

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-792V

Filed: February 21, 2019

UNPUBLISHED

MANYA CETLIN-SALTER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Processing Unit (“SPU”);
Influenza (“Flu”) Vaccine; Shoulder
Injury; Entitlement; Ruling on the
Record; Decision Without a Hearing;
Six-Month Severity Requirement;
Insufficient Proof; Alternative Cause.

*Carol L. Gallagher, Carol L. Gallagher, Esquire, LLC, Linwood, NJ, for petitioner.
Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for respondent.*

DECISION¹

Dorsey, Chief Special Master:

On July 1, 2016, Manya Cetlin-Salter (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10, *et seq.*² (the “Vaccine Act” or “Program”). The case was initially assigned to the Special Processing Unit (“SPU”) of the Office of Special Masters.

¹ Because this Decision 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 Decision 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 National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petitioner alleges that she suffered a left shoulder injury following an influenza (“flu”) vaccination on December 4, 2013. Petition at 1. For the reasons discussed herein, the undersigned finds that petitioner is not entitled to compensation due to insufficient proof.

I. Procedural History

Petitioner filed a petition for vaccine injury compensation on July 1, 2016, alleging that she suffered a left shoulder injury due to an influenza vaccination received on December 4, 2013. The initial status conference was held on August 15, 2016. During the call, respondent requested that petitioner file additional evidence. Scheduling (“Sched.”) Order dated Aug. 17, 2016 (ECF No. 10) at 1. Specifically, respondent requested that petitioner submit a more complete vaccination record, certain physical therapy records, and any records related to prior shoulder and wrist problems. *Id.* Petitioner subsequently filed these records as Exhibits 9-12. (ECF Nos. 11-12, 14).

On December 19, 2016, respondent filed a Rule 4(c) Report setting forth his position that petitioner’s claim should be dismissed for insufficient proof. Rule 4(c) Report dated Dec. 19, 2016 (ECF No. 17). Respondent argued that petitioner had failed to establish “that her current injury [was] vaccine-related, or that her initial shoulder pain following her flu vaccination, even if vaccine-related, persisted for six months.” *Id.* at 7. On December 29, 2016, in response to the Rule 4(c) Report, petitioner filed four affidavits as Exhibits 13-16. (ECF No. 18). The affidavits were from petitioner; petitioner’s mother; a nutritional and fitness coach; and the owner of a farm where petitioner occasionally helped out. *Id.*

A status conference was held on January 5, 2017, to discuss the undersigned’s preliminary views based on the evidence filed to date and possible next steps. Sched. Order dated Jan. 11, 2017 (ECF No. 19). The parties were informed that, to the undersigned, it appeared that petitioner’s left shoulder bursitis, diagnosed on December 5, 2013, may have been vaccine-related (citing Ex. 4 at 10), but that her symptoms had resolved by April 1, 2014, when a routine physical examination with Dr. Ellen Bernard revealed no relevant disease, injury, or abnormality (citing Ex. 7 at 17). *Id.* at 1. At the conclusion of the conference, the parties were encouraged to explore the possibility of a litigative risk settlement. *Id.* at 2.

Petitioner filed additional evidence on February 2 and 16, 2017, as Exhibits 17 and 18. (ECF Nos. 20, 22). Thereafter, she confirmed transmission of her settlement demand to respondent. *See* Status Report dated Feb. 16, 2017 (ECF No. 26).

On March 16, 2017, respondent filed a motion to dismiss, arguing that petitioner failed to meet the six-month severity requirement set forth in the Act. Motion to Dismiss (ECF No. 30) at 1 (citing § 11(c)(1)(D)(i)). Respondent contends that there is no evidence petitioner suffered the claimed injury “for more than *one day*, let alone six months.” *Id.* at 5 (emphasis in original). On March 24, 2017, petitioner filed a response to respondent’s motion to dismiss. Response dated Mar. 24, 2017 (ECF No. 32). On March 30, 2017, respondent filed a reply to petitioner’s response, reiterating his position that petitioner’s claim should be dismissed for insufficient proof. Reply dated Mar. 30, 2017 (ECF No. 33).

On September 28, 2017, the undersigned issued an order affording petitioner the opportunity to file a medical expert report in support of her theory that an incorrectly administered vaccination caused her injury. Sched. Order dated Sept. 28, 2017 (ECF No. 34). On December 28, 2017, petitioner filed as Exhibit 21 an expert report authored by one of her treating physicians, Dr. Kevin Heaton. (ECF No. 37).

On January 16, 2018, petitioner filed a motion for judgment on the existing record. Motion for Judgment on the Record (ECF No. 39). On January 30, 2018, respondent filed a response opposing petitioner's motion (ECF No. 40), and petitioner replied on February 6, 2018 (ECF No. 41). On May 23, 2018, the undersigned transferred the case from the SPU to her own docket. Notice of Reassignment (ECF No. 42).

After discussing the status of the case with the parties during a conference on May 31, 2018, the undersigned ordered respondent to file an expert report. Order dated June 5, 2018 (ECF No. 43). Petitioner indicated at that time that she did not wish to file an additional expert report. *Id.* Respondent filed an expert report from Dr. Jeffrey Gagliano on October 15, 2018, as Exhibit A. (ECF No. 50). The undersigned offered petitioner a final opportunity to submit a responsive expert report or any other evidence, but petitioner subsequently informed the Court that she did not wish to file anything additional. *See* Order dated Oct. 22, 2018 (ECF No. 51); Status Report dated Oct. 30, 2018 (ECF No. 52).

