In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-0014V
Filed: August 3, 2018
UNPUBLISHED

ANTHONY CAPASSO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Fact Ruling; Entitlement; Ruling on the Record; Decision Without a Hearing; Causation-In-Fact; Onset; Six-Month Severity Requirement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Shealene Priscilla Wasserman, Muller Brazil, LLP, Dresher, PA, for petitioner.
Daniel Anthony Principato, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT [1]

Dorsey, Chief Special Master:

On January 4, 2017, Anthony Capasso ("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"), alleging that as a result of receiving an influenza ("flu") vaccination on November 14, 2015, he suffered an injury to his left shoulder. Petition at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters. Petitioner now moves for a decision on the written record. This decision resolves several issues: (1) a factual dispute regarding the onset of petitioner's shoulder pain, (2) a factual dispute regarding whether petitioner has met the six month sequela requirement, and (3) determines whether petitioner is entitled

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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). 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).

to compensation. For the reasons discussed herein, the undersigned grants petitioner's motion and finds that petitioner is entitled to compensation.

I. Procedural History

Mr. Capasso filed his petition for compensation on January 4, 2017 with four medical record exhibits, alleging that the injuries he received to his left shoulder were caused by an influenza vaccine he received on November 14, 2015. Petition at 1. (ECF No. 1). Additional medical records and a Statement of Completion were filed in March 2017. (ECF Nos. 8-11).

On June 12, 2017, respondent filed a status report stating that the records had been reviewed and that respondent found the case appropriate for settlement. Respondent invited petitioner to send a settlement demand. (ECF No. 15).

Over the next three months, the parties attempted to resolve this case through informal settlement discussions. On September 8, 2017, petitioner filed a status report stating that the parties were at an impasse and requested a status conference. (ECF No. 20).

On September 27, 2017, a status conference was held with the staff attorney managing this case. During the status conference, the parties stated that they were unable to resolve the case because they were too far apart in their valuation of the damages, namely the amount for petitioner's pain and suffering. To evaluate the issues in the case, the undersigned ordered respondent to file his report pursuant to Vaccine Rule 4(c). (ECF No. 21).

On November 14, 2017, respondent filed his Rule 4(c) report stating that this case is not appropriate for compensation under the terms of the Vaccine Act for several reasons. (ECF No. 23). Respondent first argues that petitioner's allegation of onset is not substantiated by the medical records. Respondent's Report at 5. Specifically, respondent states that because petitioner did not seek medical care for his shoulder until three weeks after his flu vaccination, he has not established a "medically reasonable time to infer vaccine causation of 48 hours or less recognized in the Vaccine Injury Table." *Id*. Second, respondent argues that petitioner has not satisfied the severity requirement of six months because he was discharged from physical therapy with full strength and he returned to daily activities without pain after only four and a half months. *Id*. at 6. Respondent notes that petitioner associated his recurrence of left shoulder pain "with his activities of rowing, spreading concrete and 'doing pavers' in his driveway," and thus, has not provided reliable evidence to show that his November 14, 2015 vaccination caused his left shoulder injury. *Id*. Because petitioner has not provided evidence that satisfies his proof under *Althen*,[3] nor has petitioner provided an expert report or medical theory to support his claim, respondent recommends that petitioner's claim for compensation be denied.

[3] *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005)

After another status conference was held in the case, petitioner filed a joint status report (ECF No. 27) stating that the parties had conferred and requested permission to submit briefs on entitlement and request a ruling. A scheduling order was issued the next day, January 24, 2018, setting a briefing schedule. (ECF No. 28). Petitioner filed several additional affidavits on the issue of damages on March 13, 2018, as well as a motion for a ruling on the record. (ECF Nos. 30-31). Respondent filed a responsive brief on April 26, 2018. (ECF No. 32). No reply brief was filed. This matter is now ripe for adjudication.

II. Factual History

In November 2015, Mr. Capasso (age 41) was working at Toray Plastics where he had been employed for more than 17 years. Petitioner's Exhibit ("Pet. Ex.") 3 at 4; Pet. Ex. 8 at 1-2, ¶5. Mr. Capasso's medical history does not mention any history of shoulder injuries and does not otherwise appear to be contributory to his claim in this case.

