In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 20, 2020

SCOTT TAYLOR,	*	PUBLISHED
	*	
Petitioner,	*	No. 16-1403V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Causation-in-Fact; Tetanus-Diphtheria-Acellular Pertussis ("Tdap") Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA").
	*	
Respondent.	*	
	*	

Shealene P. Mancuso, Muller Brazil, LLP, Dresher, PA, for petitioner.
Ronalda E. Kosh, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On October 26, 2016, Scott Taylor ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that he suffered left shoulder injuries as the result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccination administered on July 13, 2015. Petition at Preamble (ECF No. 1).

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

[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). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner provided preponderant evidence that the Tdap vaccine caused petitioner's left shoulder injuries, which satisfies his burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

I. PROCEDURAL HISTORY

Petitioner filed his petition on October 26, 2016, alleging that he sustained left shoulder injuries caused by a Tdap vaccine administered on July 13, 2015. Petition at Preamble. Petitioner filed medical records with his petition. Petitioner's Exhibits ("Pet. Exs.") 1-3. Petitioner filed additional medical records and affidavits from November 2016 to March 2018. Pet. Exs. 4-14. The parties engaged in settlement discussions beginning in January 2017, until they reached an impasse in April 2018. Order dated Jan. 19, 2017 (ECF No. 15); Joint Status Report ("Rept."), filed Apr. 4, 2018 (ECF No. 45).

On June 7, 2018, respondent filed his Rule 4(c) Report, stating that the records had been reviewed by medical personnel of the Department of Health and Human Services, Division of Injury Compensation Programs, and concluded that the case was not appropriate for compensation. Respondent's ("Resp.") Rept. at 1 (ECF No. 47). In the Rule 4(c) Report, respondent acknowledged that Shoulder Injury Related to Vaccine Administration ("SIRVA") was added as a Table claim for the Tdap vaccine effective for petitions filed on or after March 21, 2017, and thus,

> the previous Table is in effect for this petition, and it does not include SIRVA injuries. Nevertheless, even if the amended Table did apply to this petition, . . . it would not meet the Table criteria[] because the contemporaneous medical records do not establish the threshold requirement of onset of pain within forty-eight hours of vaccination. See 42 C.F.R § 100.3(c)(10)(i)-(iv).

Id. at 6 n.4. Thereafter, petitioner filed updated medical records on July 6, 2018. Pet. Exs. 20-21.

On August 20, 2018, petitioner filed an expert report by Dr. Naveed Natanzi. Pet. Ex. 25. Petitioner also filed a number of medical journal articles and Dr. Natanzi's CV. Pet. Exs. 25.1-25.13, 30. On November 8, 2018, respondent filed an expert report by Dr. Geoffrey D. Abrams, along with his CV. Resp. Exs. A-B. Respondent later filed medical literature from Dr. Abrams. Resp. Ex. A, Tabs 1-20.

In December 2018, the parties resumed settlement discussions. Joint Status Rept., filed Dec. 28, 2018 (ECF No. 61). On October 16, 2019, the parties reported that they reached an impasse during settlement discussions and agreed to move forward with further litigation. Pet. Status Rept., filed Oct. 16, 2019 (ECF No. 82). The parties explained that their "attempt to settle this matter on a litigative risk basis was unsuccessful, [and] until petitioner is found entitled to an award of compensation, the parties agree the issue of damages is not ripe for consideration at this juncture." Pet. Status Rept., filed Nov. 12, 2019 (ECF No. 84).

This case was reassigned to the undersigned on February 5, 2020. Notice of Reassignment dated Feb. 5, 2020 (ECF No. 86). The undersigned held a status conference on March 18, 2020, at which time the undersigned and parties agreed that this case could be resolved through a ruling on the record and a briefing schedule was set. Order dated Mar. 18, 2020 (ECF No. 88).

On May 18, 2020, petitioner filed a motion for a ruling on the record. Motion for Ruling on the Record ("Pet. Mot."), filed May 18, 2020 (ECF No. 89). Respondent filed his response on July 31, 2020. Respondent's Response to Pet. Mot. ("Resp. Response"), filed July 31, 2020 (ECF No. 96). Petitioner filed a supplemental expert report and medical literature from Dr. Natanzi on September 17, 2020. Pet. Exs. 31-34.

This matter is now ripe for adjudication.

II. FACTUAL HISTORY

A. Medical Records

Petitioner's past medical history was significant for bilateral meniscus tears, sleep apnea, and rosacea. Pet. Ex. 2 at 29. On July 13, 2015, at fifty-two years old, petitioner saw his primary care physician ("PCP"), Dr. Sean McElhaney, who assessed petitioner with peripheral neuropathy. Id. at 29, 32. At this visit, petitioner received a Tdap booster vaccine in his left deltoid. Pet. Ex. 2 at 32; Pet. Ex. 5 at 4.

On July 28, 2015, petitioner was seen by his PCP and assessed with "[n]ewly diagnosed diabetes" and hypertriglyceridemia. Pet. Ex. 2 at 32-33. There is no indication that petitioner complained of left shoulder pain. See id. at 32-34.

On August 9, 2015, petitioner e-mailed his PCP stating, "[l]eft shoulder still quite sore from [Tdap] shot. Muscle burns a bit. Looks fine, not swollen. Is this normal?" Pet. Ex. 4 at 2. In a follow-up e-mail the following day, petitioner added there is "[n]o redness or discoloration," the shoulder joint and muscle are "sore all of the time but more when in use," and his pain "limit[s] some types of movement like lifting over [his] shoulder." Id. at 1. In response, Dr. McElhaney stated,

> The muscle ache people get in the deltoid region where shot is given wouldn't hurt this long. Usually starts 1-2 days after vaccine, lasts a few days (maybe up to a week in rare cases), but shouldn't last 2+ weeks. Given description of pains and what movements bother it, it sounds possibly like tendonitis or bursitis to the shoulder itself.

Id. Dr. McElhaney recommended petitioner ice his shoulder, take anti-inflammatories, and return if the pain does not improve. Id.

From August to October 2015, petitioner had three doctor's appointments for other medical issues. Pet. Ex. 2 at 35-47. There are no complaints or concerns of left shoulder pain documented at these visits. See id.

On November 9, 2015, petitioner presented to Dr. Arti Rajvanshi, complaining of left arm pain that "has been present for 3 months after getting Tdap" vaccine. Pet. Ex. 2 at 47-48. Petitioner described the pain as "constant" and "achy and burning" from his "shoulder to elbow." Id. at 48. The pain was noted to get worse with lifting, carrying, and moving or extending his neck. Id. On exam, petitioner exhibited a full range of motion ("ROM"). Id. at 50. On exam of his left shoulder, Dr. Rajvanshi noted "Neer's mildly positive. Jobe's positive. Provocative test for infraspinatus mildly positive." Id. The assessment was tendinopathy of left rotator cuff, and petitioner was referred to physical therapy ("PT"). Id.