The motion to dismiss and the motion for judgment on the record essentially concern the same issue: whether petitioner has shown that she is entitled to compensation for a left shoulder injury on the basis that it was caused by her December 4, 2013 flu vaccination. Because petitioner has submitted additional evidence since the briefing of the motion to dismiss, the undersigned determines that the proper course is to deny the motion to dismiss and rule on petitioner's motion for judgment on the record. Neither party has requested a hearing.

The matter is now ripe for adjudication.

II. Evidence

A. Relevant Medical History

On December 4, 2013, petitioner received a flu vaccination at a pharmacy in Exeter, New Hampshire. Ex. 1 at 2; Ex. 3 at 11. The following day, on December 5, 2013, petitioner presented to orthopedist Dr. Heaton for "extreme" left shoulder pain, which she reported began within an hour of her vaccination. Ex. 4 at 10. Dr. Heaton performed an ultrasound of the shoulder and discovered "a small undersurface partial thickness tear of the supraspinatus" and "fluid and thickening of her bursa consistent with subacromial and subdeltoid bursitis." *Id.* Petitioner relayed a "history of some minor shoulder pain from her AC joint," as well as "bursitis

in her shoulder in the past,”³ but the record notes that the present pain “seemed to directly correlate to her flu shot.” *Id.*

Dr. Heaton diagnosed petitioner with left shoulder bursitis. Ex. 4 at 10. He stated that it was doubtful that the “small undersurface partial tear” of the rotator cuff was caused by the flu shot, but he indicated that the “flu shot likely entered the subacromial and subdeltoid bursa causing her pain.” *Id.* Dr. Heaton advised petitioner to treat with icing, home exercises, and an over-the-counter analgesic. *Id.* at 11. Dr. Heaton advised petitioner to “follow up in 2 to 3 weeks if not improved or sooner if pain worsens.” *Id.* There is no mention of surgery in the records related to the December 5, 2013 visit. There is no indication in the records that petitioner followed up with Dr. Heaton in two to three weeks, as he advised her to do if her condition worsened.

On February 20, 2014, petitioner saw Certified Nurse Midwife (CNM) Jodi Demuth for an annual gynecological examination. Ex. 8 at 11-12. The record reflects no complaints related to her shoulder. *Id.*

Approximately four months after vaccination, on April 1, 2014, petitioner saw her primary care physician, Dr. Ellen Bernard, for a preventive exam. Ex. 7 at 17-21. Petitioner reported a history of “working out an hour a day, doing body building. Rare cardio.” *Id.* at 17. The records for this visit contain no reference to any injury or abnormality related to her left shoulder. *Id.* at 17-21. The visit records indicate that petitioner exercised daily, had a vigorous activity level, and had “no changes to sleep patterns.” *Id.* at 18. Her blood pressure was taken using her left arm. *Id.* at 19. Later that month, on April 30, 2014, petitioner returned to Dr. Bernard for a cough. *Id.* at 14-16. The notes for this visit also contain no mention of any issue with petitioner’s left shoulder. *Id.*

There are no records of petitioner seeing a doctor again until nearly a year later, on February 19, 2015, when she underwent her next annual gynecological exam with CNM Demuth. Ex. 8 at 8-10. Again, there was no mention of any left shoulder issue. *Id.* In a letter dated January 31, 2017, CNM Demuth stated that she did “not recall, nor did [she] note any discussion regarding shoulder problems.” Ex. 17 at 1. However, CNM Demuth explained that she does not “routinely mention non gynecological issues in . . . office notes even if they were discussed.” *Id.*

On April 30, 2015, petitioner saw Maureen McKay, a nurse practitioner at the office of Dr. Sam T. Donta, for a follow-up visit related to chronic Lyme disease. Ex. 6 at 9-10. The visit

³ Petitioner filed an “amended” version of this record as Exhibit 9. (ECF No. 11). Dr. Heaton added the following note to the record: “ADDENDUM 8/19/2016 – Discussed with patient over the phone regarding this injury. The note above states she had a previous history of left shoulder pain over the AC joint and bursitis. Patient indicates that there was no history of previous left shoulder pain or injury. Kevin Heaton 8/19/2016.” Ex. 9 at 2; Ex. 18 at 2 (duplicate). For the purposes of this decision, it is not necessary to determine whether petitioner had a history of left shoulder pain or bursitis, and the undersigned makes no such determination.

records do not mention any left shoulder problem and indicate that she “continues to go to the gym for bodybuilding, which she has found helpful.” *Id.* at 10.

On May 19, 2015, petitioner saw Dr. Heaton for left shoulder pain after hearing “a tearing sensation in her left shoulder” recently while doing an overhead weight lifting exercise known as “skull crushers.”⁴ Ex. 4 at 7. At the time of the visit, petitioner reported engaging in “a lot of fairly heavy weightlifting activities of the upper extremities.” *Id.* Dr. Heaton noted that he had seen petitioner “back in 2013 for left shoulder pain that occurred after a flu shot, and there was concern whether the flu shot might have irritated her rotator cuff or bursa. Eventually she got better with time and therapy.” *Id.* When considering petitioner’s prior shoulder history, Dr. Heaton concluded that she had suffered “a repeat injury with worse pain.” *Id.* He advised petitioner to ice, refrain from heavy or overhead lifting, and take a nonsteroidal anti-inflammatory drug. *Id.* at 8. Dr. Heaton also ordered an MRI of her left shoulder. *Id.* at 7-8. On May 22, 2015, petitioner had an MRI of her left shoulder. *Id.* at 22. The MRI findings included mild tendinosis, a flap tear of the anterior labrum, and capsulosisynovitis. *Id.*