On November 14, 2015, Mr. Capasso received a flu vaccination in his left arm at a Rite Aid Pharmacy located in Portsmouth, Rhode Island. Pet. Ex. 1 at 1; Pet. Ex. 2 at 16. In his affidavit, Mr. Capasso stated that he felt some pain in his left shoulder the day after he was vaccinated which increased over the next couple of days. Pet. Ex. 10 at 1. He stated that approximately two to three days after vaccination, he woke up and noticed that the pain from the prior night had become much more severe. *Id*. He was unable to lift his arm to put on his shirt and had to ask his wife for assistance. Mr. Capasso stated that he was unable to sleep that night due to the pain. *Id*.

On December 3, 2015, 19 days later, Mr. Capasso presented to his primary care physician, Dr. Liza Famador, for complaints of left-sided shoulder pain after receiving a flu vaccination two to three weeks prior. Pet. Ex. 2 at 17. Mr. Capasso reported that he received the flu vaccine at Rite Aid on November 14, 2015, and later that night, had "swelling on the area until the next day." *Id*. He also noted pain while moving his left arm, putting on his seatbelt, and with flexion. *Id*. Upon examination, Mr. Capasso exhibited tenderness of the left shoulder. At this time, Dr. Famador noted normal strength and normal range of motion of his left shoulder. *Id.* A diagnosis of contusion of the left deltoid region was made, and Mr. Capasso was advised to apply ice compressions to the affected area for 20 minutes, three times daily. *Id*. at 18. Dr. Famador also advised that Mr. Capasso perform range of motion ("ROM") exercises and take ibuprofen for pain. *Id*.

Mr. Capasso presented for his annual exam on January 15, 2016. Pet. Ex. 2 at 19. At this visit, he complained that his left shoulder continued to bother him. *Id.* Dr. Famador again noted that Mr. Capasso's pain started after he received a flu shot in November. *Id*. The musculoskeletal portion of the physical exam documented that Mr. Capasso continued to exhibit tenderness to his left shoulder although he still had normal range motion and normal strength of his left shoulder. *Id*. at 20. Dr. Famador also noted that there was no cervical adenopathy. *Id*. at 21. The assessment stated that

while Mr. Capasso's left shoulder pain had improved, some discomfort was still present. He was advised to continue using warm compresses and to perform a series of shoulder exercises and massages to treat his symptoms. He was advised to consider physical therapy if his shoulder pain did not improve. *Id.*

On February 22, 2016, Mr. Capasso underwent an initial evaluation at University Orthopedics with physical therapist, Diane Jones. Pet. Ex. 4 at 2. Mr. Capasso reported that his shoulder became sore after receiving a flu shot in November 2015, and he reported experiencing severe pain at the time of examination (a range from 6 - 9 out of 10). *Id*. Mr. Capasso was noted to have certain impairments with the range of motion of his left shoulder. Specifically, he was noted to have moderate impairment with the passive range of motion ("PROM") of his glenohumeral joint with external rotation. *Id*. He also had mild impairment with his active range of motion ("AROM") with shoulder flexion, shoulder scaption, and shoulder external rotation. Mr. Capasso was noted to have moderate levels of impairment of the AROM with shoulder abduction, shoulder horizontal adduction and shoulder internal rotation. *Id*. at 3. He had a moderate weakness and decreased strength at a 3/5 level. *Id*. The evaluation notes indicate that Mr. Capasso was able to engage in moderate work duty but only at a 50% level. He had mild difficulty reaching overhead and lifting and pulling light objects. *Id*. at 3. Mr. Capasso also reported moderate difficulty sleeping at night due to the pain. *Id*. The assessment was shoulder and upper arm mobility deficits associated with a sprain and strain. *Id*. at 4. The plan of care was for physical therapy for one visit per week for six weeks. *Id*. There was no specific date of onset noted for these impairments.

Mr. Capasso attended his first physical therapy session on March 1, 2016. Pet. Ex. 4 at 6. During this session, a positive finding on a special test, the Hawkins-Kennedy test, was noted. *Id*. The abnormal range of motion of his left shoulder and pain levels were all noted to be the same as the initial consultation. *Id*. at 6- 8.

Mr. Capasso continued to attend physical therapy sessions on March 7 and March 24. At the March 7, 2016 session, his range of motion and pain levels continued to be substantially the same as the initial evaluation, although there was a slight improvement noted in his passive range of motion. Pet. Ex. 4 at 9-11. By the March 24, 2017 session, it is noted that Mr. Capasso "has made good progress since [start of care] with return of full functional painfree AROM. P[atient']s strength has returned to 5 out of 5 without pain. Continued slight scapular winging but has improved since beginning exercises with PT. P[atien]t has returned to normal daily activities without pain and has met all goals initial set. P[atien]t is indep[endent] with HEP [home exercise program] and will continue on maintenance program." Pet. Ex. 4 at 15. However, the undersigned notes that there were still some mild impairments documented with Mr. Capasso's active range of motion with shoulder flexion and shoulder abduction during this session. *Id*. at 14. Mr. Capasso was discharged and instructed to return to his referring physician if his symptoms returned. *Id*. at 15. In his affidavit, Mr. Capasso stated that his physical therapy sessions went well and he could continue working pain free. However, the relief was short lived and he began to experience similar pain a month later. Pet. Ex. 10 at 2.

