

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

BEVERLY SCHICK-COWELL,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

*
* No. 18-656V
* Special Master Christian J.
* Moran
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* Filed: February 8, 2022
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* Entitlement; influenza ("flu")
* vaccine; SIRVA; shoulder
* injury.

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for petitioner;
Nina Ren, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Beverly Schick-Cowell alleges that an influenza ("flu") vaccine caused her to suffer left shoulder injuries. The parties have submitted reports from experts and argued their positions through legal briefs. An assessment of this information shows that Ms. Schick-Cowell had an 11-month history of shoulder pain prior to vaccination and that the pain was not limited to her left shoulder. Further, Ms. Schick-Cowell has not established a logical sequence of cause and effect connecting her shoulder injury to her vaccination. Accordingly, Ms. Schick-Cowell has not satisfied the criteria for an on-Table claim for a Shoulder Injury Related to Vaccine Administration ("SIRVA") or met her burden of establishing that the flu vaccine caused her left shoulder injuries. Thus, her case is dismissed.

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

I. Facts

A. Pre-Vaccination

Before vaccination, Ms. Schick-Cowell had a history of chronic neck, shoulder, and low back pain. In 1999, Ms. Schick-Cowell underwent back surgery for a ruptured disc. Exhibit 2 at 4; 53. Ms. Schick-Cowell alleges that she had no history of left shoulder injuries prior to vaccination. Pet., filed May 9, 2018, at ¶ 3.

In October 2015, Ms. Schick-Cowell established care with Richard Buck, a chiropractor, for chronic low back pain, neck pain, and bilateral shoulder pain. Exhibit 2 at 1-9. Dr. Buck recommended chiropractic adjustment, electrical stimulation, and massages. *Id.* at 9. Ms. Schick-Cowell returned for nine treatment sessions in November 2015 and seven treatment sessions in December 2015. *Id.* at 11-31. Between January 4 and September 14, 2016, Ms. Schick-Cowell returned to Dr. Buck thirty times. *Id.* at 32-74. Ms. Schick-Cowell reported left shoulder pain during several of these visits. *See, e.g., id.* at 36-38 (reporting that her left shoulder pain ranged from 4/10 to 5/10 during her February 2016 visits); *id.* at 48-49 (reporting that her left shoulder pain was a 4/10 on two visits in March 2016); *id.* at 50 (stating that her left shoulder “[felt] like her clavicle need[ed] to pop” and that she was experiencing dull, achy, stiff, and tense sensations on April 8, 2016); exhibit 17 at 53 (reporting “dull to sharp” left shoulder pain on April 18, 2016).

On May 26, 2016, Ms. Schick-Cowell informed Dr. Buck that she was experiencing “[n]eck tightness down through [her] shoulders and in [her] back,” “dull to sharp [neck] pain,” and “aching tired numb to dull pain radiating through [her] upper back shoulders.” Exhibit 2 at 53. Dr. Buck recommended continued chiropractic adjustment, electrical stimulation, and massages. *Id.* at 57.

During Ms. Schick-Cowell’s subsequent visits to Dr. Buck from May to August 2016, she continued to report neck, back, or shoulder pain. *Id.* at 60-73. Ms. Schick-Cowell reported that her shoulder pain was a 4/10 during her June 8, 2016, July 25, 2016, and August 30, 2016 visits. *Id.* at 62, 70, 73. On September 14, 2016, Ms. Schick-Cowell told Dr. Buck that her shoulders were better. *Id.* at 74.

According to Ms. Schick-Cowell, her shoulders were never thoroughly examined to determine the cause of her pain. Pet'r's Br. at 3. She cited no evidence for this assertion.

B. September 16, 2016 Vaccination

Ms. Schick-Cowell received a flu vaccine in her left arm on September 16, 2016. Exhibit 1 at 1. Ms. Schick-Cowell's mother attested that she spoke with Ms. Schick-Cowell "a couple [of] days" after receiving the flu shot, and she told her mother that "her left arm was very sore, sorer than what a flu shot normally felt like." Exhibit 23 (affidavit of Norma Henning-Schick) ¶ 3. Ms. Schick-Cowell alleges that after receiving the flu vaccine, her shoulder pain changed significantly. Pet'r's Br. at 3.

C. Post-Vaccination

On September 28, 2016, Ms. Schick-Cowell returned to Dr. Buck with complaints of shooting pain from the left shoulder up into the neck. Exhibit 2 at 75. Ms. Schick-Cowell rated her pain as 5/10. Id.² Ms. Schick-Cowell attributed her pain to the flu shot during this visit. Id. She returned to Dr. Buck seven times in October 2016 without reporting any left shoulder pain. Id. at 76-83.

Ms. Schick-Cowell sought care for back pain at ProMedica Westgate Family Medicine on October 7, 2016. Exhibit 3 at 12-14. She reported that her back pain worsened after heavy lifting. Id. at 12; see also Exhibit 2 at 79 (October 5, 2016 visit with Dr. Buck) (reporting that she was experiencing back pain and sciatic pain in her right leg after moving furniture). During this visit, Ms. Schick-Cowell also reported that her left arm hurt from her flu shot. Exhibit 3 at 12. The physical examination revealed that Ms. Schick-Cowell had a normal range of motion and radiating lower back tenderness. Id. at 14. Ms. Schick-Cowell was diagnosed with acute right-sided low back pain with right-sided sciatica, given a Toradol injection, and prescribed muscle relaxers, prednisone, and pain medication. Id. at 13-14.