On November 18, 2015, petitioner began PT with Jaime M. McCann, PT, DPT. Pet. Ex. 2 at 51. The physical therapist documented petitioner's history that "[h]e got a tetanus in the left shoulder and a few days after the shot, the pain in the shoulder started. It got better as time went on, but it hasn't gone away." Id. Petitioner's pain was also noted to be "achy and burning" and "moving down his arm to the lateral epicondyle on the left arm." Id. He rated his pain as a 5/10 and indicated that his pain decreases with rest but affects his ability to sleep. Id. The physical therapist noted petitioner's Neer test was markedly positive. Id. at 53. Petitioner had decreased ROM with shoulder abduction and internal and external rotation. Id. The assessment was "left tendinopathy of rotator cuff." Id. at 54.

Petitioner had seven additional PT sessions from November 2015 to January 2016, at which time he was discharged from PT. Pet. Ex. 2 at 56-87. During a session on December 1, 2015, petitioner continued to have decreased ROM with external rotation. Id. at 62. By December 9, 2015, petitioner had full ROM. Id. at 66. Upon discharge, petitioner still had some issues lifting and moving heavy objects. Id. at 86. He was prescribed a home exercise program. Id. at 87.

On February 17, 2016, petitioner saw orthopedic surgeon, Dr. Jefferson Cartwright, who noted that petitioner presented for a left shoulder injury caused by a Tdap vaccine seven months prior. Pet. Ex. 3 at 6. Petitioner described his pain at rest as 5/10 and pain with activity as 7/10. Id. Dr. Cartwright obtained X-rays of petitioner's left shoulder, which revealed "[m]ild to moderate arthritis of the left GHJ [Glenohumeral Joint]. No fractures are noted. The ACJ [Acromioclavicular Joint] demonstrates arthrosis. There is significant radiographic subacromial impingement." Id. at 7. On exam, petitioner tested moderately positive under the Neer and Hawkins tests. Id. at 7-8. Dr. Cartwright diagnosed petitioner with pain, impingement syndrome, bursitis, bicipital tendinitis, partial thickness rotator cuff tearing, and superior glenoid labrum lesion ("SLAP Lesion") of his left shoulder. Id. at 7. He also diagnosed petitioner with lateral epicondylitis and pain over lateral epicondyle in his left elbow. Id. Dr. Cartwright added that petitioner "clearly has impingement, rotator cuff symptomatology, and biceps and SLAP pathology and it is exceedingly unlikely that a vaccine of [any kind] produced all of [petitioner's injuries]." Id. at 8. He recommended an MRI of petitioner's shoulder. Id.

On March 3, 2016, petitioner was seen by his PCP for left shoulder pain in the left lateral deltoid, top of shoulder, and up to the neck. Pet. Ex. 2 at 92. The pain was noted to be dull and constant "since July 2015," exacerbated with certain movements, and made better with rest. Id. His PCP's assessment was probable tendinopathy and "tear of tendon vs labrum based on history and failed PT." Id. at 94-95.

Petitioner saw Dr. Cartwright for a follow up on his left shoulder on March 10, 2016. Pet. Ex. 3 at 15. Dr. Cartwright noted that petitioner's left shoulder MRI with contrast, completed on March 7, showed "1. Anteroinferior glenoid labral tearing, with adjacent glenoid labral articular cartilage defect. 2. Low-grade partial-thickness intrasubstance tear of the mid supraspinatus tendon. No full-thickness rotator cuff tear. 3. Mild chronic biceps tendon tearing. 4. Moderate acromioclavicular joint osteoarthritis." Id. at 16.

On March 24, 2016, petitioner returned to Dr. Cartwright for a left shoulder evaluation and a cortisone injection in his left shoulder. Pet. Ex. 3 at 20. After injection, petitioner's pain was noted to be 0/10. Id. at 21. On March 31, 2016, petitioner returned for a left shoulder follow-up evaluation and another cortisone injection. Id. at 25. Petitioner's pain level after his second cortisone injection was 0/10. Id. Dr. Cartwright noted "ROM shows flexion 160 degrees and abduction 156 degrees." Id. at 27.

Petitioner next saw Dr. Cartwright on April 14, 2016, for a left shoulder follow-up evaluation. Pet. Ex. 3 at 29. Petitioner rated his pain at rest as 0/10 and pain with activity as 1/10. Id. Petitioner described his pain as a "slight pinch with overhead use" and sometimes a "mild burning in the deltoid." Id. Although petitioner reported no pain while sleeping and no neck pain, he continued to have pain when carrying or picking up objects with his arms extended. Id. Shoulder flexion remained at 160 degrees and abduction increased to 162 degrees. Id. Dr. Cartwright recommended PT, but noted it was not necessary at this point, and petitioner declined. Id. at 31. Dr. Cartwright also recommended petitioner follow-up as needed and obtain an MRI if his symptoms return in less than two months. Id.

On October 17, 2016, petitioner saw orthopedist, Dr. Kenneth Oates, complaining of left shoulder pain. Pet. Ex. 7 at 8. Dr. Oates noted petitioner's "symptoms began last February following a TDAP vaccination." Id. Dr. Oates noted petitioner was "tender over subacromial space," and "[i]mpingement signs are positive for the Neer, Hawkins[,] and painful arc maneuvers." Id. at 9. A left shoulder X-ray showed "type II acromion. Moderately severe AC joint degenerative changes. Glenohumeral joint is normal." Id. Dr. Oates' impression was subacromial impingement/bursitis of left shoulder, osteoarthritis of left acromioclavicular joint, and left biceps tendonitis. Id. Dr. Oates stated that he discussed with petitioner "the possibility of his attempted intramuscular [Tdap] vaccination being injected into his subacromial bursa, causing subsequent subacromial bursitis. This in conjunction with underlying degenerative change could be the causation of his discomfort." Id.

From October 20 to November 23, 2016, petitioner attended eleven PT sessions. Pet. Ex. 6 at 4-18. The PT initial evaluation note states onset is "unknown" but describes his pain as

"developing in February 2016 after a flu shot in the left shoulder."[3] Id. at 4. On initial exam, petitioner had decreased ROM but after treatment, he had no change in internal rotation but some improvement in external rotation and flexion. Id. at 16, 18.

