In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: January 31, 2022

A.P.,	*	PUBLISHED
Petitioner,	*	No. 17-784V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Shoulder Injury Related to Vaccine Administration ("SIRVA"); Measles, Mumps, and Rubella ("MMR"); Subcutaneous Injection; Causation-in Fact.
Respondent.	*	

Anne C. Toale, Maglio Christopher and Toale, Sarasota, FL, for petitioner.
Meghan Murphy, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On June 12, 2017, A.P. ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") to her left shoulder as a result of receiving the measles, mumps and rubella ("MMR") vaccination on June 8, 2016. Petition at ¶¶ 1,7(ECF No. 1).

After the filing of multiple expert reports by both parties and several status conferences with detailed orders, the petitioner filed motions for a Ruling on the Record and for Findings of Fact and Conclusions of Law. After a review of the record as a whole, including expert reports, medical records, affidavits and briefing by the parties, and for the reasons set forth below, I

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting 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). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

hereby **DENY** petitioner's Table Claim, but **GRANT** her petition for compensation as a cause in fact claim.

I. Procedural History

Petitioner filed her claim on June 12, 2017, alleging she sustained a left shoulder injury by the MMR vaccine administered to her on June 8, 2016. Petition; Petitioner Motion for Findings of Facts and Conclusions of Law ("Pet. Mot.") (ECF No. 49). This case was initially referred to the Special Processing Unit ("SPU"). Petitioner filed medical records to support her claim on June 26, 2017 and a statement of completion the same day. Petitioner's Exhibits 1-6 ("Pet. Ex.") (ECF Nos. 7 & 8). Petitioner also filed an affidavit from petitioner on August 28, 2017. Pet. Affidavit ("Aff.") (ECF No. 10).

An initial status conference was held on August 28, 2017 by the former Chief Special Master. Scheduling Order (ECF No. 11). After several extensions of time, respondent stated that the review of the medical records had been completed and that settlement was not appropriate for this case. Respondent's ("Resp") Status Report (ECF No. 15).

Respondent filed the Rule 4(c) report, stating that, "The facts of this case, as reflected in the petition and accompanying documents have been reviewed by medical personnel of the Division of Injury Compensation Programs at the Department of Health and Human Services ("DICP") and their opinion is that this case is *not* appropriate for compensation under the terms of the Vaccine Act. Resp. Report ("Rept.") at 1-2 (ECF. No. 17). Specifically, respondent stated that petitioner is alleging a Table Injury, SIRVA, for receiving the MMR vaccine subcutaneously, which does not fit the Table criteria. Resp. Rept. at 6. Respondent argued that petitioner did not satisfy the Table criteria primarily because she received the MMR vaccination subcutaneously; that the medical records do not demonstrate that petitioner had an onset of shoulder pain within forty-eight hours of receiving the vaccination; and that petitioner did not demonstrate she had suffered the residual effects or complications of her injury for more than six months after the administration of the vaccine. *Id.* at 6-7. Further, respondent stated, petitioner had not provided an expert report setting forth a reliable medical theory or logical sequence of cause and effect. *Id.* at 8.

On February 20, 2018, the case was transferred to my docket. Notice of Reassignment (ECF No. 19). The undersigned held an initial status conference on March 28, 2018. Scheduling Order (ECF No. 21). During the status conference, respondent's counsel confirmed that the main issue in the case was that petitioner received a subcutaneous injection rather than an intramuscular injection and that subcutaneous injections were not covered by the Table for SIRVA. *Id.* I ordered the petitioner to file a supplemental affidavit explaining why she did not seek treatment for eight months after the initial period of approximately two months of treatment and to file an expert report. *Id.* at 2.

Petitioner filed a supplemental affidavit on May 9, 2018. Pet. Ex. 9 (ECF No. 23). On May 24, 2018, petitioner filed an expert report from an orthopedic surgeon, Dr. Domenick J.

Sisto.[3] Pet. Ex. 10 (ECF No. 26). Respondent filed an expert report from Geoffrey B. Abrams, M.D.[4] on December 20, 2018. Resp. Ex. A (ECF No. 28).

A Rule 5 status conference was held on February 26, 2019. Rule 5 Order (ECF No. 29). The Rule 5 Order summarized petitioner's expert, Dr. Sisto's opinion that the subcutaneous injection likely hit the posterior branch of the axillary nerve in the left shoulder area, and respondent's expert, Dr. Abrams disagreed with that theory. *Id.* at 3. After review of both reports and the multiple articles submitted therewith, I indicated that it was plausible that the subcutaneous injection of the MMR vaccination did cause petitioner's shoulder injury and that her symptoms were similar to those reported in multiple other SIRVA cases. *Id.* I also noted that the petitioner had had a good recovery and I encouraged the parties to engage in informal settlement discussions. *Id.*

After engaging in unfruitful settlement negotiations, the respondent filed a status report requesting a status conference and that this case be set for an entitlement hearing. Resp. Status Rept. (ECF No. 38). On January 9, 2020, petitioner filed a supplemental expert report by Thomas Wright, M.D.[5] Pet. Ex. 12 (ECF No. 39). Respondent filed a responsive supplemental

[3] Dr. Domenick J. Sisto, is a board-certified orthopedic surgeon. Pet. Ex. 11 at 1. Dr. Sisto currently works as an orthopaedic surgeon at the Los Angeles Orthopaedic Institute, where is specializes in adults with knee and shoulder injuries. He received his undergraduate degree at the University of Vermont in 1975 and received his medical degree from George Washington University Medical School in 1979. *Id.* Dr. Sisto did his residency at the Hospital for Special Surgery in New York City, then did a fellowship in sports medicine at the Kerlan-Jobe Orthopaedic Clinic in Inglewood, California. *Id.* He was a clinical instructor at the Department of Orthopaedic Surgery at UCLA School of Medicine between 1986-1988. *Id.* at 2. Dr. Sisto is licensed to practice medicine in New York, California, and Connecticut. *Id.* at 2. He serves as an editor for Case Reports in Surgery and is a Principal Reviewer for the American Journal of Sports Medicine. *Id.* at 3. Dr. Sisto has been the lead author in multiple published medical articles on a variety of orthopedic topics, including arthroplasty of the knees, ACL reconstruction and shoulder stability. *Id.* at 4-5.

[4] Dr. Geoffrey Abrams is a board-certified orthopedic surgeon. Resp. Ex. A at 1. He currently serves as an Assistant Professor of Orthopedic Surgery at the Stanford University School of Medicine. *Id.* Dr. Abrams received his undergraduate degree in 2000 from Stanford University and received his medical degree from the University of California, San Diego. Resp. Ex. B at 1. He did a surgical internship at Stanford University Hospital and Clinics from 2007-08 and completed his residency in 2012 at the same hospital in the Department of Orthopedic Surgery. *Id.* He has a subspecialty certificate in Orthopedic Sports Medicine. *Id.* at 2. Dr. Abrams is licensed to practice medicine in the states of California and Illinois. *Id.* Dr. Abrams has authored or co-authored numerous medical articles on various orthopedic topics. *Id.* at 2-5. He currently serves as the Director of Sports Medicine for Stanford University Varsity Athletics, as well as, the Director of the Lacob Family Sports Medicine Center at Stanford University. Resp. Ex. A at 1.

[5] Dr. Thomas Wright is a board-certified orthopedic surgeon. Pet. Ex. 13 at 2. He received his undergraduate degree in biology from Emory University in 1979 and his medical degree from the University of Florida in 1983. *Id.* Following medical school, he had an internship in General Surgery at the University of Florida and did a residency in Orthopedic Surgery from 1984-1989. *Id.* Dr. Wright also had a fellowship at the Mayo Clinic in Hand and Upper Extremity Surgery. *Id.* at 2. Dr. Wright currently serves as a professor of orthopedic surgery at the University of Florida and is the Division Chief of the Hand and Upper Extremity surgery. *Id.* at 2. He also serves as an affiliate professor of the University of Florida's College of Public Health and Health Professions. *Id.* Dr. Wright has also authored or co-authored numerous medical articles on the hand and upper extremity orthopedic topics. *Id.* at 3-20. Dr. Wright also serves as a journal reviewer for multiple medical journals, including the Journal of Bone and Joint Surgery, Journal of Hand Surgery, and Journal of Shoulder and Elbow Surgery. *Id.* at 31.

report by Dr. Abrams on April 3, 2020. Resp. Ex. C (ECF No. 40). On May 14, 2020, petitioner filed a responsive supplemental report by Dr. Wright. Pet. Ex. 15 (ECF No. 41).

A second Rule 5 status conference was held on August 11, 2020. Rule 5 Order (ECF No. 43). During this status conference, after reviewing the additional expert reports filed by both parties and petitioner's supplemental affidavit, I explained that the record, "[as the record] stands today, supports petitioner's claim and [she] has a high likelihood of success." *Id.* at 2. The undersigned again encouraged the parties to resolve the case informally. *Id.* Respondent was ordered to file another expert report, responding to Dr. Wright's responsive report. *Id.* at 3.

On October 6, 2020, respondent filed a second supplemental report by Dr. Geoffrey Abrams and supporting medical literature. Resp. Ex. D (ECF No. 45). Petitioner filed supporting medica literature on November 23, 2020. Pet. Ex. 18.

On November 23, 2020, petitioner filed the present motion for a Ruling on the Record and filed a memorandum in support of her motion the same day. Pet. Mot. (ECF No. 48); Pet. Memorandum ("Pet. Mem.") (ECF No. 49).

Respondent filed a response to petitioner's motion on January 27, 2021. Resp. Response (ECF No. 52). On February 3, 2021, petitioner filed a reply to respondent's response. Pet. Reply (ECF No. 53).

This matter is now ripe for adjudication.

II. Evidence Submitted

a. Petitioner's Medical Records

On June 2, 2016, petitioner was admitted to Baptist Medical Center in Jacksonville, Florida for the delivery of her fifth child. Pet. Ex. 2 at 125; Pet. Ex. 9 at ¶ 2. Petitioner gave birth to a healthy female infant without complications. Pet. Ex. 2 at 125. On June 8, 2016, prior to being discharged, petitioner received the MMR vaccination in her left upper arm. *Id.* The vaccine administration record provides that the vaccine was intended to be administered subcutaneously. *Id.*

On June 9, 2016, petitioner contacted her OB/GYN, inquiring about contraceptives covered by her insurance. Pet. Ex. 2 at 63. There was also an internal office note indicating that petitioner's first post-partum office visit was scheduled for July 18, 2016. *Id.*

On June 20, 2016, petitioner called her OB/GYN, this time complaining of left arm pain. Pet. Ex. 2 at 138. Under Chief Complaint it provided, "Pt calling stating unable to move left arm. Pt states [illegible] after given shot in arm after delivery. Pt states now 2 weeks later unable to move arm at all. Pt denies any swelling or pain. Pt states arm is 'frozen.'" *Id.* Petitioner had an appointment the following day on June 21, 2016. *Id.* at 109. At this appointment, it was noted that petitioner's weight was 161.2. *Id.* The record states, "Pt s/p

vaginal delivery 6/6/16 c/o unable to move left arm." *Id.* An MRI of petitioner's left shoulder was ordered. *Id.* at 58, 62.

Petitioner had an MRI of her left shoulder performed on June 24, 2016. Pet. Ex. 2 at 6. The MRI revealed a partial thickness tear of the distal infraspinatus tendon at insertion along the bursal surface (approximately 50% thickness). *Id.* On June 27, 2016, Dr. Tiffany Wells reviewed petitioner's MRI and observed that it demonstrated a "50% tear in infraspinatus tendon (part of rotator cuff)," and requested that petitioner be referred to orthopedics. Pet. Ex. 2 at 61.

On June 28, 2016, petitioner presented to Jacksonville Orthopaedic Institute for an evaluation of her left shoulder. Pet. Ex. 4 at 43. Petitioner reported that her pain had been present for approximately three weeks. *Id.* Petitioner reported she had stiffness in the shoulder and was no longer able to raise her arm overhead. *Id.* Additionally, petitioner described her pain as diffuse in location and sharp in quality. *Id.* At this appointment, petitioner associated the onset of her pain to the vaccination she received before being discharge from the hospital after delivery of her fifth child. *Id.* The record provides:

> She notes that she gave birth three weeks ago and afterwards was offered the measles, mumps and rubella vaccine. She states that after they injected into her lateral left shoulder, she began to have increased intense pain and range of motion problems.