On October 10, 2016, Ms. Schick-Cowell saw Steven Sokoloski, M.D., an orthopedist, for low back pain and radiating right leg pain. Exhibit 4 at 5. She informed Dr. Sokoloski that she had been moving a lot of furniture. Id. Dr.

² During her prior visits to Dr. Buck, Ms. Schick-Cowell's shoulder pain ranged from 3/10 to 5/10. Exhibit 2 at 36-38, 48-49, 62, 70, 73; exhibit 17 at 16-18, 23, 31-32, 53-54.

Sokoloski diagnosed Ms. Schick-Cowell with an acute L5-S1 herniated disc on the right side and referred her to physical therapy. Id.

Ms. Schick-Cowell visited her primary care provider, Stephen Przynosch, M.D., on October 21, 2016 for complaints of continued right-sided sciatica and lower back pain. Exhibit 3 at 14-15. Dr. Przynosch recorded “[r]eproducible pain throughout the right lower back and over the right sciatic notch.” Id. at 15. He did not note any shoulder pain in the record. Id. He gave a Depo-Medrol injection in Ms. Schick-Cowell’s right sciatic nerve, prescribed her Naproxen and Tramadol, and referred her to physical therapy. Id.

On October 26, 2016, Ms. Schick-Cowell went to the Center for Health Services Total Rehabilitation for a physical therapy evaluation. Exhibit 5 at 2. During this session, she reported that her left shoulder pain began after receiving her flu shot. Id. Following this visit, she returned for eighteen physical therapy sessions through January 4, 2017. Id. at 2-102.

Ms. Schick-Cowell returned to ProMedica Westgate Family Medicine on November 10, 2016, complaining of left shoulder pain and numbness and tingling through her left arm. Exhibit 3 at 16. During this visit, Ms. Schick-Cowell reported that the numbness and tingling began after her flu shot on September 16, 2016. Id. Ms. Schick-Cowell received an X-ray of her left shoulder, which was normal, and an X-ray of her cervical spine, which showed straightening of the normal cervical lordosis. Id. at 22-23. Ms. Schick-Cowell was diagnosed with left upper arm pain and chronic left shoulder pain and was directed to schedule a left shoulder MRI. Id. at 16-18.

On November 21, 2016, Ms. Schick-Cowell received a left shoulder MRI. Id. at 24-25. The MRI showed edema within the teres minor muscle and tendon and abnormal signal within the adjacent humerus. Id.

Ms. Schick-Cowell saw Anthony Frogameni, M.D., on November 25, 2016 for complaints of severe left shoulder pain and swelling and numbness and tingling in her left arm. Exhibit 6 at 4. Dr. Frogameni diagnosed Ms. Schick-Cowell with a reactive bursitis impingement and provided a left shoulder steroid injection. Id. On December 2, 2016, Ms. Schick-Cowell returned to Dr. Frogameni and reported that her pain had improved after receiving the steroid injection. Id. at 3. Dr. Frogameni diagnosed Ms. Schick-Cowell with neuritis, prescribed Mobic, and instructed Ms. Schick-Cowell to continue physical therapy. Id. During this visit, Dr. Frogameni noted that the neuritis “may be related to inflammation caused by

the flu shot that has given her some fluid around the shoulder and given her some dysesthesias” but felt “it will resolve.” Id.

On January 5, 2017, Ms. Schick-Cowell sought treatment from orthopedic surgeon Christopher Foetisch, M.D., for her left shoulder pain. Exhibit 8 at 1-4. Ms. Schick-Cowell reported that the steroid injection helped for only a few days. Id. Dr. Foetisch found that Ms. Schick-Cowell had tenderness over the lateral bursa, no impingement, no gross instability, and normal muscle strength. Id. at 2-3. Ms. Schick-Cowell’s shoulder X-ray was normal. Id. at 3. Dr. Foetisch diagnosed Ms. Schick-Cowell with brachial neuritis and noted that literature states that brachial neuritis can be caused by the flu vaccine. Id. at 3-4. He prescribed prednisone and recommended Ms. Schick-Cowell see her neurologist. Id.

Ms. Schick-Cowell underwent a cervical spine MRI on January 30, 2017. Exhibit 2 at 84; exhibit 3 at 26-27. The MRI showed central disc protrusion at C6-7 without evidence of cord compression or narrowing of the neural foramina and a minimal disc bulging at C4-5. Id.

On February 2, 2017, Ms. Schick-Cowell returned to Dr. Foetisch. Exhibit 8 at 4-7. Dr. Foetisch diagnosed Ms. Schick-Cowell with acute left shoulder pain, administered a steroid injection, and instructed her to get an electromyography (“EMG”) of the left upper extremity. Id. at 4-7. Ms. Schick-Cowell visited neurologist Mark Loomus, M.D., on February 28, 2017 for an EMG of the left upper extremity, which was normal. Exhibit 32 at 45-48.

Ms. Schick-Cowell returned to Dr. Foetisch on March 9, 2017 and reported some relief in her shoulder after receiving the steroid injection. Exhibit 8 at 7-9. She told Dr. Foetisch that her main concern at the time was back pain and shooting pain in her leg. Id. at 7.