On May 27, 2015, petitioner again saw Dr. Heaton, complaining of ongoing left shoulder pain. Ex. 4 at 5. At this visit, petitioner reported being “very active” and engaged in “significant amounts of exercise and lifting,” which helped her manage her Lyme disease. *Id.* Dr. Heaton reviewed petitioner’s left shoulder MRI and determined that she had tendinosis, flap tear of the anterior labrum, and capsule synovitis with debris within the capsule. *Id.* He indicated that he and petitioner “talked about how I [Dr. Heaton] think she [petitioner] continues to overdo it from lifting standpoint. I want her to back off completely from any upper extremity lifting.” *Id.* He recommended a course of physical therapy. *Id.*

On June 3, 2015, petitioner was evaluated for and began a course of physical therapy at Access Sports Medicine.⁵ Ex. 4 at 72. The therapist recorded that petitioner “had [a] prior injury which she attribute[d] to [a] flu shot being injected directly into [the] bursa in Dec 2014 [sic], reported to be confirmed by MRI.” *Id.* Petitioner “was able to self rehab through continued strengthening until she actually felt pop/tear in triceps while doing a ‘skull crusher’ . . . in [an] overextended position in early May 2015.” *Id.* The records describe petitioner as “an avid coached body builder” and indicated that she worked out to manage the symptoms of her Lyme disease. *Id.* Petitioner reported that her injury interfered with her activities of daily living and stated that she hoped therapy would return her to her prior level of functioning. *Id.*

⁴ A “skull crusher” is an overhead exercise that targets the triceps. *How to Do Skull Crushers with Perfect Form*, Men’s Health (Dec. 5, 2018), <https://www.menshealth.com/fitness/a25410119/skull-crushers/>. Dr. Heaton notes in his records that the exercise involves “heavy overhead lifting.” Ex. 4 at 7.

⁵ Petitioner attended physical therapy from June 3, 2015, through February 24, 2016, and attended physical therapy again one time on April 11, 2016. *See* Ex. 4 at 57-76; Ex. 5 at 6-58; Ex. 11 at 4-32.

On June 22, 2015, petitioner visited Dr. Heaton complaining of a “burning sensation” and decreased range of motion in her left shoulder. Ex. 4 at 3. Dr. Heaton noted that he sent petitioner to physical therapy and asked her “to back off lifting”; his records indicate that he thought she had done so to some extent but thought she might still be lifting “too much.” *Id.* Dr. Heaton administered a subacromial corticosteroid injection to petitioner’s left shoulder and recommended that she reduce lifting and continue physical therapy. *Id.*

On August 3, 2015, petitioner followed up with Dr. Heaton and reported that her shoulder was not getting better and, if anything, her left shoulder pain and range of motion had worsened. Ex. 4 at 1. Dr. Heaton thought this was likely due to the “worsening of some adhesive capsulitis.” *Id.* He administered a glenohumeral corticosteroid injection to the shoulder. *Id.* at 1-2. Dr. Heaton advised petitioner to refrain from exercising for one week, then restart therapy. *Id.* at 1.

Nineteen months later, on March 20, 2017, petitioner returned to Dr. Heaton complaining of ongoing shoulder pain since her vaccination in December 2013. Ex. 19 at 1. She stated that she “never fully recovered” and she wished “to discuss . . . the causality of the flu shot to her overall left shoulder pain.” *Id.* Dr. Heaton noted that he had not seen petitioner since her last cortisone injection. *Id.* He recounted that his assessment when she initially presented to him after her flu shot in December 2013 was “left shoulder bursitis.” *Id.* He noted that at that time there was also a “small articular surface supraspinatus tear,” which his notes indicated “was likely not caused by the flu shot, likely preexisting, and of unknown significance.” *Id.* In 2015, she had an MRI “due to persistent pain that showed mild tendinosis and articular surface scuffing of the supraspinatus tendon, mild peritendinobursitis, and a flap tear of the anterior labrum with capsular synovitis with an adhesive component.” *Id.* Thereafter, she received two cortisone injections, after which she “did not follow up with us again until 2017.” *Id.* An updated MRI study from 2017 “showed no evidence of tendinopathy or rotator cuff tear, no labral pathology, and no internal derangement.” *Id.* Dr. Heaton concluded with his assessment:

It is my belief and was dictated as such that the flu shot likely caused subacromial and subdeltoid bursitis and it is highly unlikely that would have caused a rotator cuff tear, nor would the flu shot have directly caused a labral tear, which was identified on a MRI. She indicates persistent pain from the bursitis since 2013, so it is certainly a possibility that the bursitis in 2013 predisposed her to further injury and ongoing pain.

Id. at 1-2.

B. Affidavits

In her affidavit, petitioner asserts that when she received her vaccination on December 4, 2013, “it was very uncomfortable.” Ex. 2 at ¶ 5. She states that by approximately 20 minutes later, she could not raise her arm to the front or side and was in excruciating pain. *Id.* at ¶¶ 6-8. Petitioner indicates that she reported her adverse reaction to the pharmacy and went to see Dr. Heaton the following morning. *Id.* at ¶¶ 11-16. She states that Dr. Heaton performed an

ultrasound and said that the pharmacist had injected the flu vaccine into her bursa and tore her rotator cuff. *Id.* at ¶ 17. She asserts in her affidavit that Dr. Heaton “did not offer any options for the tear other than it would feel better in time.” *Id.* at ¶ 18. She states that it took “a full year for my shoulder to get to the point where I could lift something and not experience excruciating pain.” *Id.* at ¶ 20.

Petitioner states, “[a]fter an MRI, it was found that I had a labral tear and after that my shoulder began seizing up.” Ex. 2 at ¶ 23. She asserts that Dr. Heaton told her that she had adhesive capsulitis and needed physical therapy. *Id.* at ¶ 24. She states that she “was given two cortisone shots, but neither did anything for [her] and provided no respite from the pain.” *Id.* at ¶ 26. While petitioner does not indicate when the MRI, physical therapy suggestion, and cortisone injections occurred, they appear to have been in 2015 based on other records.