Pet. Ex. 4 at 43. Petitioner stated that her pain was a 5/10. *Id.* A physical exam of the left shoulder revealed that petitioner's range of motion was restricted with pain, her flexion and abduction was restricted to 90 degrees (compared to the right shoulder of 180 degrees), and that her internal rotation was only to L2 (compared to the right of internal rotation to T12). *Id.* at 44. Orthopedist, Dr. Michael Adams, observed that petitioner had strength of 4/5 with external rotation and abduction, she had generalized tenderness to palpation at "about the deltoid girdle," and her bicipital groove was tender to the touch. *Id.* Dr. Adams reviewed the MRI from June 24, 2016 and observed that it showed, "increased signal along the bursal surface of the infraspinatus tendon consistent with partial thickness tear," and that petitioner had "some fluid in the biceps sheath proximally." *Id.* Dr. Adams diagnosed her with left shoulder joint pain and a left partial acute rotator cuff tear. *Id.* at 44-5. Dr. Adams recommended a steroid injection. *Id.* at 45. Under "Plan," he noted that petitioner had asked about post injection injuries. *Id.* He wrote, "I do not think it is out of the realm of question that she had post-injection stiffness and pain, but I am unclear at this time that the rotator cuff is a consequence of her vaccination." *Id.*

Dr. Adams gave petitioner a physical therapy prescription. On the prescription it explains, "36-year-old female with 3 weeks of left shoulder pain post vaccination. Partial thickness bursal sided rotator cuff tear on MRI." *Id.* at 27. The prescription was for six weeks of physical therapy 2-3 times a week. *Id.* He also gave her a steroid injection. *Id.* at 45.

Petitioner had her first physical therapy appointment on July 4, 2016. Pet. Ex. 5 at 28. The note provides, "[Petitioner] states that the initial onset occurred on 6/01/2016 when she reports she had a baby 4 weeks ago and reports insidious onset of [left] shoulder pain." *Id.* Petitioner also reported that she received a shot in the hospital, "which caused a lot of neck pain and then a few days later her shoulder began getting stiff and she began having pain." *Id.*

Additionally, petitioner reported that her cortisone injection had helped "a lot." *Id.* At this appointment, petitioner reported her pain as a 2 to 3 out of 10. *Id.* She also reported that she had pain while doing her hair, lifting her shoulder and her shoulder feels stiff. *Id.* The physical therapist noted that petitioner had 65% function of her upper left extremity and that petitioner explained that most of her pain was in the anterior lateral shoulder. *Id.* Petitioner was tender on upper trapezoid, supraspinatus tendon, biceps tendon long head, posterior cuff, and parascapular muscles. *Id.* Further, her physical examination showed that she had reduced strength upon shoulder flexion, abduction, and on external and internal rotation. *Id.* at 29-30. Petitioner's assessment was, "Signs and symptoms are characteristic of left partial acute rotator cuff tear….[Patient] presents with significant loss of shoulder function, strength and active range of motion." *Id.* at 30. The plan was for her to attend physical therapy 2-3 times per week for 8 weeks. *Id.*

On August 1, 2016, petitioner had a follow-up appointment with orthopedist, Dr. Adams. Pet. Ex. 4 at 22. Under "History of Present Illness," it was noted that petitioner had left shoulder pain that had been present for 2 months. *Id.* It explained, "It started after a post-delivery vaccine and was severe in intensity and diffuse in nature, associated with significantly decreased range of motion." *Id.* Petitioner reported that her pain was "dull and mild in severity," and that her pain level was a 1 out of 10, but it had increased in intensity during physical therapy. *Id.* A physical exam of petitioner's left shoulder showed she had full range of motion and her strength was five out of five. *Id.* at 23. Despite these findings, he suggested that petitioner finish physical therapy. *Id.* Dr. Adams also explained, "We did review some scientific evidence of post vaccine injection rotator cuff tear when placed in the wrong place. It does appear at this time though, that she is healing appropriately. No further corticosteroid injection recommended at this time." *Id.* at 23.

On August 5, 2016, petitioner had another physical therapy appointment with therapist, Kurtis P. Mullaney. Pet. Ex. 5 at 6. While petitioner's active range of motion for her left shoulder was documented as "within normal limits," her strength on flexion, abduction and external rotation was documented as 4+/5, while her right shoulder had 5/5 strength. *Id.* Therapist Mullaney noted that petitioner's general progression towards the treatment goals was at 90 percent, but she was still lacking external strength. *Id.*

Petitioner was discharged from physical therapy on August 10, 2016. Pet. Ex. 5 at 4. Therapist Mullaney wrote, "The patient notes functional improvements increased ability to reach, increased ability to lift, and improved independence with ADL's. Shoulder feels good." *Id.* at 4. Petitioner's active range of motion for her left shoulder was documented as "within normal limits." *Id.* However, she again demonstrated decreased strength on flexion, abduction, and external rotation. *Id.* Petitioner was assessed as, "General progression towards the patient's remaining treatment goals is presently at 80 percent. Knows [Home Exercise Program] well and had no questions about program." *Id.*

On April 14, 2017, petitioner returned to Dr. Adams for a follow-up of her left shoulder with persistent pain. Pet. Ex. 6 at 22. He wrote, "Initially she was seen in August 2016 with post vaccination pain in the shoulder and diagnosed by MRI with partial bursal sided rotator cuff tear." *Id.* Petitioner reported that she had improvement for about one month following her physical therapy and the corticosteroid injection she received. *Id.* She described her pain as

located in posterior aspect of her shoulder, which was dull and burning in quality and moderate in severity. *Id.* Petitioner reported that her pain was a 5 out of 10 and pain was worse with lifting and reaching. *Id.* On physical exam petitioner demonstrated a full range of motion, but with pain from "80 to 120 degrees of flexion and abduction." *Id.* at 23. Her strength was recorded as a 4 out of 5 and she showed one positive impingement sign. *Id.* Dr. Adams recommended petitioner have an additional MRI to evaluate for "persistence of tear or additional pathology," given her persistent symptoms and failure to respond to injection and therapy. *Id.* at 23.

Petitioner had a second MRI of her left shoulder on April 21, 2017. Pet. Ex. 6 at 12. The MRI found abnormal bursal surface signal of the distal anterior supraspinatus adjacent to the footplate. *Id.* The radiologist, Dr. Brad Talley, opined that the abnormal signal was more related to tendinosis rather than a low-grade bursal surface partial tear. *Id.* Additionally, "a tiny sliver of fluid" was found in the subacromial subdeltoid bursa. *Id.* at 13.

Petitioner returned to Dr. Adams on April 26, 2017 following her left shoulder MRI. Pet. Ex. 6 at 9. At this appointment, petitioner reported that her pain was a 4-5 out of 10. *Id.* Dr. Adams wrote that he had reviewed the MRIs and the MRI report from April 21, 2017. *Id.* at 10. He noted that petitioner had "mild abnormal signal on the bursal side of the anterior supraspinatus which may represent a partial tear." *Id.* at 10-11. He also wrote, "There is some persistent tenosynovitis in the proximal biceps tendon which is consistent with review from MRI from last year." *Id.* at 11. He diagnosed petitioner with left shoulder joint pain, left partial chronic rotator cuff tear, and left shoulder bursitis. *Id.*

b. Petitioner's Affidavit

On May 8, 2018, petitioner executed a detailed affidavit. Pet. Affidavit ("Aff.") (ECF No. 23). Petitioner stated that while getting ready to leave Baptist Medical Center on June 8, 2016 after the birth of her fifth child, the nurse, Christy, recommended she receive an MMR booster. Pet. Aff. at ¶¶ 2-3. She explained that the nurse, Christy, administered the shot at approximately 5:30 pm to the back of her upper left arm. *Id.* at ¶ 3. Petitioner stated, "As I received the shot, the pain was excruciating," and she had asked the nurse if it "was going into the muscle." *Id.* Petitioner stated, "the pain was so intense I felt like it was going into my bone. I almost came up off the bed that I was sitting on!" *Id.* Even though petitioner had been given Percocet and ibuprofen for afterbirth pains from labor, she could still feel the pain. *Id.* at ¶ 4.

Petitioner also described how the vaccine was administered to her by the nurse on June 8, 2016. *Id.* at ¶ 6. She explained that the nurse had her sit up on the bed, the nurse stood next to and over her to give the injection. *Id.* Petitioner stated that she "felt the shot being given and it was high on my upper arm towards the back." *Id.* The shot was "immediately and unusually painful." *Id.* In addition to the shoulder pain, petitioner began to experience "terrible neck pain," which she described as pain on her left side that "radiated down into [her] left shoulder." *Id.* at ¶ 7. Petitioner stated that, "The neck pain started after the shoulder pain." *Id.* She explained that from Wednesday until Monday, June 13th, 2016, her arm and should became stiff. *Id.* Petitioner explained that by Wednesday, June 15th, she could not lift her arm. *Id.* Petitioner stated that her arm was "weak and shaky," and she could not lift it up to a 90 degree angle of her

body. *Id.* Petitioner stated that she was unable to wash or brush her hair or apply deodorant. *Id.* She explained that the pain and range of motion, "…made taking care of my newborn and my other children extremely difficult. I was trying to nurse my newborn and yet I couldn't move my left arm." *Id.* Petitioner thought that it was a minor side effect from the MMR shot, but it was not getting better, but worse. *Id.*

Petitioner stated that she told her OB/GYN on June 20, 2016 that she was unable to move her left arm and she was able to meet with an orthopedist a week later. *Id.* at ¶ 8. Petitioner stated that the prescribed physical therapy and injectable cortisone gave her improvement by the time the therapy sessions ended in August. *Id.* at ¶ 8. She explained that, "Over the course of therapy, including my injection, my shoulder pain was reduced and therapy ended on August 5, 2016….After that point, I had motion in my arm but the pain in the back of my upper arm and shoulder returned after a month or so, and I had not regained strength in my arm." *Id.* She stated that her doctor told her that the rotator cuff should heal completely since "the tear was only 50%." *Id.* She stated that, "However…the pain and stiffness, while never completely gone, started to worsen, so I saw my orthopedist in April 2017." *Id.*

Petitioner stated that between August 2016 and April 2017 her shoulder/arm symptoms did not completely disappear, but reduced, so that she could get on with her life. *Id.* at ¶ 9. She explained that as the wife of a pastor, she is very involved in her husband's church and "keeping it running," as well as, home schooling her children. *Id.* Petitioner stated that she would, "assist in physical activities," that she was "always involved in the kids' games, including more physical ones," and that she even participated in helping build her new home while pregnant, but she was unable to do these things even after she completed her physical therapy in August 2016. *Id.* She concluded, stating, "During the gap in treatment, as I noted above and told my orthopedist, the left shoulder pain persisted and affected my ability to be [as] physical as I had been." *Id.*

c. Petitioner's Expert Reports

1. Dr. Domenick J. Sisto, MD

Petitioner submitted an expert report from Dr. Domenick J. Sisto, an orthopedist on August 24, 2018. Pet. Ex. 10 (ECF No. 26). Dr. Sisto reviewed petitioner's medical records and wrote, "Following my review of the medical records it is clear that this patient sustained an injury to her left shoulder following the injection of the vaccination that she had sometime in the early aspect of June 2016." Pet. Ex. 10 at 12. He also stated that, "My review reveals no previous records of any problems with the shoulder…." *Id.*

Dr. Sisto also noted that petitioner associated the onset of her shoulder pain to her MMR vaccination on June 8, 2016 to her orthopedist, Dr. Michael Adams. He wrote, "Her complains are clearly outlined in the report dated June 28, 2016 from Dr. Michael Adams at the Jacksonville Orthopedic Institute, who documented a post-vaccination injection stiffness of the shoulder." *Id.* at 12. Dr. Sisto observed that petitioner's medical records from Dr. Adams, "clearly show that her complaints were secondary to the injection." *Id.*

Dr. Sisto explained that, "It is well diagnosed and recognized that post-injection syndrome is unfortunately very common following vaccinations where the medication is given either intramuscularly or subcutaneously…." Pet. Ex. 10 at 12. He opined that injections given intramuscularly or subcutaneously can irritate the axillary nerve, which runs approximately 1 inch deep to the deltoid musculature. *Id.* He opined that a 5/8 inch needle used for subcutaneous injection or a one inch needle used for intramuscular injection can "cause irritation and disruption of the axillary nerve and deltoid function." *Id.* Dr. Sisto stated that, "The deltoid muscle is the main muscle that moves the shoulder and certainly can be irritated by an injection." *Id.*

With regards to the onset of petitioner's shoulder pain and dysfunction, Dr. Sisto wrote, "The timing of [stiffness and pain] is obviously consistent with post-injection syndrome. She had immediate pain and sought treatment after injection." *Id.* at 13. He opined, "….this is clearly a case of shoulder stiffness and irritation of the axillary nerve following her injection." *Id.*

Subsequently, petitioner informed the Court that Dr. Sisto was unable to continue as an expert in this case due to personal reasons. Pet. Mot. at n.1.