Mr. Capasso returned to Dr. Famador on June 3, 2016, with complaints of continued left shoulder pain. Pet. Ex. 2 at 23. Dr. Famador noted that Mr. Capasso began having left shoulder pain in November 2015 after receiving a flu shot. Although he underwent physical therapy in March 2016, his symptoms returned over the past 1-2 months. Mr. Capasso reported that he had shooting pain from his left shoulder with certain activities such as rowing or when he was spreading concrete. He reported that he was still performing his shoulder exercises at home. *Id*. His physical examination was positive for arthralgia and tenderness was of the left shoulder, but Dr. Famador documented normal range of motion and normal strength during the examination. *Id*. at 24. In the assessment, Dr. Famador recommended that Mr. Capasso return to his orthopedist for a repeat evaluation. Id. at 16. Dr. Famador stated that an MRI or steroid injection may be necessary. *Id*. Mr. Capasso was encouraged to continue performing his home exercise program and to resume using ice or heat over the shoulder area. *Id*.

On July 6, 2016, Mr. Capasso underwent an MRI of his left shoulder. Pet. Ex. 3 at 2. The MRI was abnormal and showed a partial-thickness tearing and/or tendinopathy of the infraspinatus. There was no evidence of a full-thickness rotator cuff tear. *Id*.

On August 11, 2016, Mr. Capasso was seen in follow-up by his primary care physician, Dr. Maher. Pet. Ex. 3 at 5. The chief complaint was left shoulder pain and to review the results of the MRI. *Id*. Mr. Capasso's range of motion and strength levels were not documented in these notes. *Id*. The plan was for petitioner to continue with physical therapy, ibuprofen and to continue to be seen in follow up. *Id*. No additional medical records have been filed after the August 11, 2016 visit.

In his affidavit, Mr. Capasso stated that prior to his November 14, 2015 flu vaccination, he was very active, exercised regularly and ate well. Pet. Ex. 10 at 2. He said that he never had any sort of shoulder problems in the past, even after previous vaccinations. *Id*. Mr. Capasso explained how his shoulder injury affected his job. He stated during the time he was experiencing his shoulder symptoms, he avoided working overtime because the pain was too severe to bear. *Id*. at 1-2. However, he did work the mandatory overtime so that he would not lose income or his job. He described how he asked his co-workers for assistance with strenuous tasks that required the use of his left arm and shoulder. *Id*. at 2. His coworker, Mike Chianese, also filed an affidavit confirming that Mr. Capasso had asked him to help with the "heavy lifting" due to his shoulder injury. Pet. Ex. 9 at 1. Mr. Chianese stated that Mr. Capasso "struggled with just normal duties" and that seeing him struggle at work was difficult, so he helped as much as he could. *Id*. Mr. Capasso explained that while his pain affected his ability to perform his job, he continued to work and did not take any time off due to his injury because he took pride in his perfect attendance record. Pet. Ex. 8 at 1-2. He stated that he has not called out of work sick in seven years. *Id*. at 2. At the time of his vaccination, he was only two months away from receiving an award for the fifth year in a row and he decided to work his way through the pain. Pet. Ex. 9 at 1. Mr. Capasso

explained that he considers himself a model employee and has always excelled in his performance reviews. *Id.*

Mr. Capasso also filed an affidavit from his wife, Andrea Capasso. Pet. Ex. 11. Ms. Capasso stated that initially, both she and her husband were both going to receive flu shots on November 14, 2015, but that she declined receiving a vaccine that day because she was unfamiliar with the pharmacist administering the vaccines. After observing her husband receive his flu vaccine, Ms. Capasso stated that she "had a bad feeling." *Id*. at 1. She described how she observed her husband's shoulder become swollen and sore to the touch at the injection site. She also explained that his pain became so severe that she had to help her husband dress into his clothes in the morning. By February 2016, Ms. Capasso stated that her husband's condition had deteriorated. She now had to do all the chores around the home that required any lifting, including shoveling snow. Ms. Capasso stated that her husband was very diligent about his physical therapy and while his pain and strength improved after therapy, within a month of leaving therapy, his pain returned. Ms. Capasso described that when their daughter moved back home from college from her freshman year in the summer of 2016, her husband was unable to help with moving the furniture because of the risk of further injuring his shoulder. He was unable to go out on their row boat that summer and he was unable to golf, one of his favorite activities. Ms. Capasso states that even today, two and half years later, her husband still performs shoulder exercises that are part of his home exercise program for his shoulder.