Petitioner asserts that since her shoulder injury occurred, she has “lost [her] ability to sleep at night” and is “up at least 5 times a night” because it is impossible to find a comfortable position. *Id.* at ¶ 42. Petitioner asserts that she is no longer able to perform activities of daily living with her left hand and can no longer surf or swim. *Id.* at ¶¶ 33-38.

In her supplemental affidavit, petitioner asserts that although the records from her gynecological examination do not mention her shoulder injury, she did mention the injury to her midwife. Ex. 13 at ¶ 14. She asserts that “regardless of WHAT you say to a physician, you have no control over what they type or dictate into the chart and no way to review it to be sure it is correct.” *Id.* at ¶ 15. She states that she “also informed [her] PCP of this injury when I went to see her for a different health issue following the injury and do not know why it was not recorded . . . maybe because I wasn’t there for that reason?” *Id.* at ¶ 16. She asserts that she never told Dr. Bernard, her PCP, that her sleep was restful following the vaccine injury. *Id.* at ¶ 17.

Petitioner states in her supplemental affidavit that “Dr. Heaton’s notes regarding our conversation do NOT match up to what he said to me.” Ex. 13 at ¶ 18. She asserts that Dr. Heaton told her that the pressure of an injection being forced into the bursa would cause a tear, and “that the ONLY way to repair the shoulder was with surgery.” *Id.* She explains that “[a]t the time, surgery was NOT an option.” *Id.* at ¶ 19. She states, “Dr. Heaton told me that the rotator cuff will not repair itself, and that the only eventual course would be surgery. I did not go back to him for the rotator cuff after that initial appointment because surgery was not an option for me.” *Id.* at ¶ 22. She states that she “did not have the money to spend on a co-pay to go back to [Dr. Heaton], so that he could tell me the same thing, or have him ask me why I was there for something he had already addressed. So, of course I would not go back to see him about it, he told me my option and surgery was not a financial possibility at the time.” *Id.* at ¶ 23.

Petitioner’s mother, Jeanne Cetlin, also submitted an affidavit on petitioner’s behalf. Petitioner’s mother states that petitioner called her after the vaccination “in tears to tell me that . . . she could not lift her arm to the front or the side.” Ex. 14 at ¶ 4. Petitioner’s mother indicates that after petitioner saw Dr. Heaton the day following the vaccination, “she came to my home to tell me the doctor said that the pharmacist injected the vaccine into her bursa and tore her rotator cuff. He did an ultrasound and actually saw the vaccine fluid in the bursa.” *Id.* at ¶ 9.

Petitioner's mother adds, "[s]ince the vaccine injury, Manya has experienced awful pain and had to give up so many things she loved." *Id.* at ¶ 10.

Petitioner submitted an affidavit from Peter Corriveau. Ex. 15. Mr. Corriveau states that petitioner "has been helping me on my farm since 2011." *Id.* at ¶ 1. He adds, "[a]fter Manya received her flu vaccine on December 4, 2013, she was no longer able to perform" the tasks she had previously done on his farm. *Id.* at ¶ 3. He states that petitioner called him the morning after the vaccination "to report what had happened to her the night before that, and she told me she was going to the walk in clinic at the orthopedic physician first thing that morning." *Id.* at ¶ 4. He states that "Manya had extreme pain and could not elevate her arm to the front or the side after her vaccine was administered" and that she can no longer ride her horse. *Id.* at ¶¶ 4-5.

Petitioner submitted an affidavit from Royce Claflin. Ex. 16. In his affidavit, Mr. Claflin indicates that petitioner has been seeing him for nutritional coaching and general health and fitness since late summer 2013. *Id.* at ¶ 1. He states that he had a consult scheduled with petitioner the morning of December 7, 2013, and that she complained of "significant pain in the left shoulder in which she had recently had a flu shot." *Id.* at ¶¶ 2-3. He added that he has "since had 25 to 30 one on ones with Manya, and she has complained about the shoulder in every session." *Id.* at ¶ 5. He does not indicate when these sessions occurred.

C. Expert Reports

1. Petitioner – Dr. Kevin Heaton

Dr. Kevin Heaton received his D.O. (doctor of osteopathic medicine) from the University of New England College of Osteopathic Medicine, where he graduated as a member of Psi Sigma Alpha, the Osteopathic Honor Society. Ex. 20 at 1. His current certifications include Advanced Life Support in Obstetrics, Neonatal Resuscitation Program, Advanced Cardiac Life Support, and Cardiopulmonary Resuscitation/Automated External Defibrillator. *Id.* Dr. Heaton completed his residency at the Boston Medical Center's Family Medicine Residency Program, and he has been employed at Access Sports Medicine & Orthopaedics since 2011. *Id.*

Regarding petitioner's 2013 injury, Dr. Heaton stated that the December 4, 2013 flu shot caused subacromial and subdeltoid bursitis. Ex. 21 at 5. He also noted that because petitioner "experienced acute onset of pain within the hour of her flu vaccination," he believed that "the vaccination was the actual reason for the injury." *Id.* He asserted, however, that the flu shot would likely not have caused a rotator cuff tear, and almost certainly would not have caused a labral tear. *Id.*

Regarding petitioner's 2015 injury, Dr. Heaton opined that there was "a possibility that a previous history of bursitis could lead to some functional deficits in rotator cuff function which could potentially lead to further injury in the future," but stated that "whether or not there is an absolute and direct relationship between the bursitis in 2013 and the subsequent injury for which [petitioner] was seen in 2015 after an acute injury while weight lifting is unclear." Ex. 20 at 1. He further noted that it was "unclear if her current ongoing pain is directly related to the flu

vaccination in 2013.” *Id.* He concluded that he was “unable to determine if [petitioner’s] current ongoing symptoms [were] truly from the initial flu vaccination and bursitis or if they are *more likely* a result of her repeat injury in May of 2015 while weight lifting.” *Id.* at 6 (emphasis added).