On April 14, 2017 and May 2, 2017, Ms. Schick-Cowell sought care for back, buttock, and right leg pain. Exhibit 4 at 4, 10-12. During these visits, Ms. Schick-Cowell did not report any shoulder pain. Id.

Ms. Schick-Cowell returned to Dr. Foetisch on August 24, 2017 for treatment for her left shoulder pain. Exhibit 8 at 9. Dr. Foetisch performed X-rays of Ms. Schick-Cowell’s left shoulder, which showed mild degenerative changes. Id. at 14-15. Dr. Foetisch gave Ms. Schick-Cowell another steroid injection and diagnosed her with chronic left shoulder pain, chronic left shoulder bursitis, and brachial neuritis of the left upper extremity. Id. at 9-12. Dr. Foetisch stated that

Ms. Schick-Cowell's presentation made it "difficult to say whether her current symptoms are related to her neck or shoulder or both." Id. at 11.

Ms. Schick-Cowell followed up with Dr. Foetisch on December 4, 2018 and reported continued left shoulder pain. Exhibit 18 at 75. Dr. Foetisch diagnosed Ms. Schick-Cowell with neck pain, chronic left shoulder pain, left cervical radiculopathy, and myofascial pain on the left pectoralis major. Id. at 76. Dr. Foetisch reported that Ms. Schick-Cowell's shoulder exam did not reveal any "concerning" findings. Id. Dr. Foetisch recommended physical therapy and NSAIDs. Id.

On December 17, 2018, Ms. Schick-Cowell went to Sports Care at Professional Park for an initial physical therapy evaluation, where she reported experiencing left shoulder pain since receiving the flu shot in September 2016. Exhibit 14 at 17. Ms. Schick-Cowell stated that her pain improved with physical therapy and chiropractic treatment "but never really went away completely" and "recently increased in nature along with neck pain and numbness/tingling in [the left upper extremity]." Id. Ms. Schick-Cowell returned for twelve physical therapy sessions through March 11, 2019. Id. at 10-52; exhibit 16 at 10-14.

Ms. Schick-Cowell sought care from Kevin Dankert, D.O., on May 23, 2019 for her left shoulder pain. Exhibit 22 at 5, 11. Dr. Dankert noted Ms. Schick-Cowell had full strength and abduction, flexion, and external rotation in her left shoulder. Id. at 14. Ms. Schick-Cowell's left shoulder showed limitations in her internal rotation when compared with her right shoulder. Id. Dr. Dankert diagnosed Ms. Schick-Cowell with left cervical radiculopathy, chronic left shoulder pain, and subacromial bursitis of the left shoulder joint. Id. at 16-17. He also gave Ms. Schick-Cowell two steroid injections in her left glenohumeral joint and her subacromial bursa. Id. at 15-16.

On June 27, 2019, Ms. Schick-Cowell returned to Dr. Dankert and noted 20% improvement in her pain after receiving the steroid injections. Id. at 32, 38. Dr. Dankert suggested an arthrogram of the left shoulder. Id. at 40. On July 23, 2019, Ms. Schick-Cowell underwent an arthrogram of the left shoulder, which was normal. Exhibit 29 at 12-32.

Ms. Schick-Cowell went to Rosemarie Osowik, M.D., on August 23, 2019 for her left shoulder pain. Exhibit 33 at 8-9. Ms. Schick-Cowell informed Dr. Osowik that her pain began "instantly" after receiving the flu vaccine. Id. at 8. Dr. Osowik stated that she wanted to do lab work "to see if it could be an auto immune

response to the vaccine.” Id. Ms. Schick-Cowell was diagnosed with left shoulder pain and extremity numbness and referred to a neurologist. Id.

On October 24, 2019, Ms. Schick-Cowell saw Purvi Saraiya, M.D., a neurologist, for upper extremity paresthesia. Exhibit 32 at 5-7. Dr. Saraiya diagnosed her with left upper extremity numbness and brachial plexopathy and recommended an EMG and a brachial plexus MRI. Id. at 6-7. Ms. Schick-Cowell underwent a brachial plexus MRI on November 7, 2019, which was normal. Id. at 40-41. On December 6, 2019, Ms. Schick-Cowell underwent an EMG, which was also normal. Exhibit 32 at 78-79.

In April and May 2021, Ms. Schick-Cowell sought continued treatment for her shoulder, back, neck, and buttock pain from Harmony Chiropractic Center. Exhibit 51 at 1-34. These are Ms. Schick-Cowell’s most recent medical records.

II. Procedural History

Ms. Schick-Cowell filed a petition for compensation on May 9, 2018. Pet., filed May 9, 2018. She filed initial medical records on May 9, 2018 and additional medical records on August 15, 2018. On August 15, 2018, she filed an amended petition specifying that she suffered “left shoulder injuries, a table injury.” Amend. Pet., filed Aug. 15, 2018, at 1. She filed additional medical records in November and December 2018.

The Secretary reviewed this material and recommended that compensation be denied. Resp’t’s Rep., filed Apr. 26, 2019. The Secretary argued that Ms. Schick-Cowell did not satisfy the criteria for an on-Table claim for a SIRVA. Id. at 10. He asserted that Ms. Schick-Cowell’s pain did not appear to occur within 48 hours of vaccine administration, she had a history of left shoulder pain for nearly a year prior to vaccination, and her pain was not limited to her left shoulder. Id. at 10-11. The Secretary also argued that Ms. Schick-Cowell failed to establish that her left shoulder injury was caused-in-fact by the flu vaccine. Id. at 11-12.