2. Dr. Thomas W. Wright

On January 9, 2020, petitioner filed a supplemental expert report from Dr. Thomas W. Wright, an orthopedic surgeon. Pet. Ex. 12 (ECF No. 39). In his first report, Dr. Wright stated, "It is my opinion that [petitioner] sustained an injection site injury to her left shoulder due to the MMR vaccine injection on 6/8/2016." Pet. Ex. 12 at 1. He noted that petitioner had no pre-existing history of pain in her left shoulder. *Id.* He also stated, "….the pain started immediately after the injection and persisted [for] at least 10 months." *Id.*

Dr. Wright stated that he did not believe that petitioner's axillary nerve was directly injured with the injection, but instead, the injection could have started a local inflammatory process near the nerve, which can cause pain. *Id.* He opined that petitioner had "a direct injection into the subacromial space and possibly into the infraspinatus which might explain the edema in the infraspinatus on the initial MRI." *Id.* He opined that, "An injection into the subacromial space can be responsible for initiating a major inflammatory event in the subacromial bursae resulting in persistent, severe pain." *Id.*

Dr. Wright referenced the article *Vaccination-related shoulder dysfunction*, by Bodor and Montalvo, to support his opinion. Pet. Ex. 14.[6] The Bodor article examined two case reports where two healthy individuals developed shoulder and arm pain, weakness and loss of range of motion following vaccination. *Id.* at 1. The authors hypothesized that the vaccine was injected into the subdeltoid bursa in the two individuals, which caused a "robust local immune and inflammatory response." *Id.* at 2. Using ultrasound, the authors measured the location of the subacromial bursa and found that it extended from 3.0 to 6.0 cm beyond the lateral border of the acromion. *Id.* at 2. They also measured the depth below the skin of the subacromial bursa and found that it lay between 0.8 cm to 1.6 cm below the skin. *Id.* Bodor and Montalvo explain,

[6] Bodor, M. and Montalvo, E., *Vaccination-related shoulder dysfunction*, 25 Vaccine 585-587 (2007). [Pet. Ex. 14].

"Given that the subdeltoid bursa is continuous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule." *Id.* at 2. The authors explained that the first individual developed adhesive capsulitis or frozen shoulder and the second patient had moderate to severe reduction of shoulder range of motion. *Id.* at 2-3. Bodor and Montalvo observed that both patients received multiple injections for the pain to resolve, "consistent with a primary inflammatory etiology rather than a mechanical overuse problem." *Id.* at 3. Further, the authors recommended that "future influenza and pneumococcal vaccination guidelines [should] specify that injections should not be performed in the upper third of the deltoid muscle. *Id.* at 3.

Petitioner filed a supplemental report from Dr. Wright on May 14, 2020. Pet. Ex. 15 (ECF No. 41). Dr. Wright's supplemental report was a response to respondent's expert report from Dr. Abrams.

Dr. Wright stated that while the exact location of the injection given petitioner was not known, "it is *most likely* that she was injected in the subacromial space, based on her positive response to the subacromial steroid injection, and possibly in the infraspinatus." Pet. Ex. 15 at 3 (original emphasis). Dr. Wright, responding to Dr. Abrams, stated that Dr. Abrams was assuming that the MMR vaccine was administered in the recommended site of administration for subcutaneous vaccines by the Centers for Disease Control ("CDC"). *Id.* at 3; *see also* Resp. Ex. C at 1. The CDC diagram Dr. Abrams included in his report, showing the recommended site for a subcutaneous administration for the MMR vaccine, highlighted an area on the posterior triceps muscle about half-way down the upper arm. Resp. Ex. C at 1. Dr. Wright noted that aside from petitioner's chart, which notes that petitioner received the vaccine in her "left upper," arm, it does not provide the precise site of administration. Pet. Ex. 15 at 3.

Dr. Wright also explained that the package insert for the MMR vaccine itself provides site administration instructions. Pet. Ex. 15 at 3. The package insert provides, "The dose for any age is 0/5 ml administered subcutaneously, preferably into the outer aspect of the upper arm." *Id.* Dr. Wright asserted that the package insert provides a much broader charge with regard to site administration compared to the CDC recommendation and the triceps muscle is not specified. *Id.*

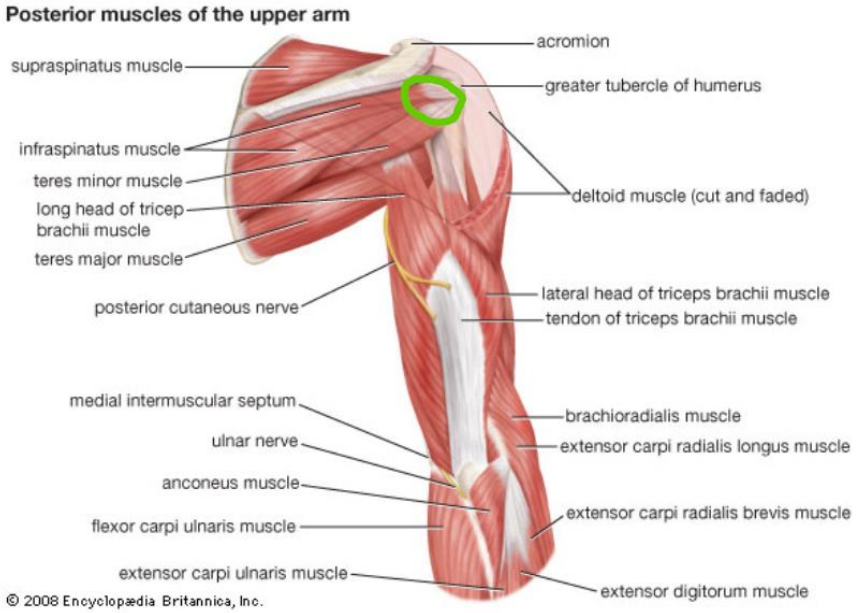
Dr. Wright also cited to article by Eileen Shepard, titled, *Injection technique 2: administering drugs via the subcutaneous route,* which provides multiple sites available for subcutaneous injection. Pet. Ex. 17 at 1.[7] The article explains that, "Recommended sites for subcutaneous injection include the lateral aspects of the upper arm and thigh, and the umbilical region of the abdomen. The back and lower loins can also be used." *Id.* at 1. Importantly, the article observes, "It is important to avoid inadvertently injecting the drug into muscle, as intramuscular injection can affect drug absorption…." *Id.* The article describes that "a lifted skinfold technique (pinching or bunching the skin) can be used to lift the subcutaneous layer away from the underlying muscle….This method reduces the risk of inadvertent intramuscular injection when undertaken correctly; however, releasing the skin too quickly before the injection is completed or lifting it incorrectly can increase that risk." *Id.* Dr. Wright asserted that the

[7] Shepard, E., *Injection technique 2: administering drugs via the subcutaneous route,* 114 Nursing Times [online], 55-57 (2018). [Pet. Ex. 17].

"lateral aspect of the lower part of the upper arm" area identified in the Shepard article could encroach on the subacromial space. Pet. Ex. 15 at 2.

Dr. Wright wrote that, "Both Dr. Adams' clinical examination of [petitioner] and the MRI findings support a conclusion that the injection was given in her shoulder area and not in the triceps region. Pet. Ex. 15 at 2. He noted that petitioner exhibited generalized tenderness to palpation near the deltoid insertion on the acromion, "which is directly over the posterior greater tuberosity and infraspinatus insertion site." *Id.* at 2. He also explained, "The MRI demonstrated an abnormal signal in the infraspinatus tendon at its insertion along the bursal surface. This is located directly underneath the deltoid, where [petitioner] felt tenderness." *Id.* at 2-3.

Dr. Wright opined that the injection was most likely given in the green circled area on the image of the posterior muscles of the upper arm (recreated below), which was "the most likely explanation for her clinical presentation and her response to treatment. *Id.* at 3.



Finally, Dr. Wright responded to Dr. Abrams' assertion that petitioner was overweight at the time of receiving the vaccine, which would have lessened the risk of axillary nerve injury. Pet. Ex. 15 at 2; *see also* Resp. Ex. A at 7. Dr. Wright stated that at the time of petitioner's first orthopedic consultation her BMI should be 25.8, according to the CDC BMI calculator. Petitioner's BMI was actually measured at 25.9 and Dr. Wright observed that the petitioner "was only several weeks post-partum and breastfeeding, any excess weight was likely concentrated in her abdominal area and breasts. This is not likely to be relevant to her shoulder anatomy." Pet. Ex. 15 at 2.

d. Respondent's Expert Reports

Respondent submitted expert reports from Dr. Geoffrey D. Abrams, an orthopedic surgeon. Respondent submitted Dr. Abrams first report on December 20, 2018. Resp. Ex. A (ECF No. 28).

In responding to Dr. Sisto's initial report, Dr. Abrams stated that there was no documented evidence that petitioner experienced sensory or motor pathology of the axillary nerve. Resp. Ex. A at 2. Dr. Abrams wrote, "In a typical axillary nerve injury, decreased sensation about the lateral shoulder would be reported," but petitioner's treating orthopedist, Dr. Adams' "indicates that the left shoulder is neurovascularly intact," which indicating no apparent dysfunction in the axillary nerve sensory function. *Id.* at 2. Dr. Abrams also stated that neither of petitioner's MRIs demonstrated findings consistent with axillary neuropathy. *Id.*

Dr. Abrams stated that the recommended subcutaneous injection site for the MMR vaccine "is the posterior triceps aspect of the upper arm." *Id.* at 4. He argued that even if the vaccine injection was not given at the recommended 45-degree angle, the depth of the axillary nerve in the "more posterior location is even deeper than found on the lateral aspect of the shoulder." *Id.* He concluded his first report that "there is no objective evidence of injury to the axillary nerve following petitioner's receipt of the vaccine administration….it is with reasonable medical certainty that the petitioner's shoulder dysfunction is not related to injury of the axillary nerve." *Id.*

Dr. Abrams second report responded to Dr. Wright's initial report. Resp. Ex. C at 1. He states that "it is unlikely" that petitioner's shoulder dysfunction was caused by a direct injection of the vaccine into the subacromial space. *Id.*

Dr. Abrams re-stated that the "location of the injection for an MMR vaccine is in the posterior triceps aspect of the upper arm. It is not possible to reach the subacromial space with an injection given in this location." *Id.* He also explained, "a subcutaneous injection is given at a 45-degree angle, specifically to avoid penetration into the intra-muscular tissues. This makes deep penetration of the needle even less likely." *Id.* at 2. Dr. Abrams stated that the standard needle length for an MMR vaccination is 5/8th" or 15.9 mm and even if the injection was given improperly, "it would not be long enough to reach the subacromial space (or the more deeper infraspinatus tendon…)." *Id.* Dr. Abrams cited to the article by Nakajima et al., which examined intramuscular injection sites and proposed a new injection site for intramuscular injections in the deltoid muscle. Resp. Ex. A, Tab 8 at 1 & 5.[8] Dr. Abrams asserted that the Nakajima article found that the subcutaneous thickness of females at the "typical injection site, as measured by ultrasound ranged from 6-8 mm and that the thickness of the deltoid muscle at this location ranged from approximately 15-20 mm." Resp. Ex. C at 2. He argued that a needle would have to traverse a minimum distance of approximately 21 mm to even reach the subacromial space. *Id.*

[8] Nakajima Y. et al., *Establishing a new appropriate intramuscular injection site in the deltoid muscle,* 13 Human Vaccines & Immunotherapeutics 2123-2129 (2017). [Resp. Ex. A, Tab 8].