2. Respondent – Dr. Jeffrey Gagliano

Dr. Jeffrey Gagliano received his M.A. in applied physiology from Columbia University and his M.D. from the University of Colorado School of Medicine. Ex. B at 1. He has co-authored ten papers and given a number of research presentations on topics such as fracture repair and shoulder arthroplasty. *Id.* at 5-6. He is also a member of a variety of professional organizations, including the American Academy of Orthopaedic Surgeons, the American Board of Orthopaedic Surgery, and American Shoulder and Elbow Surgeons. *Id.* at 2-3. Dr. Gagliano currently practices at Boulder Bone and Joint. *Id.* at 1. Additionally, he serves as surgical director of the North Suburban Surgery Center in Thornton, Colorado, and as a partner at the Foothills Surgery Center in Boulder, Colorado. *Id.*

Dr. Gagliano noted that petitioner’s early symptoms, reported within 48 hours of her 2013 vaccination, were consistent with SIRVA. Ex. A at 4. He concluded, however, that this type of injury generally “does not cause long-term or permanent shoulder dysfunction.” *Id.* at 4. He maintained that given the typical clinical course of bursitis and petitioner’s evident lack of symptoms after receiving appropriate treatment, petitioner’s vaccine-associated bursitis resolved less than four months after vaccination, long before her May 2015 weight-lifting injury. *Id.* at 4-5; *see also id.* at 5 (asserting that petitioner’s vaccine-related pain was temporary and “extremely unlikely to be causing any current symptoms”). He also observed that “a rotator cuff tear resulting from vaccine injection would be highly unusual.” *Id.* at 4.

As for petitioner’s 2015 shoulder injury, Dr. Gagliano stated that “it is impossible to link [her current] pain to her vaccination in 2013.” Ex. A at 5. He emphasized that between petitioner’s initial presentation to Dr. Heaton in December 2013 and her visit with him in May 2015, “[n]o other orthopaedic notes, nor other doctors’ notes are available, describing care for her left-sided SIRVA, over that period of greater than 17 months.” *Id.* at 4. Dr. Gagliano also noted that petitioner’s physical exam by Dr. Heaton in March 2017 recorded normal results and full range of motion, and that based on petitioner’s 2017 MRI, “no objective data exists to support a diagnosis of persistent bursitis.” *Id.* at 5.

Dr. Gagliano ultimately concluded that it was “more likely that [petitioner’s] complaints are due to other conditions or injuries.” Ex. A at 5. Specifically, he emphasized that her 2015 weight lifting injury, her chronic Lyme disease⁶, or some undiagnosed inflammatory/autoimmune disease “are most likely the key players in her persistent complaints of pain.” *Id.*

⁶ Dr. Gagliano noted that symptoms of Lyme disease often include chronic arthralgias (painful joints). Ex. A at 5.

III. Applicable Legal Standards

Under the Vaccine Act, petitioner may prevail on her claim if she “sustained, or had significantly aggravated, any illness, disability, injury, or condition” set forth in the Vaccine Injury Table (“the Table”). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that she has suffered a “Table Injury,” causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation. § 11(c)(1)(C)(ii). In such circumstances, petitioner asserts a “non-Table” or “off-Table” claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is “one of . . . simple preponderance, of ‘more probable than not’ causation.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (citing *Hellebrand v. Sec’y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993) (Newman, J., concurring)). The United States Court of Appeals for the Federal Circuit has held that to establish an off-Table injury, petitioners must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that petitioner “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* at 1353. The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

“The special master . . . may not make [] a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a)(1). In addition to proving causation, petitioner must demonstrate by a preponderance of the evidence that she meets all other statutory requirements, including, *inter alia*, that she “suffered the residual effects

or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine,” died, or suffered from a condition that required inpatient hospitalization and surgical intervention. § 11(c)(1)(D).

IV. Analysis of Petitioner’s Claim

At the time this petition was filed, shoulder injury related to vaccine administration (“SIRVA”) was not yet included in the Table. SIRVA was added to the Table while this case was pending.⁷ Thus, the petition does not assert a Table claim and causation must be shown pursuant to *Althen*. Alternatively, even analyzed as a Table claim, this petition would not be compensable because the severity requirement of the Vaccine Act is not met.

Petitioner presents two theories of recovery, neither of which is persuasive. First, if her claim is analyzed as a Table claim, she fails to provide sufficient evidence that she suffered the residual effects or complications of her injury for more than six months. Second, if her claim is not analyzed as a Table claim, in addition to her failure to satisfy the six-month requirement, petitioner fails to provide sufficient evidence to demonstrate pursuant to *Althen* that her symptoms in May 2015 and later are a “significant aggravation/exacerbation of her shoulder injury directly related to the influenza vaccine administered too high in her bursa on December 4, 2013,” as alleged in her motion. Motion for Judgment on the Record at ¶ 13.

A. Severity Requirement of the Vaccine Act

Regardless of whether or not petitioner pursues a Table claim, she cannot prevail unless she demonstrates that she meets the severity requirement of the Vaccine Act. The severity requirement is met if the vaccinee suffered the residual effects or complications of her injury for more than six months after the administration of the vaccine, died from the administration of the vaccine, or suffered an injury which resulted in inpatient hospitalization and surgical intervention. § 11(c)(1)(D).

