus, and contrary to Respondent’s urgings, I do not give great weight to the fact that Petitioner did not seek treatment until December 23, 2016. The date of this appointment is not unreasonably long after Petitioner’s November 2016 vaccination, and also reflects the first instance post-vaccination that she sought medical treatment – and her specific reason was to address left shoulder pain she maintained had been present “[e]ver since” vaccination. Exhibit 2 at 84.¹²

¹² Although at this December appointment Petitioner noted a slight improvement then regression in her pain, there is nothing to indicate Petitioner’s pain had *resolved* at this time – and indeed she thereafter continued to seek treatment for it.

In addition, I note that throughout the medical records, Petitioner consistently described the onset of her left shoulder pain as occurring in early November 2016 when she received the flu vaccine, allowing for an un rebutted inference that the pain occurred within a day or two of vaccination.¹³ Although these histories were provided by Petitioner, they were relayed to medical providers for the purpose of obtaining medical treatment during the initial six-month period after vaccination.

Based upon the record in this case, I find there is preponderant evidence which establishes the onset of Petitioner's left shoulder pain occurred close in time to vaccination, and more likely than not within 48 hours of vaccination.

B. Prior Shoulder Issues

The medical records show that prior to vaccination, Petitioner briefly complained of left shoulder pain in October 2013. She indicated she had experienced her pain for two weeks and noted she had received a flu vaccine six weeks prior. Exhibit 2 at 99. There is no evidence, however, that Petitioner complained of left shoulder pain thereafter until she received the flu vaccine alleged as causal in late 2016. It appears that the left shoulder pain Petitioner experienced in 2013 resolved without treatment. I find this report of pain was the only mention of shoulder issues during the three years prior to vaccination. There is nothing to indicate Petitioner experienced any other symptoms or issues related to her left shoulder prior to vaccination.

Regarding the spinal mass seen on the cervical MRI conducted on April 5, 2017 and thoracic MRIs conducted on May 3 and October 4, 2017, the mass appears to be a co-morbidity, unrelated to the left shoulder symptoms Petitioner was experiencing at that time. Petitioner's neurosurgeon clearly stated this conclusion in the record from her appointment on June 15, 2017. Exhibit 10 at 8.

Finally, there is preponderant evidence to show that Petitioner suffered a rotator cuff tear which most likely developed slowly due to age-related degenerative changes in her left shoulder. Both Drs. Brahmabbatt and Mehnert observed the degenerative changes in Petitioner's left shoulder. Exhibits 4 at 21, 7 (respectively).

¹³ Petitioner described a sudden onset during appointments with Dr. McTiernen on December 23, 2016 (Exhibit 2 at 84); with her physical therapist on December 28, 2016 (Exhibit 3 at 9); with Dr. Brahmabbatt on February 2 and March 6, 2017 (Exhibit 4 at 18, 15); with Dr. Rosero on March 21, 2017 (*id.* at 15); with Dr. Mehnert on March 30 and April 21, 2017 (*id.* at 12, 7); and with Dr. Szymaszek on May 23, 2017 (*id.* at 4).

IV. Expert Reports

A. Petitioner's Expert

Petitioner provided an expert report from Samir Mehta, M.D., an Associate Professor at the Department of Orthopaedic Surgery and Chief of the Orthopaedic Trauma and Fracture Service at the University of Pennsylvania. Exhibit 15 at 7. According to Dr. Mehta's CV, he received his M.D. from Temple University School of Medicine in 2000 and has been board certified by the American Board of Orthopedic Surgeons since 2010. Exhibit 16 at 1-2. Since obtaining his medical degree, he has received numerous fellowships, faculty, and hospital appointments and awards, lectured on a variety of topics, and contributed to or wrote multiple articles and books. *Id.* at 1-69.

In his expert report, Dr. Mehta provided a brief summary of Petitioner's relevant medical history and treatment. Exhibit 15 at 1-2. He mistakenly noted that Petitioner never complained of prior left shoulder pain but correctly observed that Dr. Mehnert opined Petitioner's symptoms after November 2016 were likely related to the vaccine she received. *Id.* at 2.