The Nakajima article examined the subcutaneous tissue thickness to "determine the appropriate depth of needle insertion for intramuscular injection." *Id.* at 2. The authors of the study looked at the subcutaneous thickness at four different injection sites that have been "recommended for safe and appropriate" intramuscular injection sites in the deltoid muscle. *Id.* at 1. Subcutaneous thickness measured by ultrasound in females at the four different injection sites ranged from 3.5 mm to 13.5 mm, with the thinnest subcutaneous layer found at the injection site approximately 3 cm below the mid-acromion lateral border and the thickest subcutaneous layer found at the injection site approximately 9 cm below the mid-acromion lateral border. *Id.* at 4. The article also examined the thickness of the deltoid muscle to identify which injection site is thick enough to insert the needle for an intramuscular injection. *Id.* at 3. The authors found that the deltoid muscle in both male and female were thinnest at the injection site approximately 3 to 5 cm below the mid-acromion lateral border and the deltoid muscle gradually increased distally from the mid-acromion lateral border. *Id.* at 3-4.

Additionally, Dr. Abrams asserted that petitioner had an increased BMI, which would "serve to further increase the distance the needle would have to traverse, making the claim of the subacromial penetration even less likely." Resp. Ex. C at 2. Dr. Abrams concluded, "the facts of the case and the evidence within the medical record make it extremely unlikely that the petitioner suffered a SIRVA related injury to her shoulder." *Id.* at 3.

III. Petitioner's Table Injury

a. Standard for Adjudication for a Table SIRVA

The QAI for SIRVA provides:

> (10) 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 musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury an 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 a SRIVA 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)(i)-(iv).

b. Petitioner's contentions

Petitioner contends that she has met her burden of proof for a Table SIRVA. Pet. Mot. at 7. Petitioner argues that the Vaccine Injury Table includes SIRVA as a Table Injury for the MMR vaccine. *Id.* at 8. Specifically, petitioner argues that improper administration of the MMR vaccine can satisfy the Criteria for a Table SIRVA. *Id.*

Petitioner argues that respondent's position, "that MMR can, under no circumstances, result in a table injury because it is *meant* for subcutaneous administration, rather than intramuscular," is inconsistent with the actual Vaccine Injury Table, which includes SIRVA as a table injury for MMR. *Id.* at 8-9. Further, petitioner contends that the respondent is "advancing an erroneous interpretation of the Vaccine Injury Table and its QAI for SIRVA." *Id.* at 8.

Petitioner argues that the introductory paragraph of SIRVA does four things: (1) describes how SIRVA "manifests," with shoulder pain and limited range of motion; (2) describes how SIRVA "occur[s]," "from the unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder…." (3) describes what SIRVA is not; and (4) sets forth four criteria for "who shall be considered to have suffered SIRVA." *Id.* at 10. Petitioner acknowledges that the introductory paragraph contains the phrase, "vaccines intended for intramuscular administration," but argues that it is "legally improper to read this sentence in isolation and must be considered in context and harmonized with both the Table and entire QAI. *Id.* Specifically, petitioner argues that the second sentence of the QAI SIRVA paragraph, which provides, "unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa" is not intended to exclude injuries where a vaccine should have been administered subcutaneously, "but for whatever reason, were administered intramuscularly." *Id.*

Petitioner posits that the QAI acknowledges that SIRVA occurs when the vaccine is inadvertently administered into the "tendons, ligaments, bursae, etc," as opposed to the intended muscle. *Id.* at 11. Petitioner suggests that, "The two sentences read together clearly contemplate a scenario where the vaccine *administrator* (not the manufacturer), intends to place the injection in one location, i.e. in a muscle, but inadvertently places it someplace else." *Id.* (original emphasis). Further, petitioner states, that the QAI does not explicitly exclude vaccines (to be considered for a SIRVA) which have been designed by the manufacturer to be injected subcutaneously, but instead are inadvertently injected intramuscularly, causing injury. *Id.*

Then petitioner argues that the introductory paragraph for SIRVA in the QAI would add a fifth criteria to establish a SRIVA by requiring that a vaccine must have been intended for intramuscular injection by the manufacturer. *Id.* at 11. Petitioner contends that if respondent had intended to exclude vaccines intended for subcutaneous administration from SIRVA Table

injuries, respondent should have done so explicitly and not included SIRVA as a covered injury for MMR in the Table itself. *Id.* at 11. To advance her argument, petitioner observes that the first criteria in the SIRVA QAI does not actually require that the vaccine in question have been intended for intramuscular administration, but only that the vaccine *was actually administered* intramuscularly. *Id.* at 13 (emphasis added).

Petitioner also argues that the respondent's position would "lead to an absurd result," that runs afoul of the principle of statutory interpretation that absurd results should be avoided. *Id.* at 11-12. Petitioner specifically cites to the Federal Circuit's decision in *Dupuch-Carron,* where the Court reiterated that, "[i]f a literal construction of the words of a statute be absurd, the act must be so construed as to avoid the absurdity." *Dupuch-Carron v. Sec'y of Health & Hum. Servs.*, 969 F.3d 1318, 1330 (Fed. Cir. 2020), *cert denied,* However, the Federal Circuit also explained, "When construing a statutory term or phrase to avoid an absurd result, or when the term or phrase is "ambiguous," it "must be read in [its] context and with a view to [its] place in the overall statutory scheme." 969 F.3d at 1330 (citing *Colonial Press Int'l, Inc. v. United States,* 788 F.3d 1350, 1357 (Fed. Cir. 2015); *see also Wassenaar v. Office of Pers. Mgmt.,* 21 F.3d 1090, 1092 (Fed. Cir. 1994) (stating that "[a] reading of [a statute] which would lead to absurd results is to be avoided when [it] can be given a reasonable application consistent with [its] words and legislative purpose").

Petitioner states that "under respondent's proposed interpretation of the Table and QAI for SIRVA, a vaccine petitioner, like the petitioner in the present case, who was injected incorrectly in two separate ways, i.e. intramuscularly instead of subcutaneously, *and,* too deeply into the deltoid muscle entering the bursa," would have less chance of recovery for her alleged vaccine injury than a person receiving an intramuscularly injection administered incorrectly. Pet. Mem. at 12. The respondent's position provides less protection to [a] more aggrieved petitioner and respondent's interpretation is inconsistent with the goals of the Vaccine Act. *Id.*

Finally, petitioner argues that she has satisfied the four enumerated SIRVA criteria outlined in the QAI.[9] Petitioner posits that the MMR vaccination she received was administered incorrectly and it was injected intramuscularly, therefore, she meets the first criterion for a SIRVA. *Id.* Petitioner also argues that she has demonstrated by preponderant evidence that the onset of her pain began within 48 hours of vaccine administration. *Id.* at 13.

c. Respondent's contentions

Respondent argues that petitioner has not established a Table injury because petitioner received the June 8, 2016 MMR vaccine subcutaneously. Resp. Mem. at 5-6. Respondent states that the language of the QAI defines a SIRVA as "shoulder pain and limited range of motion occurring after the administration of a vaccine *intended for intramuscular administration* in the upper arm. 42 C.F.R. 100.3(c)(10) (original emphasis). Resp. Mem. at 6. Respondent states that the MMR vaccine "is a vaccination intended for subcutaneous administration," and as such, the petitioner's claim fails to satisfy the language of the QAI. Further, respondent contends that petitioner's argument that her legal rights under the Vaccine Act are being deprived is erroneous

[9] Respondent does not dispute that petitioner has met the (iii) and (iv) criterion of a Table SIRVA.

because petitioner is not being precluded from pursuing a causation-in-fact claim under the Act. *Id.* at 7.

Respondent then argues that petitioner does not satisfy the Table SIRVA criteria's onset of pain occurring within 48 hours. Resp. Mem. at 7. Respondent contends that petitioner's failure to report her shoulder pain to her OB/GYN until June 20, 2016, approximately twelve days after receiving the vaccination, is inconsistent with her affidavit that her pain began immediately. *Id.* at 8. Respondent also argues that petitioner's failure to mention her shoulder pain on June 15, 2016 to her OB/GYN office, when they called petitioner to explain her contraceptive benefits available under her insurance, is again evidence that petitioner's onset of left shoulder pain did not occur within forty-eight hours of vaccination. *Id.*

Respondent also suggests that some of petitioner's contemporaneous medical records contradict her affidavit. *Id.* at 9. Respondent states that a physical therapy note on June 4, 2016, which provides, "She reports having a shot in the hospital which caused a lot of neck pain and then a few days later her shoulder began getting stiff and she began having pain," as contradicting her affidavit, which provides that her left shoulder pain began the same evening as the vaccination. *Id.* at 9; *see* Pet. Ex. 9 at ¶ 2. Citing to *Reusser v. Sec'y of Health & Hum. Servs.*, respondent posits that the written documentation recorded by the physical therapist is more reliable than petitioner's recollection of the events two years later. 28 Fed. Cl. 516, 523 (1993) (stating, "[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.").

Respondent concludes that petitioner is not eligible for Table SIRVA presumption of causation because she received a subcutaneous injection and the medical records do not demonstrate onset of symptoms within the requisite time of forty-eight hours or less following vaccination. *Id.* at 9.

d. Discussion of Petitioner's Alleged Table Injury

The core issue between the parties is whether petitioner can claim a Table SIRVA for the receipt of an MMR vaccine, which is only intended to be administered subcutaneously. Petitioner argues that the inconsistency between the Table and the QAI creates a genuine ambiguity, depriving her of her right under the Vaccine Act, to receive the presumption that the vaccine in question caused her left shoulder injury. Pet. Mot. at 7-9.

The starting point for analyzing the respondent's regulations begins if "there is [an] express delegation of authority [by Congress] to an agency to elucidate a specific provision of the statute by regulation. *Chevron U.S.A., Inc., v. Nat'l Resources Defense Council, Inc.,* 467 U.S. 837, 843 (1984). When granting rulemaking power to agencies, Congress usually intends to give them considerable latitude to interpret the ambiguous rules they issue. *Kisor v. Wilkie,* 139 S.Ct. 2400, 2412 (2019). Before concluding that a rule is genuinely ambiguous, a court must exhaust all the "traditional tools" of construction. *Kisor v. Wilkie,* at 2415 (citing *Chevron* at 843 n.9). If a genuine ambiguity remains, moreover, the agency's reading must still be reasonable. 139 S.Ct. at 2416; *Thomas Jefferson Univ. v. Shalalala,* 512 U.S. 504, 515 (1994). However, if

uncertainty does not exist, there is no plausible reason for *Auer* deference and "the regulation just means what it means." *Kisor* at 2415.

In this case, Congress has delegated authority to the respondent to promulgate regulations to modify the Vaccine Injury Table. §300aa-14(c)(1). The respondent may add or remove illnesses, disabilities, injuries and conditions for which compensation may be provided or change the time period for which the first symptom or manifestation of the illness, disability, injury or condition occurs. *Id.* at (c)(3). Additionally, Congress gave the respondent authority to revise the Vaccine Injury Table to add vaccines to the Vaccine Injury Table for which the Centers for Disease Control and Prevention ("CDC") has recommended for the routine administration to children and pregnant women. *Id.* at (e)(1)-(3).

As in any statutory interpretation case, [the Court starts], of course with the statutory text, and proceeds from the understanding that unless otherwise defined, statutory terms are generally interpreted in accordance with their ordinary meaning. *Sebelius v. Cloer*, 569 U.S. 369, 376 (2013). Petitioner does not dispute that the QAI introductory paragraph for a SIRVA includes the language "vaccines intended for intramuscular administration." Pet. Mem. at 11; *see also* 42 C.F.R. § 100.3(c)(10). Nor does petitioner dispute that the MMR vaccine, at the current time she received the vaccination, is not intended for intramuscular injection. *Id.* at 10. According to the CDC's Advisory Committee on Immunization Practices ("ACIP"), "routes of administration are recommended by the manufacturer for each immunobiologic." Court's Exhibit 1 ("Ct. Ex.").[10] The AICP outlined the type of vaccine, dose and route of administration for each of the vaccines. *Id.* at 11. The MMR vaccine's route of administration is noted as "subcutaneous." *Id.* Thus, under the ordinary meaning of the phrase "vaccines intended for intramuscular administration," the MMR vaccine is excluded from QAI's SIRVA definition at this time.