On November 30, 2016, petitioner returned to Dr. Oates and reported that PT was "aggravating his symptoms" and he saw "no significant improvement." Pet. Ex. 8 at 5. Dr. Oates recommended "left shoulder arthroscopic with subacromial decompression, major debridement and possible biceps tenodesis," to which petitioner agreed. Id. at 6-7.

Petitioner underwent arthroscopic surgery of the left shoulder on January 5, 2017. Pet. Ex. 8 at 8. Postoperatively, petitioner again attended PT sessions.[4] Pet. Ex. 9 at 9-31. On March 21, 2017, petitioner was noted to still be experiencing limitations in ROM, specifically flexion and abduction. Id. at 26.

At a post-operative visit with Dr. Oates on May 12, 2017, petitioner reported that he "feels like he has plateaued in [PT]" and "is feeling more achy pain in his shoulder with motion." Pet. Ex. 8 at 16. On exam, Dr. Oates noted "good strength and motion," as well as "[n]on tender over AC joint and subacromial area. Mildly positive Hawkins. Negative Neer and painful arc." Id. at 17.

Petitioner received an MRI arthrogram of the left shoulder on June 6, 2017. Pet. Ex. 8 at 19. Dr. Oates noted the MRI showed,

> AC joint resection that looks appropriate. There is a partial thickness rotator cuff tear of the supraspinatus. There is some tendinitis of the biceps. There is a sub labral hole anteriorly that does not appear to be a SLAP lesion. Sub acromial decompression appears to have been appropriately performed. There is no muscle atrophy. There are other post op changes that appear appropriate.

Id.

Petitioner next saw Dr. Oates on February 23, 2018, complaining of "'grinding[,'] pain with [ROM] (especially reaching out), limited [ROM], and weakness of the left shoulder." Pet. Ex. 14 at 1. On exam, Dr. Oates noted that petitioner had a "[m]ildly positive Hawkins. Positive Neer and negative painful arc. Negative cross-body. Negative Yergason's and Speed's tests." Id. at 2. Petitioner elected to continue with a home exercise plan. Id. at 3.

On July 3, 2018, Dr. Oates wrote petitioner "will have permanent restrictions as of July 1, 2018" and that petitioner had to "[l]imit overhead lifting to occasional and no greater than [15 pounds]." Pet. Ex. 21 at 1.

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[3] The undersigned finds this reference to administration of a flu shot instead of Tdap erroneous.

[4] Petitioner's avers he attended 29 PT sessions from January 2017 to March 21, 2017. Pet. Ex. 11 at ¶ 10. A review of petitioner's PT records, however, shows that he attended 18 PT sessions from January 19, 2017 to March 21, 2017. See Pet. Ex. 9 at 9-31.

From May 23, 2018 to March 4, 2019, petitioner presented to Dr. Jimmy Y. Cui for neck and back pain. Pet. Ex. 20 at 3-5; Pet. Ex. 28 at 7-27. Left shoulder pain was documented in petitioner's past medical history. See id.

B. Affidavits

Petitioner, Mrs. Gina Taylor, and Mr. Eric Hilton executed affidavits in support of petitioner's case. Pet. Exs. 11-13.

1. Petitioner

In his affidavit, petitioner stated that he received a Tdap vaccine on July 13, 2015 and immediately after, he "felt pain in [his] left shoulder, but didn't think much of it because [he] thought some discomfort was normal after receipt of a vaccination." Pet. Ex. 11 at ¶¶ 2-3. Two days later, the pain "was getting worse" Id. at ¶ 3. He "experienced pain with a vaccination in the past, which lasted longer than usual, but eventually it went away on its own," and "[he] hoped this pain would resolve on its own as well." Id.

He averred the pain "was specifically in [his] left shoulder and was worse with movement." Pet. Ex. 11 at ¶ 3. Petitioner described the pain as a "constant . . . burning sensation in the shoulder muscle and joint." Id. at ¶ 5. He also found it difficult to lift his left arm over his shoulder. Id. He disclosed his pain to his wife, son, and employees. Id. at ¶ 4.

After three weeks without improvement, he contacted his PCP on August 9, 2015, informing him of his "ongoing burning shoulder pain and limited left shoulder movement." Pet. Ex. 11 at ¶ 5. His PCP recommended ice and anti-inflammatories, which petitioner used over the next few months. Id. This provided him with "some relief," decreasing his pain "from very intense" to "moderate and improving." Id. at ¶ 6. However, "[a]ctivity continued to make the pain worse and it was notably more severe at night." Id. He still "hoped the pain would continue to decrease and eventually resolve on its own." Id.

Petitioner explained that he waited to see a doctor because he is "the kind of person that doesn't usually go to a doctor unless something is bleeding real[ly] bad." Pet. Ex. 11 at ¶ 7. He also stated that if he were to go to a doctor, he felt he would need to take time off work for PT. Id. Because he owns a small business and "taking time off during the work week is quite disruptive to production," he waited to see a doctor until work was slow. Id.

In November 2015, four months after vaccination, petitioner was still experiencing pain, which he described "was more intense when [he] moved [his] left arm, and had begun to slowly radiate through [his] left upper arm, down to [his] elbow." Pet. Ex. 11 at ¶ 8. On November 9, 2015, he was examined by Dr. Arti Rajvanshi, who referred petitioner to PT and prescribed Ibuprofen. Id. On November 18, 2015, petitioner began PT until January 27, 2016. Id. at ¶ 9. During this time, he was also doing a home exercise program and "continued working light duty, since [he] could not work at full-capacity in [his] business." Id.

After PT, he was still experiencing pain and sought treatment from an orthopedic specialist. Pet. Ex. 11 at ¶ 10. From February to November 2016, he "had a left shoulder x-ray and MRI, two steroid injections into [his] left shoulder, and eleven (11) additional [PT] sessions, before being scheduled for left shoulder surgery on January 5, 2017." Id. After his surgery, he "had an additional twenty-nine (29) physical therapy sessions through March 21, 2017." Id.

In May 2017, he tried going back to work full-time, but was unable to do any of the required shoulder or chest-high activities. Pet. Ex. 11 at ¶ 15. He also "could not pull or push with [his] left arm," which is "frequently required for [him] to function in this environment and work at [his] full capacity in [his] business." Id. In June 2017, he was able to return to work full-time at a reduced capacity. Id. He averred that he "cannot perform at [his] full capacity as [he] could prior to vaccination." Id.

As of December 7, 2017, the date on which petitioner executed his affidavit, he was still experiencing pain, stiffness, and soreness in the mornings for several hours. Id. at ¶ 17. He states he hit a plateau in his recovery. Id.

2. Mrs. Gina Taylor

Mrs. Gina Taylor is petitioner's wife. Pet. Ex. 12 at ¶ 2. She averred that before petitioner's July 13, 2015 vaccination, petitioner "never complained of pain or difficulty using his left arm or shoulder." Id. at ¶ 3.