Dr. Mehta's report discussed the results of the x-rays, MRIs, and EMG undergone by Petitioner in detail. Exhibit 15 at 2. Regarding the left shoulder MRI performed on January 26, 2017, Dr. Mehta observed that the characteristics of Petitioner's rotator cuff tear indicate it was not caused by trauma. He opined that the results of the EMG and cervical MRI do not show any pathology or conditions related to Petitioner's left shoulder pain. *Id.*

Dr. Mehta concluded that the left shoulder pain and limited ROM suffered by Petitioner was a direct result of the flu vaccine she received on November 11, 2016. Exhibit 15 at 2, 5. He characterized the onset of Petitioner's pain as immediate. *Id.* at 3. Noting that Petitioner's chronic rotator cuff tear was asymptomatic prior to vaccination, he maintained there are no other conditions that would explain Petitioner's symptoms. *Id.*

Discussing the medical literature provided with his report, which outlines the mechanisms by which vaccines cause shoulder injuries, Dr. Mehta concluded that the vaccine administered to Petitioner was injected into the glenohumeral joint, causing an inflammatory response which was aided by her previously asymptomatic rotator cuff tear. Exhibit 15 at 3-6.¹⁴

¹⁴ Dr. Mehta also indicated his view that all of the causation-in-fact prongs have been satisfied by the evidence in this case. Ex. 15 at 5; see also *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Of course, it is not for medical experts to opine on the satisfaction of the legal prongs that Vaccine Program claimants must meet, and so I give this aspect of his opinion little to no weight.

B. Respondent's Expert

Respondent's expert report is from David Ring, M.D., Ph.D., the Associate Dean for Comprehensive Care and Professor of Surgery and Psychiatry at the University of Texas at Austin. Exhibit A at 1. Dr. Ring's CV shows he earned his medical degree in 1993 from the University of California, San Diego, Medical School. Exhibit B at 1. For almost eight years, Dr. Ring was an instructor, Associate Professor, and then Professor of Orthopaedic Surgery at Harvard Medical School. *Id.* In 2006, he earned a Ph.D. in the Psychosocial Aspects of Arm Pain from the University of Amsterdam. He is board certified in orthopedic surgery and hand surgery. Exhibit A at 1. Like Dr. Mehta, Dr. Ring has received numerous fellowships, faculty, and hospital appointments and awards, lectured on a variety of topics, and contributed to or wrote multiple articles and books. Exhibit B at 1-99.

In his expert report, Dr. Ring indicated he is "particularly expert in the psychological and social determinants of illness; in particular the way in which the normal functioning of the human mind creates misconceptions that can contribute to greater symptoms and limitations." Exhibit A at 1. He further states he has treated patients with shoulder issues in his clinical practice since 2000 and has treated approximately 50 patients with adhesive capsulitis in the last five years. He has "studied and written on the misconception of common arm idiopathic or age appropriate conditions as new or an injury," testifying five times in the last five years. *Id.*

As a preliminary matter, Dr. Ring specified that he considers "the probability of the administration of an immunization causing permanent pathophysiology in the shoulder [to be] extremely low," and stressed that other matters such as age-related degeneration "should be taken into consideration when evaluating a SIRVA claim." Exhibit A at 1.

Regarding Petitioner's case, Dr. Ring concluded the evidence does not establish that she suffered an injury meeting the Table requirements for SIRVA.¹⁵ Exhibit A at 1.

¹⁵ The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons,

He found Petitioner at best had met the third QAI criterion, that Petitioner's pain and decreased ROM were limited to the shoulder in which the vaccination was administered but failed to meet the other three QAI criteria. *Id.* at 3.

Like Petitioner's expert, Dr. Ring opined that the results of the left shoulder MRI established that the Petitioner's rotator cuff tear is the result of age-related changes rather than acute trauma. Exhibit A at 2. Both experts stressed that one would not see the fatty atrophy visible on Petitioner's MRI had the rotator cuff tear been due to injury. *Id.*; Exhibit 15 at 2.

In his report, Dr. Ring argued the existence of this age-related rotator cuff tear meant Petitioner's left shoulder injury failed to meet both the first and last QAI criteria of a Table SIRVA. Exhibit A at 3. When advancing this argument, Dr. Ring did not explain why Petitioner's rotator cuff tear which was previously asymptomatic, except for one complaint of pain in 2013, would have been the sole cause of the severe left shoulder pain Petitioner reported in 2016 and 2017. Nor did he acknowledge that the one earlier complaint of pain, in 2013, which also shared a temporal relationship to an administered flu vaccine, was the only evidence of the "prior shoulder problems" he referenced. *Id.* at 1.

Regarding the onset of Petitioner's pain, Dr. Ring appeared to conflate onset with the point when Petitioner sought medical care. Thus, he twice asserted that Petitioner did not seek medical care within 48 hours, when arguing Petitioner had failed to satisfy this

ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

second Table criterion – even though onset in the Program is measured from manifestation of symptoms rather than when first diagnosed. Section 14(a); see, e.g., *Amos v. Sec’y of Health & Human Servs.*, No. 90-0851V, 1991 WL 146275, at *2-3 (Fed. Cl. Spec. Mstr. July 17, 1991). Dr. Ring otherwise did not address the three-prong causation-in-fact test set forth in *Althen*, 418 F.3d at 1278.