However, petitioner argues that the first sentence of the definition of SIRVA as provided in the QAI cannot be read in isolation and "must be interpreted in context and harmonized with both the Table and the entire QAI." Pet. Mem. at 10. I agree with petitioner that looking at the entire regulation as whole is instructive, as it is also dispositive.

When construing a statutory term or phrase to avoid an absurd result, or when the term or phrase is "ambiguous," it "must be read in [its] context and with a view to [its] place in the overall statutory scheme. *Colonial Press Int'l v. United States,* 788 F.3d 1350, 1357 (Fed. Cir. 2015) (quoting *Davis v. Mich. Dep't of Treasury,* 489 U.S. 803, 809 S.Ct. 1500 (1989). Petitioner argues that the inclusion of SIRVA on the Table for the receipt of an MMR vaccine and the language of the QAI creates an ambiguity that would lead to absurd results. However, the Vaccine Injury Table is preceded by an introductory paragraph, which provides:

> In accordance with Section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines and the time period in

[10] *Vaccine Recommendations and Guidelines of the ACIP,* https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration html#t6_1

> which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the program…..*Paragraph (c) of this section sets forth the qualifications and aids to interpretations for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table.*

42 C.F.R. § 100.3(a) (emphasis added). This introductory paragraph makes it clear that the terms defined in the qualifications and aids to interpretation outlined in paragraph (c) applies to the illnesses, disability, injuries or conditions that are covered by the Table. Thus, the term SIRVA as defined at 42 C.F.R. § 100.3(c)(10), which imposes a restriction that the vaccine be *intended for intramuscular administration*, governs the Vaccine Injury Table section (a)(III)(C).

Finally, examining the history of the addition of SIRVA to the Vaccine Injury Table is also instructive to determine whether the subcutaneous MMR vaccine was intended to qualify as a Table SIRVA under the regulations.

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table. *See* Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). However, the respondent began the rulemaking process to add SIRVA to the Table two years prior.

On July 29, 2015, the respondent promulgated a Notice of Proposed Rule Making ("NPRM"), to amend the Vaccine Injury Table by regulation. 80 F.R. 45132-01, 2015 WL 4538923 (July 29, 2015). Specifically, respondent proposed adding SIRVA to the Table, describing it as, "an adverse event following vaccination thought to be related to the technique of intramuscular percutaneous injection (the process where access to a muscle is obtained by using a needle to puncture the skin) into an arm resulting in trauma from the needle and/or unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder." *Id.* at 45136. In the proposed rule, respondent stated, "As proposed the proposed definition indicates, SIRVA is an injury related to the *intramuscular injection of a vaccine.* Consequently, by definition, a Table injury of SIRVA *will not result for those vaccine that are not administered by intramuscular injection*, including….subcutaneous MMR, MMRV…" *Id.* (emphasis added).

Respondent further stated, "While the Secretary propose adding SIRVA to the Table for MMR and Varicella vaccines, to meet the proposed QAI for SIRVA, the vaccine must be one *intended for intramuscular administration* in the upper arm." *Id.* (emphasis added). Respondent acknowledged that there were no MMR or Varicella vaccines that are administered intramuscularly at the time, but including SIRVA as a Table injury for those two vaccines (MMR and Varicella) would not require a modification to the Table in the future, if such of those vaccines became available to be administered intramuscularly. *Id.* The respondent further acknowledged that the "disadvantage of this proposal could be confusion about whether a Table injury for SIRVA may be satisfied for those vaccines, despite the QAI's requirement that the associated vaccine be intended for intramuscular administration." *Id.* Respondent sought

feedback from the public specifically on the proposal to include SIRVA as Table injury for the MMR and varicella vaccines. *Id.*

On January 19, 2017, the Secretary issued the final Rule amending the Vaccine Injury Table. 82 F.R. 6294-01, 2017 WL 202456 (F.R). *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table* (Jan. 19, 2017). In the final rule, respondent published a summary of the comments regarding the NPRM, which included comments about respondent's proposal to include SIRVA as a Table injury for the MMR vaccines. *Id.* at *6297. One commenter agreed with respondent's proposal to add SIRVA as a Table injury for the MMR and varicella vaccines "that are currently administered only by percutaneous injection in case an intramuscular injection is available in the future," but suggested that "the Table make clear that SIRVA only pertains to intramuscular injection so there is no confusion with respect to vaccines administered using a different method." *Id.* In responding to the comment, respondent agreed with the commenter that SIRVA should be an injury listed on the Table "for potential formulations of MRM and varicella vaccines that are administered by intramuscular injection," but also declined to further clarify the Table, stating,

> The QAI specifically states that SIRVA is a condition related to "administration of a vaccine intended for intramuscular administration in the upper arm." Thus, the Secretary believes it is clear that to meet the definition of SIRVA in the QAI, the vaccine administered must be one intended for intramuscular injection in the upper arm.

Id. The respondent's final rule ultimately added SIRVA as Table injury for the MMR and varicella vaccines. *See* 42 C.F.R. §100.3(c)(10).

To some extent, the undersigned agrees with petitioner that having SIRVA listed as a Table injury for vaccines that are not available for intramuscular injection (MMR and varicella) at this time can lead to some confusion as to whether the administration of an MMR vaccination can give rise to a covered Table SIRVA injury. The inclusion and the language in first SIRVA criterion, "(i) No history of pain….prior to intramuscular vaccine *administration*," does give rise to some confusion and ambiguity, particularly when a claimant allege that the subcutaneous vaccination was administered incorrectly, giving rise to a shoulder injury. However, as discussed above, the NPRM and response to a commenter thereto, provides further clarification that the inclusion of MMR on the table for SIRVA was merely prospective to account for a possible future MMR vaccine that was intended for intramuscular administration. It was not clear if in the course of rule making the possibility of improper intramuscular administration of a vaccine intended for subcutaneous injection could give rise to a SIRVA injury.

Nevertheless, when all available sources of clarification of the Vaccine Injury Table and QAI as applied to the MMR vaccine are utilized, it is apparent that the Secretary intended that only vaccines *intended* for administration intramuscularly can give rise to a Table SIRVA injury. Accordingly, the petitioner is not afforded the presumption of vaccine causation as a Table claim.

IV. Petitioner's Cause-in-Fact Claim

The finding above only forecloses petitioner's Table SIRVA claim. In the alternative, petitioner is alleging a cause-in-fact claim that the MMR vaccine, administered subcutaneously, was the cause of her left shoulder pain. Pet. Mot. at 14.

A. Legal Standard

1. Finding of Fact

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "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." *Curcuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined 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. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

2. Causation

Petitioner is alleging that the MMR vaccine she received on June 8, 2016 was the cause-in-fact of her left shoulder injury. Petitioner bears the burden of establishing actual causation. To do so, she must "show by preponderant evidence that the vaccination brought about the injury by providing 1) a medical theory connecting the vaccination and injury; 2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and 3) a showing of proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). There must be preponderant evidence for each *Althen* prong. *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 132 (2011), *aff. per curiam*, 463 Fed. Appx. 932 (Fed. Cir. 2012).

Under *Althen* prong one, the causation theory must relate to the injury alleged. Thus, a petitioner must provide a "reputable" medical or scientific explanation that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. It must only be "legally probable, not medically or scientifically certain." *Id.* at 549. However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Id.* at 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen*, 418 F.3d at 1280 (emphasis added).

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [her] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen*, 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Hums. Servs.*, 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148.

Althen prong three requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen* at 1281. That term has equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof

that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one). *Id.* at 1352.

The preponderance of the evidence standard requires the petitioner to demonstrate that it is "more likely than not" that the vaccine caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner must demonstrate that the vaccine was "not only [a] but for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 135 F.3d 1344, 1352-53 (Fed. Cir. 1999); *Pafford v. Sec'y of Health and Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Causation is determined on a case-by-case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). A fact-finder may rely upon "circumstantial evidence" which is consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F. 3d at 1280.

The petitioner often presents expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.,* 219 F.3d 1357, 1361 (Fed. Cir. 2000). Expert testimony in the Vaccine Program is usually evaluated according to the factors set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo,* 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Human Servs.,* 195 F.3d 1302, 1316 (Fed. Cir. 1999). A special master may use the *Daubert* framework to evaluate the reliability of expert testimony, but expert testimony need not meet each *Daubert* factor to be reliable. *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351 (Fed. Cir. 2019). The *Daubert* factors are "meant to be helpful, not definitive," and all factors "'do not…necessarily apply even in every instance in which the reliability of scientific testimony is challenged.'" *Boatmon,* 941 F. 3d at 1359 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151, 119 S. Ct. 1167, 143 L.Ed.2d 238 (1999). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly* at 1324. 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 & Human Servs.,* 219 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe,* 219 F.3d 1357 at 1362).

If the petitioner makes a *prima facie* case supporting vaccine causation-in-fact, the burden shifts to respondent to show by a preponderance of the evidence that the injury is instead due to factors unrelated to the administration of the vaccine. *Deribeaux v. Sec'y of Health & Human Servs.,* 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing § 13(a)(1)(B)). Respondent has the burden of demonstrating that: "[A] factor unrelated to the vaccination is the more likely or principal cause of injury alleged. Such a showing establishes that the factor unrelated, not the vaccination, was 'principally responsible' for the injury. If the evidence or alternative cause is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded." *Knudsen,* 35 F.3d at 551.

B. Finding of Fact

In this case, there are two issues of fact to be resolved. The first is whether petitioner's MMR vaccine was inadvertently or erroneously administered intramuscularly in the shoulder area as opposed to subcutaneously posterior to the triceps muscle. The second issue is the onset of petitioner's shoulder pain and dysfunction.

1. Site of Administration

a. Petitioner's Arguments

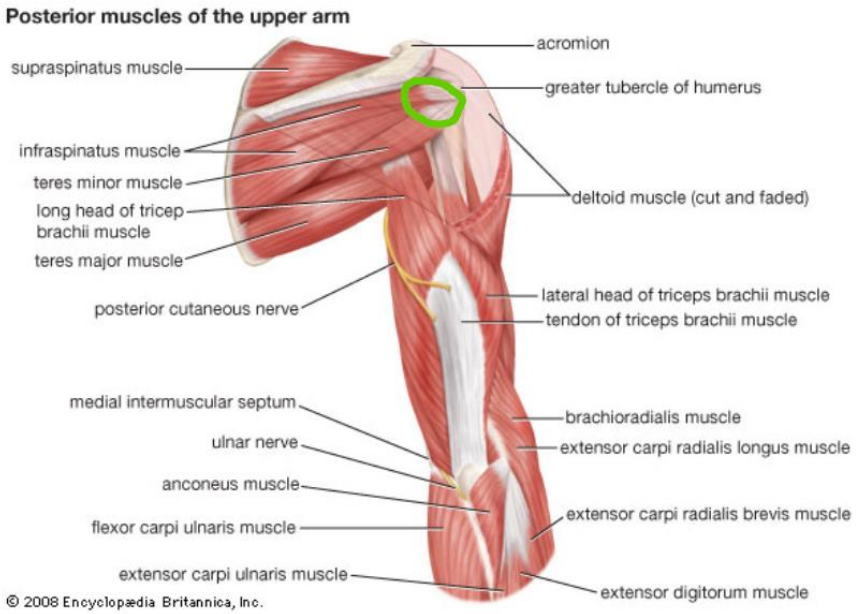
Petitioner asserts that the MMR vaccine was inadvertently administered into her deltoid muscle into her subacromial bursa. Pet. Mot. at 17-31. She argues that her statements in her affidavit and to her treating physicians, in addition to, Dr. Wright's statements, support that the vaccine was mis-administered high into her upper left arm, instead of subcutaneously, as the vaccine is intended to be administered. *Id.*

There is no doubt in the vaccination record that Baptist Medical Center ordered the MMR vaccine for petitioner. Pet. Ex. 2 at 132. Additionally, the details of the order indicate the amount of the vaccine to be given (0.5 ml) and that it is to be given subcutaneously. *Id*. Further, the medication administration from Baptist Medical Center indicates that petitioner received the MMR vaccine in her "left upper" arm. *Id.* at 200. However, this record does not provide any further detail regarding the exact location of vaccine administration in her left upper arm or if it was inadvertently administered into her muscle.