Ms. Schick-Cowell filed additional medical records and employment records in June 2019. She filed more medical records and affidavits from fact witnesses on July 1, 2019. She submitted additional medical records in January 2020, March 2020, and April 2020.

The parties filed various expert reports. To advance her case, Ms. Schick-Cowell presented a report from Naveed Natanzi, D.O., on October 15, 2019.

Exhibit 30. The Secretary submitted a report from Robert Brophy, M.D., an orthopedic surgeon, on February 6, 2020. Exhibit A. Dr. Natanzi submitted a second expert report. Exhibit 37. Dr. Brophy also presented a second report. Exhibit C. The Secretary submitted an additional report from Mark Bromberg, M.D., Ph.D., a neurologist, on June 22, 2020. Exhibit D. Ms. Schick-Cowell then presented a responsive report from radiologist Tinoosh Zand, M.D., a responsive report from neurologist Frederick Nahm, M.D., Ph.D., and an additional report from Dr. Natanzi on October 1, 2020. Exhibits 43, 46, and 47. The Secretary then filed responsive expert reports from Dr. Brophy and Dr. Bromberg. Exhibits F and G. The parties also filed several medical articles their experts cited.

Following the completion of the expert report stage, the parties were instructed to file briefs advocating for their positions. Order, issued June 11, 2021. Ms. Schick-Cowell filed a brief in support of entitlement on August 8, 2021, and the Secretary submitted his brief on October 8, 2021. Ms. Schick-Cowell did not submit a reply brief. Therefore, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty).

IV. Analysis

The analysis falls into two categories, reflecting the two causes of action Ms. Schick-Cowell has alleged. The first is an on-Table SIRVA claim. The second is an off-Table shoulder injury.

A. **On-Table SIRVA**

A petitioner may establish causation by showing that she suffered an injury contained in the Vaccine Injury Table corresponding to the vaccine she received within the appropriate timeframe. 42 U.S.C. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). In such a case, causation is presumed. *Id.* To satisfy the elements for an on-Table SIRVA claim, a petitioner must show that she had no history of shoulder pain prior to vaccination, the onset of pain occurred within 48 hours after vaccination, the injury is confined to the shoulder in which she received the vaccine, and there is no evidence of any alternative cause of her pain. 42 C.F.R. § 100.3(a), (c)(10).

First, Ms. Schick-Cowell has not established that she had no history of pain in her left shoulder prior to vaccine administration as required by the Vaccine Injury Table. Ms. Schick-Cowell alleges that she had no history of left shoulder injuries before her vaccination. Pet., filed May 9, 2018, at ¶ 3. However, she received chiropractic treatment for her shoulder pain for about 11 months prior to her September 16, 2016 vaccination. Exhibit 2 at 1-83. Ms. Schick-Cowell established care with Dr. Buck on October 28, 2015. *Id.* at 1-9. Subsequently, she returned for 46 sessions through September 14, 2016, during which she consistently reported shoulder pain. *See, e.g., id.* at 36-38 (reporting that her left shoulder pain ranged from 4/10 to 5/10); *id.* at 48-49 (reporting that her left shoulder pain was a 4/10); *id.* at 50 (stating that her left shoulder “[felt] like her clavicle need[ed] to pop” and that she was experiencing dull, achy, stiff, and tense sensations); exhibit 17 at 53 (reporting “dull to sharp” left shoulder pain).

Ms. Schick-Cowell concedes that she visited Dr. Buck for complaints of bilateral shoulder pain between October 2015 through September 2016. Pet’r’s Br. at 21. However, Ms. Schick-Cowell argues that her complaints to Dr. Buck changed on September 28, 2016 after receiving her flu vaccine. *Id.* Ms. Schick-Cowell attempts to distinguish her pre-vaccination shoulder pain, noting that complaints were related to both shoulders, and complaints specific to the left shoulder were limited and related to activities like lifting her children. *Id.* at 28 (citing exhibit 2 at 13-31, 53, 70). Ms. Schick-Cowell also notes that she reported

her shoulders were better before receiving the flu shot. Id. at 29 (citing exhibit 2 at 74-75).

Dr. Natanzi based his opinion that Ms. Schick-Cowell's flu vaccine caused her shoulder injury in part on "the absence of any pre-vaccination shoulder dysfunction." Exhibit 30 at 11-12. He acknowledged that Ms. Schick-Cowell began seeing Dr. Buck in October 2015 for chronic neck, shoulder, and low back pain. Id. at 8. He opined that Ms. Schick-Cowell's pre-vaccination shoulder pain was "markedly less severe in [its] intensity, duration, and frequency in comparison to her left shoulder pain after the vaccination." Id. He concluded, "A comparison of the debility brought on post vaccination versus her prior level of activity and function during the course of chiropractic treatments leads me to believe . . . that no significant structural shoulder injury existed prior to the vaccination." Id.

In contrast, Dr. Brophy noted that Ms. Schick-Cowell reported shoulder pain of 5/10 on September 28, 2016 (12 days after vaccination), which is similar to her report of shoulder pain of 4/10 on August 30, 2016 before vaccination. Exhibit A at 10. Despite Ms. Schick-Cowell's attempts to distinguish her pre-vaccination shoulder pain, the medical records indicate an 11-month history of shoulder dysfunction prior to her September 16, 2016 flu shot. Therefore, Ms. Schick-Cowell has not established that she had no history of shoulder pain prior to vaccination.