On the day after petitioner's Tdap vaccination, she noticed his left shoulder was hurting. Pet. Ex. 12 at ¶ 4. Mrs. Taylor explained that "[h]e was getting dressed and could barely lift his arm to put on his shirt." Id. She "continued to notice [petitioner] struggling to do things like get dressed or reach up to get a plate or cup from the kitchen cabinet." Id. at ¶ 5. One day, she was re-decorating and needed petitioner's help moving furniture, "but [he] was unable to help because his shoulder hurt too much." Id. The yard work and home repairs that petitioner used to do became her responsibility. Id. Mrs. Taylor averred that petitioner "is not a guy that complains much about his ailments but after several weeks of watching him wince in pain, [she] eventually convinced him to call his doctor about it." Id.

Petitioner completed PT but it did not seem to help, and he got very discouraged. Pet. Ex. 12 at ¶ 6. "[Mrs. Taylor] noticed [petitioner's] pain more at home than at work." Id. at ¶ 7. She manages the business office, so she did not often see him working in the welding or machine shop. Id.

She averred that "[t]his injury has had a tremendous impact on [petitioner]." Pet. Ex. 12 at ¶ 9. "Before the vaccination, he was his normal self—very physical and active and never having to hesitate to move any part of his body in order to do something, be it work, play[,] or otherwise." Id. Mrs. Taylor asserted that he "is not his normal 'pre-vaccination self' to date and [she] [does not] know if he ever will be." Id.

3. Mr. Eric Hilton

For the past eleven years, Mr. Eric Hilton has worked at Arlington Machine and Welding, which is owned and operated by petitioner. Pet. Ex. 13 at ¶ 2. Mr. Hilton "was mostly in control of the fabrication side of the company with [petitioner's] help and [petitioner] was in charge of the machining aspects." Id. at ¶ 5. He averred that before petitioner's July 13, 2015 vaccination, petitioner "never complained of pain or difficulty using his left arm or shoulder." Id. at ¶ 3.

Mr. Hilton stated that the day after petitioner received his Tdap vaccine, petitioner complained about a sore shoulder during their lunch break. Pet. Ex. 13 at ¶ 4. He thought petitioner's pain was normal. Id. Mr. Hilton noted petitioner's "work was effected immediately after his vaccination." Id. "[H]e started to rely on others to do things he would normally be able to do himself." Id. As Mr. Hilton and petitioner continued to work together, Mr. Hilton "could tell that [petitioner] was in pain and could not work as he used to." Id.

In the following months, petitioner would ask Mr. Hilton to help "unload or load stuff as [their] job requires some heavy lifting." Pet. Ex. 13 at ¶ 5. In the beginning of 2017, petitioner explained to Mr. Hilton that because he was going to have surgery on his shoulder, Mr. Hilton would not have much assistance at work. Id. at ¶ 7.

Mr. Hilton averred that petitioner "is still not back to his usual self." Pet. Ex. 13 at ¶ 8. On an October 23, 2017 installation, Mr. Hilton "was still required to most of the hard work when before [petitioner] was always working with [him] side by side." Id.

III. EXPERT REPORTS

A. Petitioner's Expert, Dr. Naveed Natanzi

1. Background and Qualifications

Dr. Natanzi is a board certified specialist in physical medicine and rehabilitation. Pet. Ex. 25 at 1. He received his B.A. from University of California, Santa Barbara in 2007 and his D.O. from Western University of Health Sciences in 2012. Pet. Ex. 30 at 2. From 2012 to 2016, Dr. Natanzi completed a rotating internship at Downey Regional Medical Center and a residency and fellowship in physical medicine and rehabilitation at University of California, Irvine. Id. at 1. Thereafter, he worked as a fellow and an attending physician in interventional regenerative sports and spine medicine at the Bodor Clinic. Id. Currently, Dr. Natanzi is an attending physician in interventional pain management at the Pasadena Rehab Institute and is the founder of the Regenerative Sports and Spine Institute. Id. Dr. Natanzi has served on various committees and authored or co-authored numerous publications. Id. at 3.

2. Opinion

Dr. Natanzi opines that the records show that petitioner sustained a SIRVA injury due to his Tdap vaccination on July 13, 2015. Pet. Ex. 25 at 10. Before reaching his opinions, Dr.

Natanzi reviewed petitioner's medical records, affidavits, MRI, and respondent's Rule 4(c) Report. Id. at 1-5. He also reviewed and cited supporting medical literature. Id. at 6-7, 11-12.

Dr. Natanzi opines that in petitioner's case, an "inadvertent over penetration of the vaccination needle" resulted in "tendinous and or bursal penetration," causing petitioner's radiating pain to his elbow, "typical of rotator cuff and bursal referred pain." Pet. Ex. 25 at 9. He further explained that the "vaccine interacts with naturally occurring antibodies from a prior vaccination[5] resulting in [] months of a robust and prolonged inflammatory response" and the "development of bursitis, impingement, tendinopathy, and mild capsulitis." Id.

Dr. Natanzi believes that over penetration by the vaccination needle is "increasingly likely" based on medical literature and logistics of vaccine administration—"the standing position of the injector and resting (non-abducted) left arm position while the injection [is] performed." Pet. Ex. 25 at 9. As support, Dr. Natanzi cites Atanasoff et al.[6] In Atanasoff, the authors identified thirteen cases filed from 2006 to 2010 in the database of claims submitted to the Vaccine Program where "vaccine administration led to significant shoulder pain and dysfunction." Pet. Ex. 25.5 at 1-2. Based on their investigation, the authors' proposed mechanism "is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Id. at 1. "[T]he rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Id. at 3. The authors noted that some of their MRI findings "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation. Other findings such as fluid collections, localized tendon inflammation, and bursitis are more consistent with the vaccine needle over-penetration mechanism." Id. at 3-4.

Dr. Natanzi also cites Bodor and Montalvo,[7] where the authors examined two patients with shoulder pain and weakness following vaccination and hypothesized that the "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Pet. Ex. 25.2 at 1-2. They explained, "[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule," as well as "adhesive capsulitis." Id. at 2. Because multiple structures within the shoulder were involved in both patients, Bodor and Montalvo found this suggested "a primary inflammatory etiology rather than a mechanical overuse problem." Id. at 3. The authors concluded that "the diagnosis of vaccination-related shoulder dysfunction . . . [should] be considered in patients presenting with shoulder pain and weakness following a vaccine injection." Id.

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[5] A vaccine administration record showing petitioner's prior Tdap vaccination was not filed. However, the fact that he received a "Tdap booster" on July 13, 2015, implies that he had previously received the Tdap vaccine. See Pet. Ex. 2 at 32.