In her supplemental affidavit, petitioner provided additional detail regarding the location of the vaccination. She stated, "Christy [my nurse], administered the shot at approximately 5:30 pm on June 8. It was given in the back of my upper left arm." Pet. Ex. 9 at ¶ 3. Petitioner also provided, "What I do remember physically about the shot was that, as I was waiting for my baby and me to be discharged, I was lying on the hospital bed in my room….When the nurse came into give me the shot, she had me sit up on the bed. She stood next to and over me to give the injection. I felt the shot being given and it was on my upper arm toward the back." *Id.* at ¶ 6. The shot was itself was extremely painful immediately. *Id.* at ¶ 5.

Later, when petitioner went to see orthopedist, Dr. Michael Adams, petitioner described that she received the MMR vaccine in her "lateral left shoulder," providing a more specific location to where she was injected. Pet. Ex. 4 at 43. When Dr. Adams examined petitioner's left shoulder, he noted, "Generalized tenderness to palpation about the deltoid girdle. Tender to palpation over the bicipital groove." *Id.* at 44. On April 26, 2017, at a follow-up appointment with Dr. Adams for ongoing left shoulder pain, petitioner indicated that her pain was "posterior in location." Pet. Ex. 6 at 9. The physical examination revealed that petitioner had "tenderness to palpation [on the] posterior rotator cuff." *Id.* at 10.

Petitioner's expert, Dr. Wright, acknowledged that it would be difficult to identify the exact location petitioner received the MMR vaccine, he opined that the injection was "most likely" injected into the subacromial space. Pet. Ex. 15 at 1; Pet. Ex. 12 at 1. Dr. Wright noted that petitioner exhibited generalized tenderness to palpation near the deltoid insertion on the acromion which is directly over the posterior greater tuberosity and infraspinatus insertion site. Pet. Ex. 15 at 2. He explained, "This is located directly underneath the deltoid, where [petitioner] felt tenderness." *Id.* Dr. Wright also noted that on petitioner's MRI of her left shoulder "demonstrated an abnormal signal in the infraspinatus tendon at its insertion along the bursal surface." *Id.* Based on what petitioner stated in her affidavit and the medical records, Dr. Wright opined that it was likely petitioner received the injection in the deltoid muscle near its insertion at the acromion, passing through the infraspinatus insertion site at the bursa, into the subacromial bursa. Pet. Ex. 15 at 2-3; Pet. Mot. at 25. Dr. Wright provided a diagram depicting where he believed petitioner received the MMR vaccine, re-created below:



Pet. Ex. 15 at 3. The green circle represents area in which Dr. Wright opined that petitioner received the MMR injection.

Referencing the Bodor and Montalvo article, Dr. Wright stated that "an injection into the subacromial space can be responsible for initiating a major inflammatory event in the subacromial bursae resulting in persistent severe pain." Pet. Ex. 12 at 1; Pet. Ex. 14 at 2. The article highlights two case reports of shoulder dysfunction and pain following intramuscular vaccination. Pet. Ex. 14. The authors hypothesized that vaccine was injected into the subdeltoid bursa. *Id.* at 2. The authors explained that the subacromial bursa's depth below the skin was approximately 0.8 cm (8 mm) to 1.6 cm (16 mm) below the skin. *Id.* at 2. They wrote, "We hypothesize that in both of our cases vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response. Given that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule." *Id.* at 2.

Petitioner argued that the skin and deltoid muscle at Dr. Wright's proposed injection site is thinner than at the proposed injection site by Dr. Abrams. Using the diagram below from the Nakajima article, petitioner asserted that the Dr. Wright's proposed injection site is the region between b' and 1/3 bb'. Pet. Mot. at 32.

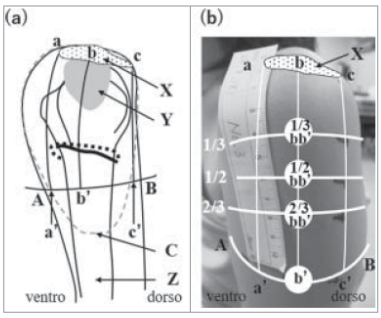


Figure 1. Anatomical structure of the left shoulder (a) and locations of 4 examined sites in a living body (b). A: The upper end of the anterior axillary line, B: the upper end of the posterior axillary line, a: the anterior edge of the mid-acromion lateral border, C: Deltoid tuberosity for attachment of the deltoid muscle, b: the midportion of the mid-acromion lateral border, c: the posterior edge of the mid-acromion lateral border, a': the intersection between the perpendicular line drawn from the anterior edge of the mid-acromion lateral border and line AB, b': the intersection between a perpendicular line drawn from the mid-acromion lateral border and line AB, c': the intersection between the perpendicular line drawn from the posterior edge of the mid-acromion lateral border and line AB, X: acromion, Y: subdeltoid/subacromial brusa, Z: humerus, dotted circle: the deltoid muscle, dotted line: the posterior circumflex humeral artery (PCHA), black line below the PCHA: the axillary nerve. (b) One third, half, and two thirds of bb' are marked on the skin. 1/3 bb', 1/2 bb', 2/3 bb', and b' are the sites examined in the present study.

Resp. Ex. A, Tab 8 at 24. Petitioner stated that, "The total thickness at 1/3 bb' of skin is 5-6 mm…and of deltoid muscle is 9-13 mm thick….for a total range of 14-19 mm at that site." Pet. Mot. at 32; Resp. Ex. A, Tab 8 at 3-4. Petitioner asserted that, "Therefore, even if a 15.9 mm needled intended for subcutaneous administration was used, it could indeed have reached the bursa in the manner proposed by Dr. Wright." Pet. Mot. at 32.

b. Respondent's Arguments

Respondent contests that the "medical records reflect that the MMR vaccine was administered subcutaneously in petitioner's left arm," which is consistent with the CDC recommendation for subcutaneous injection of an MMR vaccine. Resp. Brief at 11. Specifically, respondent states that petitioner described the vaccination site as "high on [the] upper arm toward the back," which is consistent with the proper injection site being in the posterior triceps aspect of the upper arm. *Id.*

Respondent argued that Dr. Wright's proposed injection site is not supported by the record because petitioner did not state that the injection was given on her shoulder or "completely on the back of her arm." Resp. Brief at 12. Instead, respondent argued that petitioner only stated that the vaccine was injected "towards" the back of her arm, which is "consistent with the CDC recommendation for subcutaneous injection of an MMR vaccine in the posterior triceps aspect of the upper arm." *Id.* at 11.

Using the diagram from the Nakajima article (above), Dr. Abrams put the petitioner's injection site between ½ bb' and 2/3 bb' and respondent argued that "this region more closely fits with petitioner's description in her supplemental affidavit that the injection was high on her *upper arm*-not on her shoulder." Resp. Brief at 13 (original emphasis).

Dr. Abrams noted that the standard needle length for an MMR vaccination is 5/8" or 15.9 mm, which would make it difficult for the injection to reach the subacromial space. Resp. Ex. C at 2. He stated that, "The subcutaneous (skin) thickness of females at the typical injection site, as measured by ultrasound, range from 6-8 mm. In addition, the thickness of the deltoid muscle at this location would have to traverse a minimum distance of approximately 21 mm to even reach the subacromial space-and this was in a patient population significantly below the body mass index of the petitioner." *Id.* at 2. Respondent stated that the even if the needle was injected "high in the upper aspect of the lateral arm, such as near site, 1/3 bb' it is highly unlikely that the needle passed into the structures behind the muscle due to the angle of administration." Resp. Brief at 14.

Dr. Abrams also asserted that a subcutaneous injection given at a 45-degree angle to specifically "avoid penetration into the intra-muscular tissue." Resp. Brief at 14; Resp. Ex. C at 2. Respondent argued that the way in which petitioner described the administering nurse "standing over her" while injecting the vaccine supports proper administration angle of the vaccine. Resp. Brief at 15. Respondent stated, "From a standing position over a patient, it would be natural for the needle of the syringe to point downward at an angle towards the floor, because of the way healthcare professionals hold a syringe between their fingers. Depressing the syringe perfectly perpendicular to the patient's arm while standing above the patient would require holding the syringe in a very awkward manner. It is highly unlikely that this nurse injected petitioner's upper arm at the 90-degree angle required to reach the subacromial space, while petitioner was sitting-down and the nurse was standing over her." *Id.*

c. Conclusion regarding site administration

Petitioner has presented preponderant evidence that the June 8, 2016 MMR vaccine was administered high on her left lateral shoulder in the deltoid muscle into the subacromial bursa.

Petitioner explained that she received the vaccination in her left "upper arm, towards the back," in her supplemental affidavit. Consistent with her affidavit, when petitioner presented to orthopedist, Dr. Adams, she reported that her injection was into the "lateral left shoulder." Pet. Ex. 4 at 43. These two descriptions given by petitioner do not indicate that the vaccine was administered in her triceps region as proposed by respondent, which is lower on the back of the arm, but instead, both descriptions would put the injection site as being high towards the back of her arm, closer to her shoulder.

Petitioner's statement that the vaccine was administered on her "upper arm toward the back," is consistent with the physical examinations post-vaccination. For example, Adams noted petitioner had, "Generalized tenderness to palpation about the deltoid girdle. Tender to palpation over the bicipital groove." Pet. Ex. 4 at 44. Petitioner also had "tenderness to palpation [on the] posterior rotator cuff." Pet. Ex. 6 at 10. During her first physical therapy evaluation on July 4,

2016, petitioner demonstrated tenderness on her biceps tendon long head, supraspinatus tendon and the posterior cuff. Pet. Ex. 5 at 29.

Additionally, petitioner's MRIs are also consistent with her description of where the vaccine was injected into her left arm. The MRI taken on June 15, 2016 revealed the following, "The infraspinatus tendon demonstrates abnormal increased T2 signal at its insertion." Pet. Ex. 2 at 6. The impression of the radiologist was, "Partial thickness tear distal infraspinatus tendon at its insertion along the bursal surface." *Id.* Her follow-up MRI taken on April 21, 2017 showed "abnormal bursal surface signal of the distal anterior supraspinatus adjacent to the footplate," and, "a tiny sliver of fluid in the subacromial subdeltoid bursa." Pet. Ex. 6 at 13.

Petitioner's description of the vaccination site being high towards the back of her upper left arm, makes it more likely that the vaccine was administered in a manner that would have been in or around the subacromial bursa, as suggested by Dr. Wright. The image below shows the posterior view of the shoulder, recreated from the S. Atanasoff article, demonstrates the relationship between the deltoid muscle, the subacromial bursa space to the supraspinatus tendon.

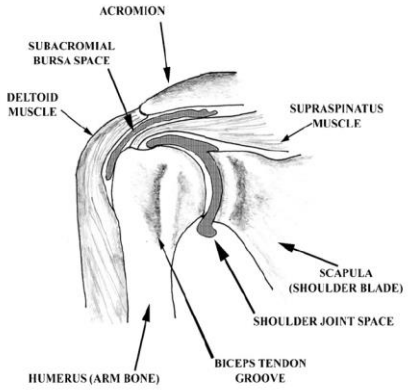


Fig. 1. Anatomy of the shoulder girdle. The relationships of the subdeltoid/subacromial bursa and shoulder joint space to the supraspinatus tendon and to the greater tuberosity on which it inserts.

Pet. Ex. 18 at 3.[11] The Bodor article explained that the subacromial bursa extends from 3.0 cm to 6.0 cm beyond the lateral border of the acromion and that it lay anywhere from 0.8 cm (8 mm) to 1.6 cm (1.6 mm) below the skin surface. Pet. Ex. 14 at 2. At Dr. Wright's proposed injection site, it is conceivable that a 15.9 mm (or 1.59 cm) needle used for the MMR vaccine could penetrate into the subacromial bursa, given its depth of 0.8 cm to 1.6 cm below the skin surface.