Second, Ms. Schick-Cowell has not shown that her pain was limited to her left shoulder. The medical records created after vaccination frequently reference pain extending beyond Ms. Schick-Cowell's left shoulder. See, e.g., exhibit 2 at 75 ("[n]eck pain that shoots up from the shoulder"); exhibit 3 at 16-18 (numbness and tingling in the left arm); exhibit 5 at 10 (left hand numbness, tingling, and coldness). At an October 5, 2016 visit with Dr. Buck, Ms. Schick-Cowell reported back pain and sciatic pain in her right leg after moving furniture. Exhibit 2 at 79. On October 7, 2016, Ms. Schick-Cowell went to ProMedica Westgate Family Medicine for complaints of back pain that worsened after heavy lifting. Exhibit 3 at 12-14. At an October 10, 2016 appointment with Dr. Sokoloski and an October 21, 2016 appointment with Dr. Pryznosch, she again sought care for low back pain and radiating right leg pain. Exhibit 4 at 5; exhibit 3 at 14-15. The medical records from her October 10 and October 21, 2016 appointments do not reference shoulder pain. Id. Thus, the medical records show that Ms. Schick-Cowell's pain was not limited to her left shoulder.

Third, whether the onset of Ms. Schick-Cowell's injury occurred within 48 hours of her September 16, 2016 vaccination is unresolved. The Secretary asserts that Ms. Schick-Cowell's claim that onset occurred within 48 hours of vaccination is unsupported by the medical records or medical opinion. Resp't's Br. at 20. The Secretary notes that Ms. Schick-Cowell's shoulder pain following vaccination is first documented at her appointment with Dr. Buck on September 28, 2016, 12 days after vaccination. Resp't's Br. at 21; exhibit 2 at 75.

Ms. Schick-Cowell argues that her affidavit and affidavits from witnesses provide support for her assertion that onset occurred within 48 hours. Pet'r's Br. at 27. Ms. Schick-Cowell testified in her affidavit that "this vaccination caused [her] to suffer excruciating pain in my left shoulder at the location of the vaccination (upper shoulder cap) and throughout [her] shoulder, arm[,] and neck." Exhibit 27 at ¶ 7. Ms. Schick-Cowell's coworker, Melissa Cogar, testified that Ms. Schick-Cowell complained of arm pain "after she received her vaccination." Exhibit 24 at ¶ 3. Ms. Schick-Cowell's husband, Andre Cowell, testified that Ms. Schick-Cowell was no longer able to participate in family activities, including basketball, volleyball, and swimming "after her vaccination." Exhibit 26 at ¶ 2, 3. Ms. Schick-Cowell's and witnesses' statements regarding onset are entitled to consideration. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1381-84 (Fed. Cir. 2021). However, they are not specific to date of onset and therefore not dispositive.

Ms. Schick-Cowell argues that Williams v. Secretary of Health & Human Services, No. 17-1046V, 2020 WL 3579763 (Fed. Cl. Spec. Mstr. Apr. 1, 2020), provides support for her contention that the onset of her symptoms began within 48 hours of her vaccination. Pet'r's Br. at 27. In Williams, the special master found that the petitioner's onset of shoulder pain started within 48 hours of vaccination because the medical records consistently referred to onset "after" vaccination, "following" vaccination, "since" vaccination, and "very soon after" vaccination. 2020 WL 3579763 at *5. Here, Ms. Schick-Cowell notes that she consistently used similar language when discussing the onset of her pain. Pet'r's Br. at 26-27.

Conversely, the Secretary argues that Williams is distinguishable from Ms. Schick-Cowell's case because in Williams, the petitioner's references to onset were confirmed by his primary care provider, who testified that "he did recall petitioner expressing that his shoulder pain began 'immediately' or 'right after' his vaccination." Resp't's Br. at 20; Williams, 2020 WL 3579763 at *5. The Secretary also asserts that Ms. Schick-Cowell's statements regarding onset are less definite than those in Williams. See Resp't's Br. at 21. He notes that when Ms.

Schick-Cowell first reported “[n]eck pain that shoots up from the shoulder ([left] from flu shot)” to Dr. Buck on September 28, 2016, she did not say when the neck pain began. *Id.*; exhibit 2 at 75. Additionally, when she next reported pain following her flu shot on October 7, 2016, she did not state when the pain began. Resp’t’s Br. at 21; exhibit 3 at 12-14; 16-18.

The Secretary also notes that some of the medical records contradict Ms. Schick-Cowell’s assertion that pain began within 48 hours of vaccination. The medical records from Ms. Schick-Cowell’s initial physical therapy evaluation on October 26, 2016 state that her chronic left shoulder pain began on September 21, 2016, 5 days after vaccination. Exhibit 5 at 2. The medical records from ProMedica Flower Hospital state that Ms. Schick-Cowell’s left shoulder pain began on November 10, 2016. Exhibit 29 at 8.

Although the timing of onset is uncertain, resolution of this issue is unnecessary because as discussed above, Ms. Schick-Cowell had an 11-month history of shoulder pain prior to vaccination and the pain was not confined to her left shoulder.