[6] S. Atanasoff et al., Shoulder Injury Related to Vaccine Administration (SIRVA), 28 Vaccine 8049 (2010).

[7] Marko Bodor & Enoch Montalvo, Vaccination-Related Shoulder Dysfunction, 25 Vaccine 585 (2007).

Dr. Natanzi notes that prior to the vaccination at issue, petitioner had no history of left shoulder pain or dysfunction. Pet. Ex. 25 at 8. An MRI from March 7, 2016 revealed "glenolabral tearing with a labral articular cartilage defect, a partial thickness supraspinatus tendon tear, chronic biceps tendon tear, and moderate acromioclavicular degenerative joint disease." Id. Additionally, orthopedic evaluations conducted by Drs. Cartwright and Oates "revealed signs of impingement syndrome and bursitis of the left shoulder." Id.

Dr. Cartwright found petitioner "clinically demonstrated signs of rotator cuff, biceps, and SLAP pathology" and concluded it was "exceedingly unlikely" that petitioner's symptoms are due to a vaccine. Pet. Ex. 25 at 8. Dr. Natanzi opines that "it is more likely than not that chronic degenerative changes in the labrum and acromioclavicular joint are age related and were present and asymptomatic before and after the injury." Id. He further opines that findings of mild rotator cuff tearing and impingement are typical "in cases of SIRVA needle over-penetration or become symptomatic as a result of vaccine-associated synovial inflammation." Id. at 8-9. He concludes that "either clinically indistinguishable scenario demonstrates a clear causal associated relationship." Id. at 9.

Dr. Natanzi, quoting the Qualifications and Aids to Interpretation ("QAI") relative to SIRVA in the Vaccine Injury Table, explains

> [a] vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> i. No history of pain, inflammation or dysfunction of the affected shoulder prior to intra-muscular 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 intra-muscular 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).

Pet. Ex. 25 at 9 (emphasis omitted). Dr. Natanzi opines that petitioner meets all of the criteria. Id.

Given the temporal association between vaccination and petitioner's symptoms and the absence of any pre-vaccination dysfunction, Dr. Natanzi concludes "with a high degree of likelihood," the July 13, 2015 Tdap vaccination caused petitioner's left shoulder dysfunction. Pet. Ex. 25 at 10.

In a supplemental expert report, Dr. Natanzi notes that both he and Dr. Abrams agree that (1) petitioner suffers from a shoulder condition, (2) petitioner had no history of shoulder pain prior to vaccination, and (3) petitioner has a history of uncontrolled diabetes. Pet. Ex. 31 at 1.

With regard to the effect of petitioner's diabetes, Dr. Natanzi concedes that petitioner's "underlying hyperglycemic state may have predisposed him more to an injury," but opines that "the injury to the rotator cuff or subacromial bursa would only happen if the needle penetrated those structures." Pet. Ex. 31 at 2. He further explains that "had the vaccine been correctly administered," petitioner's vaccine-related bursitis or tendinitis could not have developed and thus, the over-penetration of the vaccination needle led to an injury that was exacerbated by petitioner's diabetes. Id.

Dr. Natanzi opines that "although it is possible that the bursitis, tendinitis, and possible capsulitis spontaneously and coincidentally surfaced in the days post-vaccination, it is extremely improbable," especially given the fact that petitioner had no prior shoulder pain and petitioner's symptoms are characteristic of a SIRVA injury. Pet. Ex. 31 at 3. Additionally, petitioner's underlying diabetes "may have contributed to the severity of his shoulder pain[,] but had no role in the initiation of pain." Id. Therefore, he maintains that "to a reasonable degree of certainty that a SIRVA injury caused [petitioner's] shoulder pain." Id.

B. Respondent's Expert, Dr. Geoffrey D. Abrams

1. Background and Qualifications

Dr. Abrams is a board certified orthopedic surgeon with a subspecialty certification in sports medicine. Resp. Ex. A at 2. He received his B.A. from Stanford University in 2000 and his M.D. from the University of California, San Diego in 2007. Resp. Ex. B at 2. Thereafter, he completed a surgical internship in general surgery and residency in orthopedic surgery at Stanford University Hospitals and Clinics, as well as a fellowship in orthopedic sports medicine at Rush University Medical Center. Id. Dr. Abrams currently works as an Attending Physician at Veterans Administration Hospital, Palo Alto, Assistant Professor at Stanford University School of Medicine, and Director of Lacob Sports Medicine Clinic at Stanford University. Id. He also serves as team physician for numerous professional and collegiate sports teams. Resp. Ex. A at 2; Resp. Ex. B at 24-25. Dr. Abrams has authored or co-authored over 180 publications and serves on various committees and journals. Resp. Ex. B at 3-9, 11-24.

2. Opinion

Dr. Abrams agrees with Dr. Natanzi's statement that "it is more likely than not that chronic degenerative changes in the labrum and acromioclavicular joint are age related and were present and asymptomatic before and after the injury." Resp. Ex. A at 4 (quoting Pet. Ex. 25 at 8). However, he argues Dr. Natanzi failed to consider the effect of petitioner's diabetes diagnosis on the "pain, function, and structure of his shoulder nor the high incidence of rotator cuff pathology in the adult population." Id. at 5. Dr. Abrams opines that petitioner's "history of extremely high glucose levels at the time in question may have [led] to, or been a major factor[] in[,] the development of his shoulder pain and dysfunction." Id. at 8.

Based on the medical records, Dr. Abrams finds "it is nearly certain that [petitioner] was experiencing hyperglycemia," which is "known to have significant negative effects on the shoulder and makes patients more susceptible to inflammatory conditions," for years prior to

vaccination. Resp. Ex. A at 5. He explains that "hyperglycemia permanently alters tissue macromolecules through accelerated advanced glycation end-products (AGEs) formation," and the "AGEs cause qualitative and quantitative changes in extracellular matrix components which can affect cell adhesion, growth, and matrix accumulation." Id. In particular, Dr. Abrams points out that "AGEs are known to affect collagen, a major component of the rotator cuff." Id.

According to Dr. Abrams, hyperglycemia not only damages tendon tissues, but is also linked to inflammation. Resp. Ex. A at 5. Although Dr. Natanzi opines that petitioner's impingement and bursitis were caused by the Tdap vaccine, Dr. Abrams notes "AGEs are involved in a cycle of inflammation," leading to "a self-renewing process of inflammation." Id. Therefore, "due to [petitioner's] underlying extreme hyperglycemia, his body was primed to initiate an exaggerated inflammatory response to what otherwise was likely to be an innocuous event." Id. at 5-6.