V. Ruling on Entitlement

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). Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner’s allegations must be supported by medical records or by medical opinion. *Id.*

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

A. Table Injury: SIRVA

I have determined there is preponderant evidence to establish that the onset of Petitioner’s left shoulder pain occurred immediately upon vaccination. Thus, she has met the timing required for a Table SIRVA, fulfilling the second of the four QAI Table criteria. The third criteria (that Petitioner’s pain and decreased ROM was limited to her left shoulder) has also been met preponderantly, based on my review of the record. Indeed, Dr. Ring (whose report focused only on the age-related rotator cuff tear suffered by Petitioner and did not mention the spinal mass or one report of occasional pain radiating to Petitioner’s fingers and neck) seems to have conceded this, and it appears that, like Petitioner’s treating physicians, he viewed her other prior symptoms as unrelated.

However, the medical record does not preponderantly support the first and fourth criteria for a Table SIRVA. The first criterion requires “[n]o history of pain, inflammation or

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

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.” 42 C.F.R. § 100.3(c)(10)(i). The fourth criterion requires that “[n]o other condition or abnormality is present that would explain the patient’s symptoms.” 42 C.F.R. § 100.3(c)(10)(iv). Although brief, Petitioner’s earlier report of left shoulder pain, coupled with the rotator cuff tear shown on the MRI which appears to have developed over time, prevents her from satisfying these requirements for a Table SIRVA.

As a result, to be entitled to compensation Petitioner must show that the flu vaccine she received on November 11, 2016 caused her left shoulder pain and limited ROM, and therefore needed to satisfy the evidentiary elements established for a causation-in-fact claim.

B. Causation-in-Fact: SIRVA

If a petitioner suffered a shoulder injury that does not meet the requirements for a Table SIRVA, she may still receive damages, if she can prove that the administered vaccine caused injury to receive Program compensation. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, the petitioner asserts a “non-Table or [an] off-Table” claim and to prevail, must prove her claim by preponderant evidence. Section 13(a)(1)(A). The Federal Circuit has held that to establish an off-Table injury, petitioner must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

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 & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen*, 418 F.3d at 1278. 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.

Although the first and second prongs of *Althen* appear to be similar, these analyses involve different inquiries. See *Doe 93 v. Sec’y of Health & Human Servs.*, 98 Fed. Cl. 553, 566-67 (2011). The first prong focuses on general causation, whether the administered vaccine can cause the particular injury suffered by the petitioner, and the second prong focuses on specific causation, whether the administered vaccine did cause the injury. *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). his distinction “has been described as the ‘can cause’ vs. ‘did cause’ distinction.” *Stapleton v. Sec’y of Health & Human Servs.*, No. 03-234V, 2009 WL 1456441, at *18 (Fed. Cl. Spec. Mstr. May 1, 2009).

1. First *Althen* Prong

In determining that Petitioner has satisfied the first *Althen* prong, I take judicial notice of the fact that Respondent has added SIRVA after receipt of an intramuscularly administered seasonal influenza vaccine to the Table. Such recognition of the causal link between vaccine and injury has been held to support the establishment of the theory require by the first *Althen* prong, since it suggests the existence of reliable medical or scientific evidence supporting the “can cause” prong. See *Doe 21 v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 178, 193 (2009), *rev’d on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013). Indeed – in proposing the Table addition of SIRVA, Respondent discussed the scientific evidence regarding the means by which this injury is caused – and in so doing specifically referenced two articles also offered in connection with Dr. Mehta’s report. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45136-37 (July 29, 2015); S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Exhibit 17(b) (ECF No. 31-2) (“Atanasoff”); M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Exhibit 17(d) (ECF No. 31-4) (“Bodor”).

The mechanism set forth in Atanasoff is described as “the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction.” Atanasoff at 8049. As its authors indicated, this results in an inflammatory response which may be prolonged due to pre-existing antibody in the synovial tissue from an earlier naturally occurring infection or vaccination. *Id.* at 8051. They also observed that bursitis and greater fluid in the bursa were two of the findings often seen in MRI studies

of vaccine injured shoulders. Atanasoff further mentioned that many of the patients they studied may have had prior conditions such as rotator cuff tears which became symptomatic following the improper vaccine injection. To distinguish this type of vaccine-related shoulder injury from conditions caused by a mechanical injury or overuse, the authors pointed to “the rapid onset of pain with limited range of motion following vaccination” which was seen in the patients they studied. *Id.* at 8051. Bodor provides additional support for this proposed mechanism. Exhibit 17(d).

I find the evidence discussed above comprises preponderant evidence sufficient to show that the seasonal influenza vaccine, when administered intramuscularly but improperly injected in the synovial space, can cause an inflammatory response resulting in shoulder injury. Petitioner has established that the seasonal influenza vaccine can cause SIRVA by this described mechanism, and thus, has satisfied the first *Althen* prong.

2. Second *Althen* Prong

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu ex rel. Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1375-77 (Fed. Cir. 2009)); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” an injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280).