Finally, the question of alternative causes remains unresolved. Ms. Schick-Cowell received numerous diagnoses throughout her treatment course, including left upper arm pain, chronic left shoulder pain, brachial neuritis, reactive bursitis impingement, acute pain of the left shoulder, chronic left shoulder bursitis, and left cervical radiculopathy. Exhibit 3 at 16-18; exhibit 6 at 4; exhibit 7 at 4-7; exhibit 8 at 1-4; exhibit 18 at 69-82. Ms. Schick-Cowell argues that left upper arm pain, acute and chronic left shoulder pain, impingement, and bursitis are all musculoskeletal injuries common in SIRVA cases. Pet’r’s Br. at 18. However, Ms. Schick-Cowell acknowledges that brachial neuritis and cervical radiculopathy are both neurological injuries. *Id.* Dr. Nahm and Dr. Bromberg agreed that Ms. Schick-Cowell likely did not have neurological injury such as bursitis, cervical radiculopathy, brachial plexitis, or Parsonage Turner syndrome due to her normal MRI findings. Exhibit 47 at 28-34; exhibit D at 13-14.

Dr. Brophy asserted that Ms. Schick-Cowell’s long history of neck and shoulder pain indicates that the most likely cause of her symptoms is thoracic outlet syndrome (TOS). Exhibit A at 6. He noted that on November 4, 2017, Ms. Schick-Cowell’s physical therapist wrote, “Patient showing signs for TOS.” *Id.* at 7; exhibit 5 at 14. In contrast, both Dr. Nahm and Dr. Bromberg agreed that Ms. Schick-Cowell did not have TOS. Exhibit 47 at 28-32; exhibit D at 13.

Furthermore, Dr. Brophy opined that Ms. Schick-Cowell's heavy lifting reported in early October is more likely the cause of her shoulder injury than the flu vaccine. Exhibit A at 7; exhibit C at 1. Conversely, while Dr. Natanzi conceded that heavy lifting can cause shoulder pain in theory, he stated that there is no clinical documentation to support this alternative cause. Exhibit 37 at 1.

Dr. Brophy and Dr. Bromberg also suggested that Ms. Schick-Cowell's long history of chronic neck, shoulder, and back pain indicate an alternative cause for her shoulder pain. Dr. Brophy explained that patients with a pre-existing shoulder problem often first notice the problem around the time of vaccination. Exhibit A at 10. Dr. Bromberg opined that "[g]iven the long history of musculoskeletal pain with no previous diagnosis(es)[,] there is a high likelihood for recall bias to the vaccination as a natural wish to find a cause for some aspect of [Ms. Schick-Cowell's] chronic pain." Exhibit D at 14.

It appears that the Secretary has identified alternative explanations for Ms. Schick-Cowell's shoulder pain that are not frivolous. Determination of whether there is preponderant evidence of an alternative cause for Ms. Schick-Cowell's shoulder pain is not necessary because Ms. Schick-Cowell has not shown that she had no history of shoulder pain before vaccination or that the pain was limited to her left shoulder. If Ms. Schick-Cowell had met her burden regarding these elements, then an assessment of the role, if any, of non-vaccine potential causes would also be required.

For the above reasons, Ms. Schick-Cowell has not satisfied the elements for an on-Table SIRVA claim.

B. Off-Table Shoulder Injury

When pursuing an off-Table injury, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

1. Althen Prong 1: A Causal Theory Connecting the Vaccine to Ms. Schick-Cowell's Shoulder Injury

The first Althen prong requires the petitioner to provide a “sound and reliable” medical theory demonstrating that the vaccine can cause the alleged injury. Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). The petitioner must also offer “a reputable or scientific explanation that pertains specifically to [their] case.” Moberly, 592 F.3d at 1322.

With respect to prong 1, Ms. Schick-Cowell first argues that “SIRVA is listed on the Vaccine Injury Table. Therefore, a reputable medical theory causally connecting the vaccination and injury is clearly established and accepted by the government.” Pet’r’s Br. at 30. Conversely, the Secretary asserts that Ms. Schick-Cowell does not meet her burden under prong 1 merely because she is alleging an on-Table SIRVA claim. Resp’t’s Br. at 24. In a case where a petitioner alleges both an on-Table SIRVA and off-Table shoulder injury, the petitioner must put forth a theory of causation to meet her burden for the off-Table claim. See Grant v. Sec’y of Health & Hum. Servs., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992) (distinguishing between on-Table and off-Table claims). Therefore, the fact that Ms. Schick-Cowell is alleging an on-Table SIRVA claim does not satisfy her burden regarding her off-Table shoulder injury claim under Althen prong 1.

Through Dr. Natanzi, Ms. Schick-Cowell presented a medical theory of causation. Dr. Natanzi explained that the accidental over-penetration of the vaccination needle can cause trauma to the shoulder. Exhibit 30 at 9-11. He opined that “[i]nadvertent over-penetration of the vaccination needle, resulting in teres minor tendinous penetration and contact with the humerus [can cause] . . . immediate pain, limited range of motion, and discomfort.” Id. at 10-11. Dr. Natanzi continued, “The vaccine interacts with naturally occurring antibodies from a prior vaccination, resulting in an exaggerated robust and prolonged inflammatory response, and further resulting in inflammation of the rotator cuff, development of impingement on clinical exam, and ongoing limited range of motion.” Id. at 11.