Finally, respondent's argument that petitioner was seated during the vaccine administration and the administering nurse was standing makes it more likely that the vaccine was administered in a downward angle, thus making it difficult to penetrate into the subacromial bursa is not credible. The Atanasoff article explains, "…while patients are often seated for vaccinations, the standing position of the provider administering the injection may also contribute to injecting inadvertently high into the deltoid….Thus, concurrent seating positions for both the administrator and the receiver may minimize the risk of the injection being too

[11] Atanasoff, S. et al., *Shoulder Injury Related to Vaccine Injury (SIRVA)*, 28 Vaccine 8049-8052 (2010). [Pet. Ex. 18].

high." Pet. Ex. 18 at 4. In this case, petitioner stated that when she received the MMR vaccination, she was seated on the bed and the administering nurse was standing above and behind her. Pet. Ex. 9 at ¶¶ 3 and 9. Additionally, petitioner described the injection site was "high" on her left arm. Pet. Ex. at ¶ 9. Given the seated position of the petitioner while receiving the vaccine and that she described the site as being "high" towards the back of her left arm, it is more likely that the administering nurse injected the vaccine high on the back of petitioner's left arm, penetrating into and around the subacromial bursa.

Consistent with the above, I find that petitioner has established by preponderant evidence that the MMR vaccine she received was administered in the subacromial space, high on her left arm. The administration appears to have been more consistent with an unintended intramuscular administration, such that it penetrated into and around petitioner's subacromial bursa.

2. Onset of Petitioner's Pain

a. Respondent's arguments

Respondent argues that the evidence does not demonstrate that petitioner experienced shoulder pain or dysfunction within 48-hours of receiving the MMR vaccine. Resp. Brief at 7. Respondent specifically argues that, "the contemporaneous medical records do not provide independent evidence of onset within 48 hours of vaccination, and petitioner's own statements are insufficient to meet her burden." *Id.* at 9. Respondent states that, "the contemporaneous medical records reflect that she did not complain of shoulder pain until the June 20, 2016 phone call to the office of her OB/GYN." *Id.* at 8. Respondent states that petitioner had contacted her OB/GYN's office five days prior, on June 15, 2016 and did not complain of shoulder pain. *Id.* Additionally, respondent argues that petitioner's supplemental affidavit contradicts the medical records. Resp. Brief at 8. Respondent states that petitioner stated in her supplemental affidavit that on June 15, 2016 "her condition was so poor that she could not lift her arm or use it at all," however, petitioner waited an additional five days to seek medical treatment. *Id.*

Respondent also argues that petitioner's description of onset of left shoulder pain in the medical records fails to demonstrate that the pain began within 48 hours. *Id.* at 9. Respondent notes that at a physical therapy appointment on July 4, 2016, petitioner reported that, "a shot in the hospital…caused a lot of neck pain then a few days later her shoulder began getting stiff and she began having pain." *Id.* at 9. But later, in her affidavit, petitioner asserted that the neck pain started after the shoulder pain." *Id.* Respondent stated that this contradiction "calls into question the reliability of petitioner's supplemental affidavit." *Id.* Respondent concluded that the medical records do not demonstrate that petitioner's onset of symptoms was within 48 hours or less following the MMR vaccination. *Id.* at 10.

b. Petitioner's arguments

Petitioner argues that the medical records and her affidavit support onset of her left shoulder injury within 48 hours of receiving the MMR vaccination on June 8, 2016. Pet. Mot. at 32. Petitioner states that she called the OB/GYN office on June 20, 2016 and "the notes of the call reflect that she stated that her arm was sore after the post-delivery vaccination." *Id.* at 19;

Pet. Ex. 3 at 138. Petitioner also states that she told the same to her orthopedist, Dr. Adams at the June 28, 2016 appointment, the record from which reported that "after they injected into her lateral left shoulder, she began to have increased intense pain and range of motion problems." *Id.* at 20; Pet. Ex. 4 at 43. Additionally, petitioner asserts that at the same appointment, Dr. Adams and petitioner appeared to have reviewed a website, which may have been the VICP or the Table, and he wrote, "I do not think it is out of the realm of question that she had post-injection stiffness and pain…" *Id.* at 21; Pet. Ex. 4 at 45.

Petitioner also asserts that her supplemental affidavit supports the onset of pain within 48 hours of receiving the vaccination. Petitioner explains in her affidavit that she felt excruciating pain during the vaccination, so much that she nearly came off the bed. Pet. Mot. at 19; Pet. Ex. 9 at ¶ 1. Further, when petitioner called the office on June 20, 2016, the note reads, "Pt. calling stating unable to move left arm. Pt. states sore after given shot in arm after delivery. Pt. states now 2 weeks later unable to move warm at all." Pet. Ex. 3 at 138.

Petitioner concluded that the evidentiary record documents that the onset of her shoulder injury followed within 48 hours of the vaccination at issue, which is within a medically appropriate proximate timeframe.

c. Conclusion regarding onset of petitioner's should pain and dysfunction

Petitioner has demonstrated by preponderant evidence that the onset of her shoulder pain occurred within 48 hours of her MMR vaccination on June 8, 2016.

The medical records demonstrate that petitioner consistently attributed the pain in her left shoulder to the MMR vaccination on June 8, 2016. She called her OB/GYN on June 20, 2016 and reported that she was "unable to move her left arm," and that her arm has been "sore after given shot in arm after delivery," and stated that her arm was "frozen." Pet. Ex. 3 at 138. Respondent argued that petitioner spoke to her OB/GYN's office five days earlier, on June 15, 2016, but did not mention that her left arm was sore. Resp. Brief at 8. However, the records from the call on June 15, 2016 indicate that the call was about petitioner's health insurance benefits covering a specific form of contraceptive. Pet. Ex. 3 at 63. Specifically, on June 9, 2016, the day following the vaccination, it was noted that, "Patient is interested in getting the Mirena IUD inserted at her postpartum visit. Could you please check benefits and let her know if it would be covered?" *Id.* On June 14, 2016, the note indicates that the OB/GYN office checked petitioner's health benefits and left a message with petitioner to call back. *Id.* Petitioner called back on June 15, 2016 and spoke to Ms. Christina Catlett who noted, "Pt called back-aware of benefits." *Id.* It is clear from the OB/GYN's internal messaging system, that the purpose of the call was for checking benefits and not for the purposes of medical treatment.

As the Federal Circuit articulated in *Kirby,* there is no "presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Following *Kirby,* a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition. *Hanna v. Sec'y of Health & Hum. Servs.,* No. 18-1455V, 2021 WL 3486248, at *14 (Fed. Cl. Spec. Mstr. July 15, 2021). In this case, the phone call

between the petitioner and the OB/GYN's office on June 15, 2016 does not appear to constitute a medical encounter, instead is appears to be focused on an administrative matter, rather than for medical care. Further, in prior SIRVA cases it has been held that neither a delay in seeking treatment in itself, nor a failure to report symptoms to a specialist or emergency room provider prior to later seeking treatment, is necessarily dispositive of whether a petitioner's shoulder pain began within 48 hours of vaccination. *See Forman-Franco v. Sec'y of Health & Hum. Servs.,* No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec'y of Health & Hum. Servs.*, No 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); *Gurney v. Sec'y of Health & Hum. Servs.,* No 17-481V, 2019 WL 2298790 (Fed. Cl. Mar. 19, 2019). As petitioner explained in her supplemental affidavit, she has five children under the age of 13 and the delay in telling her medical provider by 12 days is reasonable, given that she was caring for a newborn at the time, in addition to four other children at home. Indeed, the reporting of her shoulder pain and inability to lift her arm within 12 days of vaccination is far faster than many of the cases seen in this program.

Additionally, when petitioner had her first appointment with orthopedist. Dr. Adams, on June 28, 2016, she once again attributed the onset to her left shoulder pain to the MMR vaccination. Pet. Ex. 4 at 43. Under "History of Present Illness," the note states, "[Petitioner] notes that she gave birth three weeks ago and afterwards was offered the measles, mumps and rubella vaccine. She states that after they injected into her lateral left shoulder, she began to have increased intense pain and range of motion problems." *Id.*

On July 4, 2016, petitioner had her first physical therapy evaluation. Pet. Ex. 5 at 28. At this appointment under the "Subjective" section it states, "[Petitioner] states that the initial onset occurred on 6/01/2016 when she [] reports she had a baby 4 weeks ago and reports insidious onset of left shoulder pain. She reports she does not know why the pain started. She reports having a shot in the hospital which caused a lot of neck pain and then a few days later her shoulder began getting stiff and she began having pain." *Id.* Respondent argued that this record shows that petitioner had neck pain and *then* shoulder pain, which indicates that the shoulder pain began after forty-eight hours after vaccine administration. Resp. Brief at 9. However, there is no specific timeframe mentioned in this notation, except for a vague timeframe of "a few days later." Further, this notation is the only notation in the record that puts neck pain prior to the onset of her shoulder pain, which she consistently attributed to the MMR vaccination. This record was sufficiently vague and unclear as to dates of onset, date of delivery of the baby and date of vaccination to raise questions about the care taken in questioning about and recording the onset of pain. It is also the only record introducing this confusion, as when interviewed by an orthopedist on June 28, 2016, six days prior to the physical therapy appointment, petitioner unequivocally described the delivery of her baby three weeks before and the onset of pain after they injected into her lateral left shoulder causing intense pain and range of motion problems. Pet. Ex. 4 at 43.

Additionally, at her follow-up appointment with Dr. Adams on August 1, 2016, he noted that petitioner's left shoulder pain had been present for two months and stated, "It started after a post-delivery vaccine and was severe in intensity and diffuse in nature associated with significant decreased range of motion." *Id.* at 22.

Petitioner's supplemental affidavit also supports onset of her left shoulder pain being within 48 hours of receiving the MMR vaccination on June 8, 2016. She stated, "As I received the shot, the pain was excruciating." Pet. Ex. 9 at ¶ 4. She described the pain as "intense" and "as if it was going into my bone." *Id.* She also indicated that she could feel the pain even though she had been given Percocet for after birth pain. *Id.* In her affidavit, she explained that she was having terrible shoulder pain and then neck pain that radiated down to her shoulder. She articulated that the neck pain started *after* the shoulder pain. *Id.* at ¶ 7. Petitioner's statements regarding the onset of her left shoulder pain in her supplemental affidavit do not contradict her medical records and are quite consistent with those recorded by her orthopedist, Dr. Adams.

The evidence in the record as whole, supports petitioner's position that the onset of her shoulder pain began within 48 hours of receiving the MMR vaccine on June 8, 2016. The twelve-day delay in treatment for her shoulder is consistent with the length of time of that many other people seek care for shoulder pain following vaccination. *See e.g. Smallwood v. Sec'y of Health & Human Servs.*, No. 18-291V, 2020 WL 2954958, at *10 (Fed. Cl. Spec. Mstr. Apr. 29, 2020) (observing that it is "common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own."); *see also Hartman v. Sec'y of Health & Human Servs.,* No. 19-1106V, 2021 WL 4823549, at *5 (Fed. Cl. Spec. Mstr. Sept. 14, 2021) (petitioner reported shoulder pain less than one more after vaccination and repeatedly sought treatment to relieve her pain and loss of function.).

Therefore, petitioner's statements about the onset of her left shoulder pain occurring within 48 hours of receiving the MMR vaccine on June 8, 2016 are consistent with the medical records, which repeatedly note that petitioner attributed the onset of her pain to the vaccination at issue in this case. As such, petitioner has demonstrated that her left shoulder pain occurred within 48 hours of vaccination.

C. Causation

1. *Althen* prong one

Under *Althen* prong one, the causation theory must relate to the injury alleged. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen,* 35 F.3d at 548. It must only be "legally probable, not medically or scientifically certain." *Id.* at 549. However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Id.* at 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen,* 418 F.3d at 1280 (emphasis added).

a. Petitioner's arguments regarding *Althen* prong one

Petitioner's expert, Dr. Wright opined that petitioner had a "direct injection into the subacromial space and possibly into the infraspinatus," which can "be responsible for initiating a major inflammatory event in the subacromial bursae resulting in persistent severe pain." Pet. Ex.

12 at 1. He acknowledged that he did not know the exact location of petitioner's injection, but found it likely that she had received the injection in the subacromial space and possibly in the infraspinatus, based on her positive response to the steroid injection and the edema found on her MRI. Pet. Ex. 15 at 1.