In his expert report, Dr. Mehta opined that the flu vaccine Petitioner received was incorrectly administered in her glenohumeral joint, causing an inflammatory response which was aided by her previously asymptomatic rotator cuff tear. Exhibit 15 at 3-6. He clarified that

[w]hile I do not believe the vaccination caused her rotator cuff tear, I do believe her previously asymptomatic rotator cuff tear created a region for her shoulder pain to reside once the vaccine was likely administered improperly. Or, said another way, her existing rotator cuff tear increased the likelihood that the inflammatory reaction would include the glenohumeral joint. As a result, it is plausible that such a scenario would create ongoing complaints of shoulder pain in the glenohumeral and/or rotator cuff region. Her MRI is consistent with this.

Id. at 5-6.

The evidence contained in Petitioner's medical records supports a finding that the flu vaccine caused her shoulder injury in a manner consistent with Dr. Mehta's opinion. As I previously found, except for a report of a pain in 2013 for a few weeks following an earlier vaccination, Petitioner's left shoulder rotator cuff tear was asymptomatic until she received the flu vaccine in early November 2016. Upon vaccination, however, she experienced immediate pain and developed limited ROM which was observed at her initial PT evaluation. Exhibit 3 at 11. Subchondral bursitis and mild excess fluid in the bursa were noted on Petitioner's left shoulder MRI. Exhibit 4 at 21, 31. As Atanasoff's authors observed, similar symptoms and characteristics were shared by many of the patients they studied. Atanasoff at 8051.

Admittedly, treater support for the second prong is mixed – although ultimately it preponderates for Petitioner. Dr. McTiernan unquestionably indicated in December 2016 that she did not believe Petitioner's shoulder injury was related to the flu vaccine she received, but (as Dr. Mehta astutely noted) Dr. McTiernan is a primary care provider who would not be as knowledgeable about shoulder injuries. Exhibit 15 at 6. The orthopedists who initially treated Petitioner were, by contrast, only unsure of the cause of her left shoulder pain. For example, Dr. Brahmabbatt noted the existence of the rotator cuff tear seen on Petitioner's MRI which he opined was age-related and not caused by the flu vaccine she received. Exhibit 4 at 21. Nevertheless, due to the sudden onset of Petitioner's pain immediately following vaccination, he later theorized the flu shot may have caused an injury to her axillary nerve, and thus referred her to Dr. Rosero who ordered an EMG and cervical MRI. *Id.* at 18.

It was only after the results of this additional testing were obtained, the unrelated spinal mass was discovered, and the lack of cervical or neurological symptoms related to Petitioner's shoulder injury was confirmed that Dr. Mehnert finally opined that Petitioner's left shoulder pain may in fact have been caused by the flu vaccine. Exhibit 4 at 7. At that visit, he prescribed an ultrasound-guided injection which provided substantial relief. The next time he saw Petitioner, Dr. Mehnert described her injury as bursitis with a possible component of synovitis. *Id.* at 33. He later provided a handwritten note to Petitioner indicating that he believed her vaccination caused her left shoulder injury. Exhibit 19. As Dr. Mehta noted in his expert report, Dr. Mehnert's comments regarding causation "are more persuasive given that shoulder injuries are his expertise as a sports medicine physician at the Rothman Institute." Exhibit 15 at 6.

Petitioner's treatments are also consistent with a vaccine-caused shoulder injury. In total, Petitioner received three ultrasound-guided injections. As noted by Atanasoff, an ultrasound-guided injection is the optimal treatment for the SIRVA they described. Atanasoff at 8051. And the opinion provided by Dr Mehta aligns with the information provided throughout Petitioner's medical records. The record in this case thus contains preponderant evidence that the flu vaccine Petitioner received on November 11, 2016 did not cause her rotator cuff tear as Petitioner originally alleged but did cause her left shoulder pain and decreased ROM.

3. Third *Althen* Prong

The third *Althen* prong "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). As Dr. Mehta noted in his expert report, in the majority of SIRVA cases, the petitioner has suffered pain within 48 hours of vaccination, with many cases presenting more immediate pain (i.e. in less than a day). This sudden onset is a key component of the theory advanced by Dr. Mehta – and, consistent with my fact findings above, it is present in this case. Accordingly, Petitioner has satisfied the third *Althen* prong.

VI. Conclusion

Having reviewed the affidavits, medical records, expert reports, and documentation in this case, I find that Petitioner has provided preponderant evidence to establish causation-in-fact. Based on the entire record in this case, Petitioner has proven that the flu vaccine she received on November 11, 2016, likely caused her to suffer pain and reduced ROM in her left shoulder. Petitioner is therefore entitled to compensation under the Vaccine Act. A damages order will be issued setting the next deadline in this case.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master