In response to Dr. Natanzi's opinion that rotator cuff tearing and impingement are often found in needle over-penetration cases, Dr. Abrams argues injection "is unlikely to be [] causal [] as rotator cuff pathology is extremely common in the adult population, even in those without shoulder pain." Resp. Ex. A at 6. As support, Dr. Abrams cites Yamaguchi et al.,[8] which examined over 500 patients presenting with unilateral shoulder pain and found a majority had rotator cuff tearing on their contralateral, or asymptomatic, shoulder. Resp. Ex. A, Tab 18 at 2-3. The Yamaguchi study also found "a high correlation between the onset of rotator cuff tears (either partial or full thickness) and increasing age," observing "the average age was 48.7 years for patients with no rotator cuff tear, 58.7 years for those with a unilateral tear, and 67.8 years for those with a bilateral tear." Id. at 1, 3. The authors further noted their "finding of a strong (50%) likelihood of a bilateral tear after the age of sixty-six years is consistent with an intrinsic etiology for rotator cuff tears associated with natural aging." Id. at 5. Similarly, Reilly et al.[9] conducted a systematic review and found "[r]otator cuff tears are frequently asymptomatic." Resp. Ex. A, Tab 13 at 1. However, Reilly noted age was not frequently recorded and determined it was inappropriate to reach a conclusion regarding age. Id. at 5.

Additionally, Dr. Abrams opines that "imaging-proven rotator cuff pathology in asymptomatic patients is more common in those with diabetes." Resp. Ex. A at 6. In Abate et al.,[10] the authors examined 80 subjects, 48 with diabetes and 32 controls, who did not complain of shoulder pain or dysfunction and concluded that "age-related rotator cuff tendon changes are more common in diabetics." Resp. Ex. A, Tab 1 at 2, 5.

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[8] Ken Yamaguchi et al., The Demographic and Morphological Features of Rotator Cuff Disease: A Comparison of Asymptomatic and Symptomatic Shoulders, 88 J. Bone & Joint Surgery 1699 (2006).

[9] P. Reilly et al., Dead Men and Radiologists Don't Lie: A Review of Cadaveric and Radiological Studies of Rotator Cuff Tear Prevalence, 88 Annals Royal Coll. Surgeons Eng. 116 (2006).

[10] Michele Abate et al., Sonographic Evaluation of the Shoulder in Asymptomatic Elderly Subjects with Diabetes, 11 BMC Musculoskeletal Disorders 278 (2010).

Dr. Abrams maintains that shoulder impairments are very common in those with diabetes and cites Shah et al.,[11] which found 63% of patients with diabetes reported shoulder pain or disability. Resp. Ex. A at 6 (citing Resp. Ex. A, Tab 15 at 5). Dr. Abrams argues many of these shoulder impairments were due to tendinopathy of which diabetes is a well-known risk factor. Id. Petitioner exhibited "evidence of 'lateral epicondyle tenderness, pain with resisted wrist extension,'" which Dr. Abrams opines is "consistent with lateral epicondylitis (tennis elbow), a type of tendinopathy more frequently found in those with diabetes and indicative of a state of overall compromised tendon health." Id.

Dr. Abrams opines that Dr. Natanzi inaccurately asserted that "pain radiating to the level of the elbow (is) typical of rotator cuff and bursal referred pain." Resp. Ex. A at 6. Instead, Dr. Natanzi believes that petitioner's elbow exam was "consistent with lateral epicondylitis" due to "tenderness at the lateral epicondyle and pain with resisted wrist extension" and thus, it was not caused by shoulder pathology. Id. Dr. Abrams further opines that petitioner's underlying diabetes was "more of a contributing factor to the visualized rotator cuff pathology rather than the vaccine injection." Id.

Additionally, Dr. Abrams asserts that petitioner's PT notes state that petitioner's loss of motion was primarily in external rotation, which is associated with adhesive capsulitis, or frozen shoulder. Resp. Ex. A at 6. Dr. Abrams opines that "those with poor blood sugar control over a longer period are at an increased risk of the development of adhesive capsulitis." Id. at 7. Here, "petitioner's blood sugar level was extremely elevated at initial diagnosis and remained in the uncontrolled range for at least six months following his diagnosis," which "raises the possibility that the petitioner's shoulder pain and dysfunction may have, in part, been related to adhesive capsulitis." Id. Dr. Abrams opines that petitioner's condition is "more than likely" related to petitioner's diabetes than the Tdap vaccine because "there is no evidence that the vaccine administration was given in the glenohumeral joint, the most common location of pathology in adhesive capsulitis." Id.

Because the records do not indicate the location of the injection in petitioner's deltoid, whether petitioner was standing or sitting during injection, or the length of the needle, Dr. Abrams states he is unable to determine "whether the petitioner was at increased risk for SIRVA based on the injection technique nor whether the injection was administered into the subacromial space, as hypothesized by Dr. Natanzi." Resp. Ex. A at 7. Dr. Abrams believed petitioner's "underlying medical condition (diabetes/hyperglycemia) was a significant factor in the development and persistence of his shoulder dysfunction." Id.

Even if petitioner suffered a SIRVA injury, Dr. Abrams argues that most SIRVA patients' shoulders return to full and/or pain-free function within a few months to one year after vaccination, which has not happened in petitioner's case. Resp. Ex. A at 7-8. Dr. Abrams opines this "was likely due to [petitioner's] underlying diabetes and subsequent overall inflammatory state." Id. at 8.

[11] K.M. Shah et al., Upper Extremity Impairments, Pain and Disability in Patients with Diabetes Mellitus, 101 Physiotherapy 147 (2015).

Dr. Abrams concludes that "[w]ith reasonable medical certainty, the petitioner's underlying medical condition was a significant factor in the development of his shoulder pain," and thus, he does not meet the fourth QAI requirement—no other condition or abnormality is present that would explain the patient's symptoms. Resp. Ex. A at 8.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue 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 & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] 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 & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner's claim predates the inclusion of SIRVA on the Table, he must prove his claim by showing that his injury was caused-in-fact by the vaccination in question. § 11(c)(1)(C)(ii). To do so, petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must

weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The mechanism for a SIRVA injury is well described in the medical literature filed in this case. In Atanasoff, the authors propose that the causal mechanism "is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Pet. Ex. 25.5 at 1. They found "rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Id. at 3. MRI findings supported the conclusion that shoulder impairments, such as rotator cuff tears, "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." Id. Similarly, Bodor and Montalvo proposed that a "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Pet. Ex. 25.2 at 1-2. They found multiple structures within the shoulder involved, which suggested "a primary inflammatory etiology rather than a mechanical overuse problem." Id. at 3.