Dr. Wright cited to the Bodor and Montalvo article which describes two case reports of individuals who experienced shoulder pain and weakness following vaccinations. Pet. Ex. 14.[12] The authors hypothesized that the vaccines were injected into the subdeltoid bursa causing a robust local immune and inflammatory response in the structures of the shoulder. *Id.* at 2. They explained that the inflammatory response in the subdeltoid bursa led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule. *Id.*

Petitioner also cited to the Atanasoff et al. article, which describes the mechanism of a SIRVA. Pet. Ex. 18. Petitioner argues that the mechanism of injury described in the Atanasoff article has been accepted by this Court, and respondent, as sound and reliable. Specifically, the article provides:

> If…a vaccine is inadvertently injected into the synovial space of the shoulder (bursa or joint), pre-existing antibody in the synovial tissues, present as a result of earlier naturally occurring infection or vaccination, may lead to a more prolonged inflammatory response.

Pet. Ex. 18 at 3. The authors further explained, "….the rapid onset of pain with limited range of motion following vaccination…is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." *Id.* Importantly, the authors of Atanasoff et al. observed, "Given that 62% of our cases were overweight or obese based upon BMI and that no case was considered underweight, needle length alone may not have been the cause of injection into tissues other than the deltoid." *Id.* at 4. They also noted that, "the standing position of the provider administering the injection may also contribute to injecting inadvertently high into the deltoid….Thus, concurrent seating positions for both the administer and the receiver may minimize the risk of the injection being "too high." *Id.*

Petitioner summarized Dr. Wright's theory as, "an injection in the deltoid muscle, near its insertion at the acromion, passing through infraspinatus insertion site at the bursa, into the subacromial bursa, can cause a shoulder injury." Pet. Mot. at 17; Pet. Ex. 15 at 2.

b. Respondent's arguments regarding *Althen* prong one

Respondent's expert, Dr. Abrams, does not disagree with Dr. Wright's explanation of the SIRVA mechanism. Instead, he asserts, "The location of the injection for an MMR vaccine is in the posterior triceps aspect of the upper arm. It is not possible to reach the subacromial space with an injection given in this location." Resp. Ex. C at 1.

He notes that he MMR vaccine is administered subcutaneously, which, with proper technique is given at a 45-degree angle in order to avoid penetration into the intra-muscular

[12] Bodor, M. & Montalvo, E., *Vaccination-related shoulder dysfunction,* 25 Vaccine 585-587 (2007). [Pet. Ex. 14].

tissues. *Id.* He states that the needle length for administering an MMR vaccine is not long enough to reach the subacromial space or the infraspinatus tendon. *Id.* Dr. Abrams argues that the petitioner's increased BMI would increase the distance the needle has to traverse to penetrate the subacromial space, decreasing the likelihood of "inadvertent vaccine needle penetration into the subacromial space." *Id.*

Respondent, in the response brief to petitioner's motion, does not question Dr. Wright's proposed mechanism, but instead argues that Dr. Wright's "theory is dependent…on an assumed site of injection and the manner of injection unsupported by the evidence in this case." Resp. Brief at 11.

c. Discussion and conclusion of *Althen* prong one

Petitioner has established a sound and reliable theory to explain how the MMR vaccine, when administered incorrectly, can be inserted into the synovial space of the shoulder, causing a shoulder injury related to vaccine administration. The mechanism for a SIRVA injury is well described in medical literature filed in this case. Both the Atanasoff and Bodor articles support a causal association between vaccination and shoulder dysfunction.

As discussed above, the authors of the Atanasoff article specifically opined that if a vaccine "is inadvertently injected into the synovial space of the shoulder (bursa or joint), pre-existing antibodies in the synovial tissues, present as a result of earlier naturally occurring infection or vaccination, may lead to a more prolonged inflammatory response." Pet. Ex. 18 at 3. Further, the authors of Atanasoff indicated that a person's body weight or needle length did not appear to have an effect on whether the vaccine antigen was injected into tissues other than the deltoid muscle. *Id.* at 4. While respondent argued that the needle used for MMR vaccination is only 15.8 mm, the Bodor article demonstrated that the subacromial bursa sits between 6 mm and 13 mm below the skin's surface, making it accessible with a 15.8 mm needle length. Additionally, the Nakajima article explained that the subcutaneous thickness at the proposed injection site 1/3 bb' (which corresponds with Dr. Wright's proposed injection site) was between 3.5 mm to 6.3 mm and the thickness of the deltoid muscle range from 9.0 mm to about 12 mm. Resp. Ex. A, Tab 8 at 2.

The Atanasoff article also indicates that the standing position of the vaccine administrator over a seated patient "may also contribute to injecting inadvertently high." Pet. Ex. 18 at 4. In this case, petitioner stated that she was sitting on a bed and the nurse who administered the vaccine "stood next to and over me to give the injection." Pet. Ex. 9 at ¶ 6. Petitioner described the location as being "high on my upper arm towards the back." *Id.* Petitioner's statements that the vaccine administrator was standing while she was seated and it was administered "high" on her left upper arm, makes it more likely that the MMR vaccine was mis-administered into her subacromial bursa, leading to an inflammatory event resulting in persistent pain and movement dysfunction. The description of tenderness in the shoulder girdle and bicipital groove are also consistent with a high administration point where the deltoid muscle is thinnest.

Further, petitioner was diagnosed with left shoulder bursitis, a diagnosis consistent with other SIRVA cases in the program. *Kraus v. Sec'y of Health & Human Servs.,* No. 17-2001V,

2021 WL 4705177 (Fed. Cl. Spec. Mstr. Sept. 2, 2021) (petitioner diagnosed with right shoulder bursitis following a flu vaccination); *Lang v. Sec'y of Health & Human Servs.,* No. 17-996V, 2020 WL 7873272, at *3 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (petitioner was diagnosed with bursitis following flu vaccination); *Schoonover v. Sec'y of Health & Human Servs.* No. 16-1324, 2019 WL 1040642, at *5 (Fed. Cl. Spec. Mstr. Jan. 30, 2019).

Petitioner has presented a reputable scientific theory based on a sound and reliable medical explanation, demonstrating that the MMR vaccine, when administered improperly, can cause a shoulder pain and dysfunction, thus satisfying *Althen* prong one.

2. *Althen* prong two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [her] injury." *Althen,* 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen,* 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Hum. Servs.,* 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen,* 418 F.3d at 1278; *Andreu,* 569 F.3d at 1375-77; *Capizzano,* 440 F.3d at 1326; *Grant,* 956 F.2d at 1148. 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. *Paluck v. Sec'y of Health & Hum. Servs.,* 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu,* 569 F.3d 1375).

Prior to the receiving the MMR vaccine, petitioner did not experience any left shoulder pain or dysfunction. Petitioner received the MMR vaccine on June 8, 2016 and immediately felt pain, which led to a reduction in shoulder mobility. Consistent with the finding above that the MMR vaccination was mis-administered into petitioner's deltoid muscle penetrating into her bursa, the medical history relating to petitioner's left shoulder pain and dysfunction following the vaccination at issue demonstrates a logical sequence of cause and effect showing that the vaccination was the reason for her injury.

On June 20, 2016, petitioner reported to her OB/GYN that she received a shot after the delivery of her child, and she was "unable to move her left arm." Pet. Ex. 3 at 138. Petitioner described her arm as "frozen." *Id.* The MRI of petitioner's left shoulder showed a 50% tear of the infraspinatus tendon at its insertion along the bursal surface. Pet. Ex. 2 at 6. While it is unclear if petitioner's partial thickness tear was caused by the MMR vaccination, the rapid onset of pain and shoulder dysfunction following the vaccination is consistent with the medical literature describing SIRVAs. The Atanasoff article explains that common conditions such as "impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis….may cause no symptoms until provoked by trauma or other events." Pet. Ex. 18 at 3. The authors of Atanasoff noted, "some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial pain." *Id.* at 3.

After the MRI, petitioner sought treatment from orthopedist, Dr. Adams. Pet. Ex. 4 at 43. At her first appointment, petitioner explained that she received the MMR vaccine into her "lateral left shoulder" and she began to have "intense pain and range of motion problems." *Id.* Her physical exam revealed restricted active range of motion in her left shoulder, generalized tenderness to palpation near the deltoid girdle and over the bicipital groove. *Id.* at 44. Petitioner was diagnosed with left shoulder joint pain and left partial acute rotator cuff tear. *Id.* at 45. Dr. Adams opined that her left shoulder pain could have been related to her MMR vaccination, stating, "I do not think it is out of the realm of question that she had post-injection stiffness and pain." Pet. Ex. 4 at 45.

Petitioner received a steroid injection in her left shoulder and actively participated in physical therapy. Pet. Ex. 4 at 25; Pet. Ex. 5 at 4-32. When she returned to Dr. Adams on August 1, 2016 following six weeks of physical therapy, petitioner noted decreased pain in her shoulder, but the pain began to increase as intensity in physical therapy increased. Pet. Ex. 4 at 22. Dr. Adams did not recommend another steroid injection, but recommended that she finish out physical therapy and then begin a home exercise regime. *Id.* at 4. Dr. Adams also wrote in petitioner's medical record, "We did review some scientific evidence of post vaccine injection rotator cuff tear when placed in the wrong place. It does appear at this time though, that she is healing appropriately." *Id.* at 23.

Petitioner had a repeat MRI on April 21, 2017, which showed abnormal bursal surface signal of supraspinatus tendon and a "tiny" amount of fluid in the subacromial subdeltoid bursa. Pet. Ex. 6 at 13.

When petitioner returned to Dr. Adams in April 2017, petitioner reported that her left shoulder pain was persistent and described it as, "posterior in location, dull and burning quality and moderate in severity." Pet. Ex. 6 at 9. On physical exam, petitioner demonstrated full range of motion "with painful arc from 80-120 degree of flexion and abduction," and she demonstrated one out of two impingement signs. *Id.* at 10. Dr. Adams reviewed the most recent MRI and noted that petitioner had "mild abnormal signal on the bursal side of the anterior supraspinatus," and opined that it represented a "partial tear," and that she had persistent tenosynovitis in the proximal biceps tendon, consistent with the 2016 MRI. *Id.* at 9-10. Petitioner was diagnosed with left shoulder joint pain, left partial chronic rotator cuff tear, and left shoulder bursitis. *Id.* at 11.

Finally, petitioner's expert, Dr. Wright opined, "[petitioner] sustained an injection site injury to her left shoulder due to the MMR vaccine injection on 6/8/2016. There was no pre-existing history of pain in the left shoulder, the pain started immediately after the injection, and persisted at least 10 months." Pet. Ex. 12 at 1.

Dr. Abrams' argument rests entirely on the theory that the MMR vaccine was administered correctly in accord with the directions of the CDC. It is difficult to conceive of a subcutaneously injected vaccination into the subcutaneous fat above the triceps muscle causing a SIRVA injury. However, the evidence particular to this case strongly suggests that the vaccination was not properly administered with the nurse standing next to and above the seated

patient, giving the injection high in the shoulder, where the muscle is thinnest and the documented new onset pain occurred.

Therefore, petitioner's medical records and supporting opinion by Dr. Wright, demonstrates that the MMR vaccination administered on June 8, 2016 was the cause of her left shoulder pain and dysfunction. As such, petitioner has provided preponderant evidence to satisfy *Althen* prong two.

3. *Althen* prong three

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281.

Both respondent and petitioner in this case postulate that the appropriate medically acceptable timeframe between vaccination and the injury alleged is 48 hours. Resp. Brief at 7; Pet. Mot. at 32. However, they disagree as to whether the onset of petitioner's injury occurred within 48 hours. Respondent argued that petitioner "failed to show by a preponderance of the evidence that her shoulder pain began within 48 hours of receiving the vaccine." Resp. Brief at 16. Petitioner argued that the evidentiary records, including petitioner's medical records and affidavits, demonstrate that onset of petitioner's shoulder injury followed within 48 hours of the vaccination at issue, which "fits the postulated time frame elucidated in the applicable medical literature (and the Table)." Pet. Mot. at 32.

Consistent with the finding above regarding the onset of petitioner's left shoulder pain and dysfunction, petitioner has provided preponderant evidence to satisfy *Althen* prong three.

V. Conclusion

In accordance with the above, I dismiss petitioner's Table SIRVA claim, but find that she has established by preponderant evidence that she is entitled to compensation, demonstrating that the MMR vaccination administered on June 8, 2016 was the cause-in-fact of her left shoulder pain and dysfunction. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master