Dr. Brophy disputed Dr. Natanzi’s over-penetration causation theory, opining that “the needle required to reach [the teres minor muscle and the adjacent humerus] would have been very long (greater than the standard 1 inch needle used for vaccinations) and the injection would have had to be given very far down the arm.” Id. at 7-8.

Dr. Natanzi responded to Dr. Brophy's critiques, arguing that the standard vaccination 2.54-centimeter-long vaccination needle is long enough to cause a shoulder injury like Ms. Schick-Cowell's. Exhibit 37 at 2. To support his assertion, he included an image of Ms. Schick-Cowell's MRI and measured the distance from the humeral head/teres minor attachment to the skin where the vaccination would be administered as 2.1 centimeters. Id. at 2, 4.

In response, Dr. Brophy pointed out that the line drawn on the image is exactly 2.1 centimeters, but the image includes "no frame of reference as to how distance on that [MRI] image scales to reality." Exhibit C at 2. Dr. Brophy continued, "[u]sing the image file and application sent by [Ms. Schick-Cowell's] counsel to me, I measure 27.6 mm from skin to the center of the bone bruise in the humeral head." Id. Similarly, Dr. Bromberg noted that "the 'distance measured' does not take into account enlargement/reduction of the printed MRI image related to physical dimensions, as there is no scale marker on the image." Exhibit D at 9. Dr. Bromberg concluded that the longer distance of 2.76 cm measured by Dr. Brophy "makes Dr. Natanzi's hypothesis of the needle traumatizing bone not tenable." Id.

Dr. Natanzi presented another supplemental opinion responding to Dr. Brophy's and Dr. Bromberg's critiques. Exhibit 46. Dr. Natanzi clarified that his line drawn on the MRI was not measured by a ruler but was exported from the MRI viewing software. Id. at 1. He further asserted that Dr. Brophy's measuring is "very unrealistic when put into a clinical context." Id. He argued that "for a needle to have traveled this path, it would mean that the injector would have advanced the vaccine needle all the way to the bone, contacted the bone, and then driven through the bone against resistance (which would be nearly impossible to do with the thickness of a vaccine needle)." Id. He concluded that Ms. Schick-Cowell's MRI indicates that "the vaccine react[ed] with the outer layer of bone" and caused the "inflammatory reaction." Id.

A special master may assume prong one is satisfied if another prong is dispositive. See Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) (holding that it was appropriate for a special master to assume the petitioner satisfied prong 1 when the petitioner failed to meet her burden under prong 2). Since the case largely turns on prong 2, the undersigned will assume that Ms. Schick-Cowell has satisfied her burden under prong 1.

2. Althen Prong 2: A Logical Sequence of Cause and Effect

The second Althen prong requires a petitioner to show a logical sequence of cause and effect usually supported by the medical records. Althen, 418 F.3d at 1278; Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, the logical sequence of cause and effect put forth by Dr. Natanzi lacks persuasiveness. As discussed above, Dr. Natanzi opined that “[i]nadvertent over-penetration of the vaccination needle result[ed] in teres minor tendinous penetration and contact with the humerus, causing Ms. Schick-Cowell to experience immediate pain, limited range of motion, and discomfort.” Exhibit 30 at 10-11. Conversely, Dr. Brophy persuasively explained that the needle used to administer Ms. Schick-Cowell’s vaccination was unlikely to reach her teres minor muscle and the adjacent humerus. Exhibit A at 7-8. Additionally, Dr. Brophy noted that that an “injection that deep would have likely resulted in notable bleeding for some time after the procedure” and caused Ms. Schick-Cowell to “pass[] out from the intensity of pain.” Id. at 8; exhibit C at 2. The Secretary notes that Dr. Natanzi’s over-penetration theory is inconsistent with the medical records because Ms. Schick-Cowell did not seek treatment for her shoulder pain until September 28, 2016, 12 days after vaccination. Resp’t’s Br. at 21; see also exhibit A at 8.

Furthermore, Dr. Brophy asserted that on November 21, 2016, about two months after Ms. Schick-Cowell’s vaccination, Ms. Schick-Cowell showed “no clinical evidence of injury to the teres minor[,] such as pain or weakness with external rotation strength testing, as documented at physical therapy.” Exhibit A at 7. Dr. Brophy explained that the “edema within the teres minor muscle” or “fluid in the subacromial subdeltoid space” shown on Ms. Schick-Cowell’s MRI was more likely caused by her heavy lifting in October 2016. Id. Dr. Brophy and Dr. Bromberg persuasively identified gaps in Dr. Natanzi’s theory that put the logical sequence of cause and effect into question.

With respect to the second prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano, 440 F.3d at 1326. Here, statements from treating doctors are not persuasive. On December 2, 2016, Dr. Frogameni wrote that Ms. Schick-Cowell’s symptoms “may be related to inflammation caused by the flu shot that has given her some fluid around the shoulder.” Exhibit 6 at 3. This is the only statement from a treating doctor

associating Ms. Schick-Cowell's shoulder pain with the flu shot.³ Although Dr. Frogameni indicated that the flu shot was a possible cause of Ms. Schick-Cowell's shoulder pain, statements of a treating physician do not bind a special master to adopt his conclusions. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 746 n.67 (2009).