The undersigned previously indicated on a preliminary basis that the evidence showed that petitioner’s bursitis, diagnosed on December 5, 2013, may have been vaccine-related. Sched. Order dated Jan. 11, 2017 (ECF No. 19). However, the undersigned further noted that it appeared that petitioner’s symptoms had resolved by April 1, 2014, when she underwent a routine physical examination during which there were no complaints or findings related to her left shoulder and the records noted that petitioner was engaged in vigorous exercise. *Id.* Petitioner has submitted no medical records or medical opinions that would call these preliminary statements into question, and the undersigned determines that petitioner’s initial symptoms resolved by, at the latest, April 1, 2014, less than four months following their onset.

⁷ SIRVA was added to the Vaccine Injury Table on March 21, 2017. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Delay of Effective Date, 82 Fed. Reg. 11321-01 (Feb. 22, 2017).

Petitioner asserts that her injury lasted for longer than six months; however, the medical records and expert opinion do not support this position. The medical records demonstrate that petitioner reported to orthopedist Dr. Heaton on December 5, 2013, the day following her vaccination, and that he diagnosed her with bursitis that was likely caused by the vaccination. However, the medical records also show that approximately four months following vaccination, petitioner underwent a preventive examination with her primary care physician and made no mention of any shoulder pain or abnormality. To the contrary, the notes for this visit indicate that petitioner exercised daily, had a vigorous activity level, and had no changes to sleep patterns. Her blood pressure was taken using her left arm. The record for this visit is notable for its lack of any mention of shoulder pain or limitations, or other musculoskeletal complaints. Petitioner saw Dr. Bernard again on April 30, 2014, for a cough, and again these records contain no notations of any shoulder problem. Similarly, petitioner's records from her gynecological examinations on February 20, 2014, and February 19, 2015, are silent on any shoulder issues.

The medical records reflect that petitioner returned to Dr. Heaton with left shoulder pain on May 19, 2015, over 17 months after her first visit for left shoulder pain. Dr. Heaton's notes indicate that petitioner's prior injury had improved with time and therapy and that petitioner suffered a repeat injury while weight lifting in May 2015. Similarly, petitioner's June 3, 2015 physical therapy initial evaluation indicates that petitioner was able to "self rehab" her prior injury and that petitioner described her pain as having begun in early May 2015 when she heard a pop or tear in her triceps while lifting weights. In his opinion, Dr. Heaton stated that it was unclear how long her symptoms continued after the flu vaccination. Dr. Gagliano, however, opined that based on the medical records described above, petitioner's transient shoulder bursitis had resolved less than four months after the vaccination.

Based on the medical evidence, the undersigned finds that petitioner's initial injury from her December 4, 2013 flu shot healed in less than four months and that the symptoms she experienced beginning in May 2015 were from a new injury caused by "skull crushers" and other exercise, as evidenced in Dr. Heaton's records. Thus, petitioner did not suffer the complications of her initial injury for six months and cannot satisfy the severity requirement.

The affidavits of petitioner's mother, petitioner's nutritional and fitness coach, and the owner of a farm where petitioner occasionally helped out provide only conclusory statements about petitioner's limitations, and none of them specifically pertains to the six-month period following petitioner's initial injury. Thus, none of them supports a finding that petitioner's injury continued for six months after vaccination.

Petitioner filed affidavits in support of her own petition. In her initial affidavit, petitioner asserts that it "took a full year for my shoulder to get to the point where I could lift something and not experience excruciating pain." Ex. 2 at ¶ 20. In her supplemental affidavit, petitioner asserts that she did mention her immunization injury to both her primary care physician and the midwife who performed her gynecological examination but that a patient has "no control over what they type or dictate into the chart and no way to review it to be sure it is correct. They type what they hear, remember or perceive that you said. Many physicians dictate their notes following the appointment and do not accurately record precisely what the patient reported." Ex.

13 at ¶ 15. Petitioner also asserts that she “NEVER reported to Dr. Ellen Barnard that my sleep was restful following the vaccine injury [O]ne of the WORST parts of this injury was the horrendous pain and incessant sleep interruptions due to the injury.” *Id.* at ¶ 17.

The Vaccine Act states that in making findings as to whether petitioner has demonstrated by a preponderance of evidence the matters required in Vaccine Act § 11(c), a special master or court “may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a)(1). In this case, only the claims of petitioner would support a finding that her injury continued for six months after vaccination, and she has not provided medical records or medical opinion to support her claims. Moreover, several of her claims are inconsistent with the medical evidence. For instance, she states that Dr. Heaton indicated that only surgery would heal her injury; however, his notes contain no indication that surgery was discussed or considered. In addition, petitioner asserts that it took a full year before she could lift something without excruciating pain; however, at a routine physical examination less than four months after vaccination, her medical records contain no mention of a shoulder problem.

The undersigned finds that petitioner received an influenza vaccination on December 4, 2013, and suffered left shoulder bursitis on December 5, 2013. The undersigned finds that the bursitis resolved sometime between December 5, 2013, and April 1, 2014, and was no longer present by April 1, 2014. The undersigned finds it more likely than not that the shoulder pain petitioner reported to Dr. Heaton on May 19, 2015, was, as Dr. Heaton characterized it, a “repeat injury with worse pain,” and not a continuation of the injury suffered in December 2013. The undersigned finds that petitioner’s injury, even if caused by a covered vaccine and otherwise compensable, does not meet the six-month severity requirement of the Vaccine Act. Because petitioner does not meet the six-month severity requirement, petitioner is not entitled to compensation.

B. Causation Analysis

1. Significant Aggravation

Petitioner also claims that her ongoing symptoms in May 2015 and later are “a significant aggravation/exacerbation of her shoulder injury directly related to the influenza vaccine administered too high in her bursa on December 4, 2013.” Motion for Judgment on the Record at ¶ 13.