Further, when proposing the addition of SIRVA to the Vaccine Table, respondent discussed the mechanism by which this injury is caused. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015).

The undersigned takes judicial notice of the fact that respondent added SIRVA after receipt of an intramuscularly administered Tdap vaccine to the Table. Such recognition of the causal association between vaccine and injury has been held to support the establishment of the theory required by the first Althen prong. See Doe 21 v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 178, 193 (2009), rev'd on other grounds, 527 F. App'x 875 (Fed. Cir. 2013).

Additionally, the undersigned notes that, prior to the adoption of the revised Table, which is effective for petitions filed on March 21, 2017 and later, respondent conceded entitlement in numerous SIRVA cases alleging causation by an intramuscularly administered Tdap vaccine. See, e.g., Larson v. Sec'y of Health & Hum. Servs., No. 16-219V, 2016 WL 3006349 (Fed. Cl. Spec. Mstr. Mar. 23, 2016). Even after the revised Table became effective, respondent continued to concede cases which may not have met the Table criteria, but in which respondent, nevertheless, believed causation had been established. See, e.g., Muller-Carillo v. Sec'y of Health & Hum. Servs., No. 19-183V, 2020 WL 1079508 (Fed. Cl. Spec. Mstr. Feb. 4, 2020).

Moreover, petitioner submitted the expert opinion of Dr. Natanzi who provided a sound and reliable medical and scientific theory of causation supported by medical literature. Dr. Natanzi explained that the injection resulted in tendinous and/or bursal penetration, leading to a "robust and prolonged inflammatory response" and the "development of bursitis, impingement, tendinopathy, and mild capsulitis." Pet. Ex. 25 at 9.

The undersigned finds petitioner has provided by preponderant evidence a sound and reliable theory that the Tdap vaccine administered intramuscularly can cause SIRVA, and therefore, petitioner has satisfied the first Althen prong.

B. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

With regard to the second Althen prong, the undersigned finds there is a preponderance of evidence in the record to support a logical sequence of cause and effect showing the July 13, 2015 Tdap vaccination to be the cause of petitioner's left shoulder pain. See Althen, 418 F.3d at 1278. First, Dr. Natanzi's report and the medical literature provide a framework for evaluating whether petitioner's claim is consistent with SIRVA. The criteria are as follows:

> [a] vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> i. No history of pain, inflammation or dysfunction of the affected shoulder prior to intra-muscular 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 intra-muscular 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).

Pet. Ex. 25 at 9.

1. Prior Condition

Based upon a review of the record as a whole, including the medical records, affidavits, and expert reports, the undersigned finds there is no evidence that petitioner experienced any issues with his left shoulder prior to vaccination.

2. Pain Onset

Respondent argues that petitioner has not established that his left shoulder pain began within a temporally appropriate time frame. Resp. Response at 26. Respondent acknowledges that "the affidavits . . . support petitioner's claim . . . that his pain started immediately after the Tdap vaccine," but contends "these statements should be afforded minimal weight as they were prepared in preparation of litigation over two years after the date of the vaccination in question." Id. at 28. Respondent also argues the medical records do not support petitioner's assertion that his pain began immediately after vaccination, and cites to various records that describe onset. Id. at 27-28.

Relying on the affidavits and contemporaneous medical records, petitioner argues he experienced left shoulder pain and increased pain in his left shoulder with movement within 48 hours of the Tdap vaccination. Pet. Mot. at 10-14. Additionally, petitioner's expert, Dr. Natanzi, opined that petitioner's left shoulder pain began "immediately after vaccination" and "is a direct result of the Tdap vaccine." Pet. Ex. 25 at 1, 9; see also Pet. Ex. 31 at 2.

The earliest in time document regarding onset is the e-mail that petitioner sent to his PCP on August 9, 2015. Petitioner wrote, "[l]eft shoulder still quite sore from [Tdap] shot." Pet. Ex.

4 at 2. The next day, August 10, petitioner sent a follow-up e-mail explaining that his shoulder was "sore all of the time but more when in use" and his pain was limiting his movement. Id. at 1. In response, Dr. McElhaney stated that "muscle ache . . . where shot is given wouldn't hurt this long . . . shouldn't last 2+ weeks. Given description of pains and what movements bother it, it sounds possibility like tendonitis or bursitis to the shoulder itself." Id.

In this e-mail exchange, petitioner used the phrase, "still quite sore." A plain reading of the e-mail exchange is that petitioner had pain at the time of his vaccination or immediately after, and the pain was still present on August 9 and had never gone away. Petitioner did not describe pain onset that began at some time later but related it back to vaccination.

On November 9, 2015, petitioner was seen by Dr. Rajvanshi, who noted "[p]ain has been present for 3 months after getting Tdap" vaccination. Pet. Ex. 2 at 48. Dr. Rajvanshi does not describe any gap of time between vaccination and pain onset.

Dr. Cartwright, on February 17, 2016, wrote petitioner's "symptoms caused by a vaccine - Tdap 7 months ago." Pet. Ex. 3 at 6 (emphasis omitted). On March 3, 2016, petitioner was seen by Dr. McElhaney who documented, "[p]ain has been present for since July 2015." Pet. Ex. 2 at 92.

The most specific record, documented November 18, 2015 by petitioner's physical therapist, places onset of pain "a few days after the [Tdap] shot."[12] Id. at 51. The undersigned considers "few" to mean two or three days.[13]

The affidavits support a finding that petitioner's pain began within 48 hours of vaccination. Petitioner claims he immediately began to have pain in his left shoulder after receipt of the Tdap vaccination. Pet. Ex. 11 at ¶ 3. He described the pain as a "constant . . .

[12] Later records from 2016 reference onset in February 2016. Dr. Oates, on October 17, 2016, noted petitioner's "symptoms began last February following a [Tdap] vaccination." Pet. Ex. 7 at 8. Petitioner's initial PT evaluation on October 20, 2016 documents onset as "unknown" but describes petitioner's pain as "developing in February 2016 after a [] shot in the left shoulder." Pet. Ex. 6 at 4. The reference to administration of a flu shot instead of Tdap is erroneous. Descriptions of onset in February are inconsistent with the earlier in time and most contemporaneous records, and thus, the undersigned finds them to be less reliable.