III. <u>Findings of Fact</u>

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. 42 U.S.C. § 300aa–13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed.Cir.1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally

consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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

a. <u>Onset Ruling</u>

The first issue to be addressed is the parties' dispute over whether the onset of petitioner's shoulder injury was within 48 hours of the vaccination. Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). *See* Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings are informed by the Qualifications and Aids to Interpretation ("QAI") for SIRVA criteria used to evaluate such claims. The criteria are as follows:

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

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052). The criteria at issue in this case is whether Mr. Capasso's pain occurred within the specified time-frame of 48 hours or less after administration of his November 14, 2015 flu vaccination. The undersigned finds that it did.

The contemporaneous medical records demonstrate that Mr. Capasso repeatedly and consistently placed the onset of his shoulder injury within 48 hours of his vaccination. The first time Mr. Capasso sought medical treatment for his injury, which was only 19 days after vaccination, he specifically reported that he received a flu shot on November 14, 2015, and "[l]ater that night, he noted swelling on the area until the next day. Then he noted pain when he moved … around like pulling on his seatbelt and flexion." Pet. Ex. 2 at 17.

At his annual exam on January 15, 2016, Mr. Capasso again reported that his pain started when he received a flu shot in November 2015. Pet. Ex. 2 at 19. At his initial evaluation at University Orthopedics on February 22, 2016, Mr. Capasso again reported that his shoulder "became sore after receiving flu shot Nov 2015." Pet. Ex. 4 at 2. On June 3, 2016, Mr. Capasso's primary care physician again noted that petitioner "[s]tarted having L shoulder pain in Nov 2015, which he relates to getting a flu shot." Pet. Ex. 2 at 23. Mr. Capasso also filed an affidavit from his wife, who was present when he received the flu vaccination on November 14, 2015, and who was with him over the next 48 hours. Pet. Ex. 11. Ms. Capasso averred that "[w]ithin 24 hours, his shot site was swollen and warm to the touch… However, with ice and rest over the next day or two, these symptoms did not get any better… I recall that Tony was very concerned to work, as his swollen left shoulder was getting more painful and stiff over the next few days, following vaccination." *Id*. at 1, ¶5.

Respondent argues that a complaint of shoulder pain reported "nearly three weeks after his flu vaccination" is not "within the medically reasonable time to infer vaccination causation of 48 hours or less recognized in the Vaccine Injury Table." Respondent's Report at 5. The undersigned does not find this argument to be persuasive. To the contrary, in this particular instance, 19 days appears to be a reasonable time for Mr. Capasso to determine whether his shoulder pain would resolve on its own or whether he needed to seek medical treatment. Medical records generally "warrant consideration as trustworthy evidence" and in this case, the contemporaneous medical records indicate that Mr. Capasso's shoulder pain occurred within 48 hours of vaccination. *Cucuras v. Sec'y of Health & Human Servs.,* 993 F.2d 1525, 1528 (Fed.Cir.1993). Additionally, the undersigned finds petitioner's sworn statement, and the statement of his wife, to be reasonable and credible. There are no inconsistencies between the medical records and petitioner's statements or the statements of his witnesses regarding onset. Thus, the undersigned finds that petitioner has provided preponderant evidence that his shoulder pain began within 48 hours of his November 14, 2015 flu vaccination.

b. <u>Six Month Severity Requirement Ruling</u>

Under the Vaccine Act, a petition for compensation must contain "supporting documentation, demonstrating that the person who suffered [a vaccine related injury] ... suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa–11(c)(1)(D)(i). The burden is on the petitioner to establish, by a preponderance

of the evidence, the persistence of a vaccine-caused injury for longer than six months. *Song v. Sec'y of Health & Human Servs.,* 31 Fed. Cl. 61, 65–66, *aff'd*, 41 F.3d 1520 (Fed.Cir.1994). The undersigned finds that Mr. Capasso has met the six month severity requirement.