The Vaccine Act provides compensation for a person who “sustained, or had significantly aggravated, any illness, disability, injury, or condition” either set forth in the Table within the time period set forth therein, or not in the Table but caused by a Table vaccine. § 11(c)(1)(C). Congress included claims for significant aggravation “in order not to exclude serious cases of illness because of minor events in the person’s past medical history.” *Whitcotton v. Sec’y of Health & Human Servs.*, 81 F.3d 1099, 1102 (Fed. Cir. 1996) (quoting H.R. Rep. No. 908, 99th Cong. 2d Sess. 1, *reprinted in* 1986 U.S.C.C.A.N. 6287, 6356). Critically, the Vaccine Act requires that the injury or significant aggravation “occurred within the time period after vaccine

administration set forth in the Vaccine Injury Table” or “was caused by a vaccine” set forth in the Table. § 11(c)(1)(C). It does not provide compensation for a significant aggravation of an injury if the significant aggravation itself is unconnected to the administration of the vaccine. *See Childs v. Sec’y of Health & Human Servs.*, 33 Fed. Cl. 556, 559 (1995) (“There can be no question that the reference [in § 11(c)(1)(C)] to ‘significant aggravation’ is to the action of the vaccine on a pre-existing condition, i.e., a condition not precipitated by the vaccination in question.”). Thus, petitioner could prevail on this theory only if she demonstrates that the later injury was a significant aggravation that was actually caused by her vaccination.

Significant aggravation claims are usually evaluated based on the expanded version of the *Althen* test articulated in *Loving v. Sec’y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009). Petitioner, however, does not present an actual significant aggravation claim. Rather than alleging that her vaccination significantly aggravated a pre-existing condition, petitioner alleges that some unspecified force⁸ significantly aggravated her post-vaccination condition. On the contrary, petitioner explicitly denies any pre-existing conditions, even asking that certain medical records be amended because they implied a prior history of shoulder pain. Ex. 9 at 2 (“Patient indicates that there was no history of previous left shoulder pain or injury.”); *see also* Ex. 13 at ¶ 12 (stating that prior to her vaccination, petitioner “felt great and was very fit”).

Such a claim does not readily lend itself to analysis under the *Loving* test, precisely because this is not the type of significant aggravation claim the Vaccine Act was intended to cover. The Vaccine Act defines significant aggravation as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” § 33(4). The Court of Federal Claims elaborated: “Webster’s dictionary defines ‘aggravate’ as ‘to make worse.’ This definition plainly implies the presence of an agent or force acting to make the condition worse. Here the agent or force must be a vaccination.” *Childs*, 33 Fed. Cl. at 559; *see also Deribeaux v. Sec’y of Health & Human Servs.*, No. 05-306V, 2011 WL 6935504, at *136 (Fed. Cl. Spec. Mstr. Dec. 9, 2011) (noting that the *Childs* interpretation “is compelled by legislative history”), *mot. for review denied*, 105 Fed. Cl. 583 (2012), *aff’d*, 717 F.3d 1363 (Fed. Cir. 2013); *Feierabend v. Sec’y of Health & Human Servs.*, No. 12-35V, 2012 U.S. Claims LEXIS 803, at *6 (Fed. Cl. Spec. Mstr. Apr. 23, 2012) (“A person who is not suffering from a disorder at the time of vaccination cannot allege that the vaccine aggravated it.”). Because petitioner alleges that some other “agent or force” exacerbated her condition, and not the vaccine itself, petitioner cannot prevail on a significant aggravation theory.

2. *Althen*

Under the first prong of *Althen*, petitioner must set forth a reliable medical theory that explains how a particular vaccination can cause the injury in question. *Althen*, 418 F.3d at 1279.

⁸ Petitioner is presumably referring to her 2015 weight lifting injury. *See* Motion for Judgment on the Record at ¶ 7 (“On May 19, 2015, petitioner returned to Dr. Heaton due to a tearing sensation in the same shoulder which occurred when she was at the gym.”). For further discussion of this injury, *see* Section IV.B.3, *infra*.

In this case, petitioner submitted an expert report from her treating physician, Dr. Heaton, stating that “[t]here is certainly a possibility that a previous history of bursitis could lead to some functional deficits in rotator cuff function which could potentially lead to further injury in the future, but whether or not there is an absolute and direct relationship between the bursitis in 2013 and the subsequent injury for which she was seen in 2015 after an acute injury while weight lifting is unclear.” Ex. 21 at 5. Dr. Heaton used the word “possibility,” not “probably” or “likely.” Speculation as to possible causes is not sufficient to support a finding that a vaccine caused an injury. *See Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1348 (Fed. Cir. 2010) (noting that physician speculated that fever experienced after vaccination might have caused neurological abnormalities and determining that this was not a conclusion that the vaccine caused petitioner’s alleged injury). Therefore, petitioner has not provided preponderant evidence of a reliable medical theory.

The second prong of *Althen* requires petitioner to establish that the vaccination was the reason for the injury. *Althen*, 418 F.3d at 1279. Dr. Heaton’s expert report states, “The patient experienced acute onset of pain within the hour of her flu vaccination, thereby providing a logical sequence of cause and effect, causing me to believe that the vaccination was the actual reason for the injury.” Ex. 21 at 5. The context indicates that Dr. Heaton referred to the 2013 injury, not the 2015 injury. However, with respect to the 2015 and continuing injury, Dr. Heaton noted that it was “unclear if her current ongoing pain is directly related to the flu vaccination in 2013.” *Id.* The fact that Dr. Heaton was petitioner’s treating physician adds gravity to this statement. *See Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (“[T]reating 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). Dr. Gagliano agreed that the pain and the vaccination could not be directly linked, stating more decisively that it was “impossible to define a connection of her persistent symptoms to her vaccination.” Ex. A at 5. The undersigned interprets Dr. Heaton’s statement as indicating that he could not attribute her later injury to the vaccination, and thus, the second *Althen* prong is not satisfied with respect to the later injury.⁹

Althen prong three requires petitioner to establish a proximate temporal relationship between the vaccination and injury. *Althen*, 418 F.3d at 1279. In this case, Dr. Heaton’s expert report states, “Regarding a temporal relationship between the vaccination, the injury, and the total duration of symptoms from the flu vaccination; this is unclear. . . . I see no direct documentation of how long she had symptoms from the bursitis from her flu vaccination. Without such information I am unable to determine if her current ongoing symptoms are truly from the initial flu vaccination and bursitis or if they are *more likely* a result of her repeat injury in May of 2015 while weight lifting.” Ex. 21 at 5-6 (emphasis added).