Ms. Schick-Cowell also points to her own statements attributing her shoulder pain to the flu shot during her medical visits to support a logical sequence of cause and effect. She notes that at her September 28, 2016 visit with Dr. Buck, she attributed her left shoulder pain to the flu shot. Exhibit 2 at 75; Pet'r's Br. at 33. At her next post-vaccination medical visit on October 7, 2016, she reported that her arm "hurts from her flu shot." Exhibit 3 at 12. She also reported shoulder pain "following her flu shot" at her physical therapy evaluation on October 26, 2016. Exhibit 5 at 2. At her visits to Dr. Frogameni on November 25, 2016 and Dr. Foetisch on January 5, 2017, she attributed the left shoulder pain to her flu shot. Exhibit 6 at 4; exhibit 8 at 1. Ms. Schick-Cowell argues, "This pattern of reporting the same history at just about every medical appointment demonstrates that [she] clearly recognized both the onset and source of her pain." Pet'r's Br. at 33. Ms. Schick-Cowell's statements in the medical records regarding onset are entitled to consideration. See Kirby, 997 F.3d at 1381 (holding that it was appropriate for a special master to consider petitioner's statements about her arm pain contained in the medical records to support a finding that her injury lasted for more than 6 months). However, Ms. Schick-Cowell's statements regarding causation do not overcome the lack of persuasive medical opinion or support of treating physicians. See 42 U.S.C. § 300aa-13(a) (indicating that a special master may not award compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion"). Therefore, Ms. Schick-Cowell has not presented a logical sequence of cause and effect connecting the flu vaccine to her shoulder injury.

³ At a January 5, 2017 medical visit, Dr. Foetisch diagnosed Ms. Schick-Cowell with brachial neuritis and noted that literature states that brachial neuritis can be caused by the flu vaccine. Exhibit 8 at 3-4. However, Dr. Foetisch did specifically state that Ms. Schick-Cowell's injury was related to her flu shot. Further, Ms. Schick-Cowell, Dr. Nahm, and Dr. Bromberg concluded that Ms. Schick-Cowell does not suffer from a neurological injury like brachial neuritis. Pet'r's Br. at 18; exhibit 47 at 28-34; exhibit D at 13-14.

3. Althen Prong 3: A Showing of a Proximate Temporal Relationship Between Vaccination and Ms. Schick-Cowell's Shoulder Injury

The third Althen prong requires the petitioner to show a “proximate temporal relationship” between the vaccination and the alleged injury. Althen, 418 F.3d at 1281. The timing prong of Althen actually contains two parts. A petitioner must show the “timeframe for which it is medically acceptable to infer causation” and the onset of the disease occurred in this period. Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff’d without op., 503 F. App’x 952 (Fed. Cir. 2013).

First, Dr. Natanzi did not appear to discuss a medically appropriate interval in his expert report. See exhibit 30 at 9. From Ms. Schick-Cowell’s brief, it appears she is putting forward 48 hours as a medically appropriate timeframe. See Pet’r’s Br. at 37. Ms. Schick-Cowell notes that Dr. Natanzi referenced a case report by Marko Bodor and Enoch Montalvo, which discusses two cases of shoulder pain, weakness, and reduced range of motion “within 2 days” after vaccination. Id.; exhibit 31 at 1, 2.

Next, Dr. Natanzi opined that the statements contained in the medical records and affidavits linking the onset of Ms. Schick-Cowell’s shoulder injury to the date of vaccination “clearly corroborate a temporal relationship between the vaccination and the onset of symptoms.” Exhibit 30 at 9. Dr. Bromberg disputed the temporal relationship, stating, “Ms. Schick-Cowell describes an increase in left shoulder pain after the flu vaccination, but there is no record of immediate pain after the injection, or at visits for the next many weeks, and shoulder pain did not become the focus of clinic visits until the visit of 10 November 2016.” Exhibit D at 8.

Assuming 48 hours is a medically appropriate timeframe for onset, whether Ms. Schick-Cowell’s onset occurred within 48 hours of vaccination remains unresolved. See section IV.A. Further, even if Ms. Schick-Cowell satisfied prong 3, her failure to meet prong two prevents a finding of entitlement.

V. A Hearing Is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c))

& (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec’y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Ms. Schick-Cowell has enjoyed a fair and full opportunity to present her case. After Dr. Natanzi presented his opinion initially, Dr. Brophy and Dr. Bromberg critiqued it, persuasively pointing out gaps and flaws in Dr. Natanzi’s opinion. Ms. Schick-Cowell then presented supplemental opinions from Dr. Natanzi and opinions from Dr. Zand and Dr. Nahm. Ms. Schick-Cowell’s efforts to repair any deficiencies during the briefing process were not persuasive.

The main issue with Ms. Schick-Cowell’s case is that she had 11 months of treatment for shoulder pain before receiving the flu vaccine. Testimony will not change that history. Ms. Schick-Cowell’s long history of chronic shoulder pain and the fact that her pain was not limited to her left shoulder prevent her from establishing an on-Table SIRVA claim. Additionally, Ms. Schick-Cowell’s was unable to establish a logical sequence of cause and effect because her medical records are inconsistent with Dr. Natanzi’s theory of causation. Therefore, a hearing would not resolve the problems in Ms. Schick-Cowell’s case.

VI. Conclusion

Ms. Schick-Cowell has not met her burden of demonstrating that she suffered an on-Table SIRVA following her flu vaccination. Additionally, Ms. Schick-Cowell has not established, more likely than not, that the flu vaccination was the cause-in-fact of her shoulder injury. Accordingly, the Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court’s website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master