Although a petitioner cannot establish the length or ongoing nature of an injury merely through his self-assertion, the fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from his alleged injury. *See, e.g.*, *Herren v. Sec'y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (finding that a petitioner suffered from residual symptoms that due to their mild nature did not require medical care).

Respondent argues that because Mr. Capasso was discharged from physical therapy with full strength and returned to his normal daily activities after only four and a half months, he has not met the Vaccine Act's severity requirement of six months. Respondent's Report at 6; Response to Motion for Ruling on the Record ("Resp. to Mot.") at 5-6. Respondent further argues that because Mr. Capasso was asymptomatic for approximately one month after he was discharged from PT without pain and after meeting all functional goals, his claim should be denied. *Id*. Respondent further argues that the *Atanasoff* article[4] cited by petitioner, provides support for this argument. *Id*. at 6. Respondent states that in the *Atanasoff* article, the authors note that all SIRVA patients had persistent pain for at least six months*. Id.* Because respondent views petitioner's injury as a waxing and waning clinical course, he argues that petitioner's clinical course is not consistent with SIRVA. *Id*.

Here, there is no dispute that Mr. Capasso received the flu vaccine on November 14, 2015, and he must therefore show that his alleged injuries lasted more than six months after administration of the vaccine. *Herren*, 2014 WL 3889070, at *2; *see also Hinnefeld v. Sec'y of Health & Human Servs*., No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's Guillain-Barré syndrome resolved less than two months after onset). Thus, Mr. Capasso must demonstrate by preponderant evidence that his injuries continued through May 14, 2016.

Mr. Capasso was discharged from physical therapy on March 24, 2016. Pet. Ex. 4 at 15. At that time, Mr. Capasso had made good progress since the start of care and his full strength had returned without pain. *Id*. He was discharged to a home exercise program and instructed to return to his primary care physician if his symptoms returned. However, at his last physical therapy visit on March 24, 2016, he was noted to have "continued slight scapular winging"[5] and mild impairments with his active range of

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[4] Pet. Ex. 12 (Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052)).

[5] A scapula is defined as "the flat, triangular bone in the back of the shoulder, articulating with the ipsilateral clavicle and humerus; called also *shoulder blade*." *Dorland's Illustrated Medical Dictionary*

motion with flexion and abduction of the left shoulder. Pet. Ex. 4 at 14-15. In his affidavit, Mr. Capasso stated that his relief from physical therapy was short lived and he began to experience pain in his shoulder about one month later. He stated that he did not injure his shoulder following physical therapy, but activities that he had been able to do without pain before his November 14, 2015 vaccination, such as working out, were painful again. He states "[t]he pain I felt was the same pain that I had experienced before physical therapy." Pet. Ex. 10 at 2.

On June 3, 2016, Mr. Capasso returned to Dr. Famador with complaints of continued left shoulder pain. After a physical examination where Dr. Famador noted arthralgias and tenderness of the left shoulder, Mr. Capasso was encouraged to see his orthopedist for a repeat evaluation. On July 6, 2016, an MRI showed a partial thickness tearing and/or tendinopathy of the infraspinatus. On August 11, 2016, Dr. Maher recommended that Mr. Capasso continue with physical therapy.

The undersigned notes, and the parties agree, that there is no evidence that Mr. Capasso had a shoulder injury prior to vaccination. And although respondent argues that the *Atanasoff* article argues against a waxing and waning clinical course, the undersigned finds this argument to be unpersuasive in this case. Reviewing Mr. Capasso's medical records and his clinical course, it is apparent that Mr. Capasso took great care to follow his physician's and physical therapist's advice and adhered to his physical therapy and home exercise programs. His diligence in performing his home exercise program led to a temporary cessation of his pain. Once he stopped being formally treated in PT, his pain return within just a few weeks, demonstrating to the undersigned that petitioner's underlying shoulder injury had not resolved.

The *Atanasoff* article does not specifically state that a waxing and waning of symptoms disqualifies an individual from having a SIRVA injury. In the undersigned's experience, it is very common for individuals with SIRVA injuries to have different levels of shoulder pain depending on movement, activity, and degree of severity. Many physical therapy notes document pain levels at each session and those numbers frequently vary. Indeed, Mr. Capasso's own PT records demonstrate that at one of his PT sessions (before he was formally discharged), he rated his shoulder pain at 0 out of 10, although he had other objective measures of continuing shoulder dysfunction such as mild and moderate impairments of his active range of motion. Pet. Ex. 4 at 6-11. Even at his final physical therapy session on March 24, 2016, he still had mild impairments with his active range of motion with flexion and abduction of his left shoulder. *Id*. at 14. The *Atanasoff* authors merely state that individuals with a SIRVA injury have persistent pain for six months. The undersigned finds that in this instance, Mr. Capasso's shoulder pain did persist for six months, albeit to varying degrees. Had Mr. Capasso's shoulder pain subsided for a substantial period of time, the undersigned may have entertained respondent's argument that his shoulder injury resolved, however, that is not the case here. The physical examinations and MRI results from

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1673 (32d ed. 2012). A "winged" scapula is defined as "a scapula having a prominent vertebral border." *Id*.