The undersigned has no choice but to find, on the basis of petitioner’s expert report, that petitioner has not established the third prong of *Althen*. Dr. Heaton’s expert report indicates that

⁹ While Dr. Heaton’s report indicates that the second *Althen* prong was met, he refers only to the 2013 injury, stating that “direct evidence of bursitis was seen on ultrasound at that time.” Ex. 21 at 5.

a temporal relationship is “unclear” and states that her current and ongoing symptoms are “more likely” a result of a repeat injury in May 2015 than a result of the initial flu vaccination. Without any further support for her petition, petitioner’s claim must fail on *Althen* prong three. Because petitioner must meet all three *Althen* prongs and petitioner cannot meet any of them, petitioner’s case cannot prevail.

3. Alternative Cause

Under the Vaccine Act, compensation shall be awarded where the petitioner demonstrates the requirements set forth under the Act by a preponderance of the evidence, and “there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(A)-(B). The Act provides that “factors unrelated to the administration of the vaccine” are those “which are shown to have been the . . . agents principally responsible for causing the petitioner’s illness, disability, injury, condition or death.” § 13(a)(2)(B). “[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.” *Stone v. Sec’y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012).

Because petitioner did not meet her burden of proof on causation under *Althen* or *Loving*, respondent does not bear the burden of establishing that a factor unrelated to the vaccination caused petitioner’s injury. *See Doe v. Sec’y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (“[Petitioner] never established a prima facie case, so the burden (and attendant restrictions on what ‘factors unrelated’ the government could argue) never shifted.”). Significantly, however, Dr. Gagliano opined that petitioner’s 2015 injury was likely caused not by her vaccination, but by her weight lifting. As with petitioner’s theory of causation, the undersigned has evaluated this alternative cause using the *Althen* prongs.

a. *Althen* Prong One

A reliable medical theory links petitioner’s weight lifting to her injury. Dr. Gagliano opined that petitioner’s weight lifting, coupled with her Lyme disease or some other undiagnosed disease, “are most likely the key players in her persistent complaints of pain.” Ex. A at 5 (also noting that these alternative causes “make it more likely that her complaints are due to other conditions and injuries” rather than to the vaccination). Dr. Heaton’s report provides a further explanation for the mechanism of petitioner’s injury. Observing that a May 2015 MRI revealed “a flap tear of the anterior labrum” in petitioner’s shoulder, Dr. Heaton concluded that this labral tear would not have been caused by the flu shot. Ex. 21 at 3; *see also id.* at 5 (opining that it was “essentially impossible” for the flu shot to cause a labral tear). He described the May 2015 incident as an “acute injury while weight lifting,” and noted that petitioner “heard a tearing sensation in her left shoulder” during the exercise. *Id.* at 2. Based on the analysis of both experts, the undersigned concludes that weight lifting is the most likely mechanism for an injury like that suffered by petitioner.

b. *Althen* Prong Two

A logical sequence of cause and effect demonstrates that petitioner's weight lifting caused her injury. As noted above, Dr. Gagliano described petitioner's weight lifting, as well as other ailments unrelated to the vaccination, as the "most likely" causes of her injury. Ex. A at 5. Dr. Heaton's expert report was, at best, ambivalent on this point. *See* Ex. 21 at 6 ("I am unable to determine if [petitioner's] current ongoing symptoms are truly from the initial flu vaccination and bursitis or if they are more likely a result of her repeat injury in May of 2015 while weight lifting."). However, Dr. Heaton's treatment records offer additional insight. After the injury, Dr. Heaton advised petitioner repeatedly to limit, or even temporarily cease, her body building activities. *See id.* at 7-8 ("Until [after her MRI], I want her to back off overhead lifting and even any heavy lifting below her chin."); *id.* at 5 ("We talked about how I think she continues to overdo it from [a] lifting standpoint. I want her to back off completely from any upper extremity lifting."); *id.* at 3 ("[I asked] her to back off lifting. It sounds like she has done it to some extent but I am still worried about her doing too much."). Based on the analysis of both experts, taken together, the undersigned concludes that this alternative cause satisfies *Althen* prong two.

c. *Althen* Prong Three

A proximate temporal relationship connects petitioner's weight lifting and her injury. The onset of petitioner's 2015 injury occurred as she performed a "skull crusher" exercise, and at that moment she "actually felt [a] pop/tear" in her muscle. *See* Ex. 4 at 72. This instantaneous reaction, a tearing sensation accompanied by the acute onset of pain, further supports her weight lifting as the true cause of her injury, consistent with the expert reports.

For the reasons set forth above, the undersigned concludes that petitioner's weight lifting injury, a factor unrelated to her vaccination, is the most likely cause of her 2015 injury.

V. Conclusion

The motion for judgment on the record is granted and the undersigned determines on the record that petitioner has not shown entitlement to compensation because she has submitted insufficient proof. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment herewith.¹⁰

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

¹⁰ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.