[13] If "few" means two days, then onset would be within 48 hours, meeting the causation-in-fact requirement. If "few" instead means three days, or 72 hours, then petitioner still meets the causation-in-fact requirement. See Jewell v. Sec'y of Health & Hum. Servs., No. 16-0670V, 2017 WL 7259139 (Fed. Cl. Spec. Mstr. Aug. 4, 2017). Like petitioner's PT notes, the PT notes in Jewell place onset "a few days" after vaccination. Id. at *3. Relying heavily on the PT records, the undersigned in Jewell found the onset of the petitioner's shoulder injury to be within 72 hours and thus, was medically appropriate. Id. In making this determination, the undersigned also relied on Atanasoff, who found that while most patients experienced pain within 48 hours, 8% of patients experienced shoulder pain at four days. Id.; Pet. Ex. 25.5 at 2 tbl.1.

burning sensation in the shoulder muscle and joint" that was worse with movement. Id. at ¶¶ 3, 5. He also found it difficult to lift his left arm over his shoulder. Id. at ¶ 5. Petitioner's wife, Gina Taylor, confirms that she began to notice petitioner's left arm pain the day after vaccination. Pet. Ex. 12 ¶ at 4. Petitioner's longtime employee, Mr. Hilton, recalls petitioner complaining of a sore shoulder the day after vaccination and noted petitioner's "work was effected immediately after his vaccination." Pet. Ex. 13 at ¶ 4.

The difficulty in ruling on onset in some SIRVA cases is exemplified by the facts here. Tdap vaccinations can cause soreness. As explained by petitioner's PCP in his email, post Tdap vaccine site soreness usually lasts a few days. If the soreness does not go away, then there is concern for tendonitis or bursitis, the hallmarks of SIRVA. It may be difficult for a petitioner to determine whether their soreness is a normal reaction to vaccination, or something more. Regardless of this difficulty, here, based on the petitioner's email exchange with his physician, the medical records, and affidavits, the undersigned finds the onset of petitioner's shoulder pain began immediately after vaccination, and well within two days, or 48 hours of his July 13, 2015 Tdap vaccination.

3. Pain and Limited Range of Motion

Based on the petitioner's affidavit and medical records, petitioner's vaccine-related symptoms were limited to his left shoulder. Records from petitioner's August 9, 2015 email to his PCP and November 9, 2015 visit to Dr. Rajvanshi documented complaints of left shoulder pain. Pet. Ex. 2 at 47-48. On November 18, 2015, petitioner's physical therapist, Jaime McCann, noted petitioner's pain in his left shoulder, that was moving down to his elbow, and assessed petitioner with "left tendinopathy of rotator cuff." Id. at 54. At that visit, petitioner exhibited decreased ROM with shoulder abduction and internal and external rotation. Id. at 53.

Petitioner saw orthopedic surgeon, Dr. Cartwright, on February 17, 2016, complaining of a left shoulder injury for seven months, and he found petitioner "clearly has impingement, rotator cuff symptomatology, and biceps and SLAP pathology." Pet. Ex. 3 at 6-8. In March 2016, Dr. Cartwright noted "ROM shows flexion 160 degrees and abduction 156 degrees." Id. at 27.

On October 17, 2016, petitioner saw orthopedist, Dr. Oates, complaining of left shoulder pain and Dr. Oates' impression was subacromial impingement/bursitis of left shoulder, osteoarthritis of left acromioclavicular joint, and left biceps tendonitis. Pet. Ex. 7 at 8-9. From October to November 2016, petitioner attended PT. Pet. Ex. 6 at 4-18. On initial exam, petitioner had decreased ROM. Id. at 4. By discharge, petitioner had improved ROM, but it was not normal. Id. at 16, 18.

After his January 4, 2017 left shoulder surgery, petitioner attended additional PT sessions. Pet. Ex. 9 at 9-31. Upon discharge, petitioner was still experiencing limitations in flexion and abduction. Id. at 26.

Petitioner's expert, Dr. Natanzi, opined that petitioner's pain and decreased range of motion were isolated to his left shoulder. Pet. Ex. 25 at 9.

4. Other Condition or Abnormality

Dr. Natanzi identifies no other condition or abnormality that explains petitioner's symptoms. Pet. Ex. 25 at 9. In contrast, Dr. Abrams opines that petitioner's "underlying medical condition (diabetes/hyperglycemia) was a significant factor in the development and persistence of his shoulder dysfunction," and thus, this criteria was not met. Resp. Ex. A at 7-8. In response, Dr. Natanzi concedes that petitioner's underlying hyperglycemic state and diabetes may have predisposed him to an injury, but the injury occurred due to the injection needle penetrating the structures. Pet. Ex. 31 at 2. Thus, Dr. Natanzi opines petitioner's diabetes "had no role in the initiation of [petitioner's shoulder] pain." Id. at 3.

Based upon the medical literature filed by respondent, it appears that it is not uncommon for people with diabetes to have shoulder impairments. However, the Atanasoff authors stated that in many cases, conditions including "impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis[,] and adhesive capsulitis[,] . . . may cause no symptoms until provoked by trauma or other events." Pet. Ex. 25.5 at 3. The authors concluded that "some of the MRI findings . . . may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." Id. Here, petitioner may have had pre-existing pathology, but he was not symptomatic until after vaccination.

While petitioner's diabetes may have made it more likely for him to have suffered a shoulder injury, and may have affected his clinical course, the undersigned finds that his diabetes was not an alternative cause, or factor unrelated to vaccination, which caused petitioner's symptoms. As Dr. Natanzi explained, petitioner's shoulder symptoms began only after vaccination, which is further supported by Atanasoff. Thus, the undersigned finds petitioner's vaccination was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

In conclusion, petitioner's injury meets the criteria for a SIRVA injury and the clinical course of petitioner's injury mirrors a typical SIRVA injury. Therefore, the undersigned finds petitioner has proven by preponderant evidence a logical sequence of cause and effect and has satisfied the second Althen prong.

C. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been equated to mean a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." De Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

As stated above, the undersigned finds the onset of petitioner's left shoulder pain occurred within 48 hours of vaccination. The timing of onset shows a proximate temporal relationship between vaccination and injury. See Althen, 418 F.3d at 1278. The temporal association is appropriate given the mechanism of injury. Thus, petitioner has satisfied the third Althen prong.

D. Alternative Causation

Because the undersigned concludes that petitioner has established a prima facie case, petitioner is entitled to compensation unless respondent can put forth preponderant evidence "that [petitioner's] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to Althen Prong Two, the undersigned found the respondent failed to establish evidence to show that petitioner's SIRVA injury was caused by a source other than his vaccination. Thus, respondent did not prove by a preponderance of evidence that petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

VI. CONCLUSION

Based on the record as a whole and for the reasons discussed above, the undersigned finds there is preponderant evidence to satisfy all three Althen prongs and to establish petitioner's July 13, 2015 Tdap vaccination caused his left shoulder pain and limited range of motion, resulting in the need for surgery. Thus, the undersigned finds that petitioner has established by preponderant evidence that he is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master