June, July and August 2016 document objective evidence of a continuing shoulder injury.

Respondent also argued that Mr. Capasso may have reinjured his shoulder with activities such as rowing, spreading concrete and "doing pavers." This argument is equally unpersuasive. These are activities that Mr. Capasso did without pain prior to vaccination. Pet. Ex. 10 at 2. The Vaccine Act six-month severity requirement states that an individual must have suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine. The undersigned finds that petitioner has met his burden.

IV. Ruling on Entitlement

In light of the above findings of fact, the undersigned further finds that this case is ripe for adjudication on the question of whether petitioner is entitled to compensation for his alleged SIRVA. For the reasons described below, the undersigned finds that Mr. Capasso is entitled to compensation.

A. Legal Standard

In this case, because petitioner's claim predates the inclusion of SIRVA on the Vaccine Injury Table, petitioner must prove his claim by showing that his injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279.

The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Under the leading *Althen* test, petitioner must satisfy three elements. The *Althen* court explained this "causation-in-fact" standard, as follows:

> Concisely stated, *Althen's* burden is 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 proximate temporal relationship

> between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

B. Analysis

The undersigned finds that petitioner satisfies the three prongs of *Althen* as follows:

a. ***Althen* Prong 1 - A Medical Theory Causally Connecting the Vaccination and Injury**

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. *See Pafford v. Sec'y of Health & Human Servs.*, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. *See, e.g.*, *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (reputable); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). *See* Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g.

NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

The undersigned's findings and conclusions are as follows:

1. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed Mr. Capasso's medical history prior to his influenza vaccination. He did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccination, and thus, petitioner satisfies this criterion.

2. Onset occurred within the specified time frame.

As discussed above, the undersigned finds that the onset of petitioner's shoulder pain began within 48 hours of vaccination.

3. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

As described in Section II, Factual Findings, Mr. Capasso's complaints of shoulder pain and reduced range of motion were all limited to his left shoulder. The examination for cervical adenopathy was negative. *See* Pet. Ex. 2 at 21. For these reasons, the undersigned finds that Mr. Capasso experienced pain and decreased range of motion limited to the shoulder in which he received the vaccine, his left shoulder.

4. No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

There is no evidence in the record that demonstrates any type of condition or abnormality that would explain petitioner's symptoms. Mr. Capasso had no evidence of a left shoulder injury prior to vaccination and an examination for cervical adenopathy was negative. Respondent argued that Mr. Capasso may have reinjured his shoulder with activities such as rowing, spreading concrete and "doing pavers" after he completed his physical therapy in March 2016, but the undersigned found this argument to be unpersuasive. These are activities that Mr. Capasso did regularly without pain

prior to vaccination. Pet. Ex. 10 at 2. Thus, the undersigned finds that Mr. Capasso's injury meets the QAI for SIRVA and he has satisfied *Althen* prong one.

b. *Althen* Prong 2 – A logical sequence of cause and effect showing the vaccine was the reason for the injury

Guided by the criteria for evaluating a Table SIRVA injury, the undersigned finds that petitioner has shown, by a preponderance of the evidence, a logical sequence of cause and effect showing that his November 14, 2015 flu vaccine was the reason for his shoulder injury. The SIRVA criteria provides a perfectly logical sequence of cause and effect including (1) no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

In light of the factual history and analysis set forth above, the undersigned finds that all four of the criteria listed in the QAI for SIRVA are satisfied by preponderant evidence. Thus, the undersigned finds that petitioner has satisfied *Althen* prong two.

c. *Althen* Prong 3 - Proximate temporal relationship between vaccination and injury

"The proximate temporal relationship prong [under *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. *See Langland v. Sec'y of Health & Human Servs.,* 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner's shoulder injury must begin within 48 hour or less of the vaccination. The undersigned has found that the onset of petitioner's shoulder injury began within 48 hours of the vaccination, and thus, petitioner has satisfied *Althen* prong two.

V. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records and the parties' respective motions, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master