In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 19, 2019

BONNIE FORMAN-FRANCO,	*	PUBLISHED
	*	
Petitioner,	*	No. 15-1479V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Causation-in-Fact; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Findings of Fact; Onset of Petitioner's Shoulder Pain.
Respondent.	*	

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for petitioner.
Adriana R. Teitel, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On December 7, 2015, Bonnie Forman-Franco ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that she suffered a shoulder injury as the result of an influenza ("flu") vaccination she received on December 30, 2013. Petition at Preamble.

[1] The undersigned intends to post this Ruling on the United States Court of Federal Claims' website. **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished Ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in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).

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

After a review of the record as a whole, a fact hearing, expert reports and medical literature, briefing by the parties, and for the reasons set forth below, the undersigned finds by preponderant evidence that the petitioner is entitled to compensation.

I. Procedural History

Petitioner filed her petition on December 7, 2015, alleging that she sustained shoulder injuries caused by a flu vaccine administered to her on December 30, 2013. Petition at Preamble. On August 24, 2016, respondent filed his Rule 4(c) Report, stating that the records had been reviewed by medical personnel of the Department of Health and Human Services, Division of Injury Compensation Programs, and concluded that the case was not appropriate for compensation. Respondent's Report ("Resp. Rept.") at 1-2 (ECF No. 23). In the Rule 4(c) Report, respondent acknowledged that

> [w]hile the Secretary ha[d] proposed adding shoulder injury related to vaccine administration ("SIRVA") to the Vaccine Injury Table for the flu vaccine, *see* 80 Fed. Reg. 45132-54 (July 29, 2015), petitioner would not qualify for compensation based on the proposed criteria, which include: 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; 2) pain occurs within the specified time frame (within 48 hours of vaccine administration); and 3) pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered. *See* Fed. Reg. 45152 (July 29, 2015).

Resp. Rept. at 7 n.1. SIRVA was added as a Table claim for the flu vaccine effective for petitions filed on or after March 21, 2017. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294, Jan. 19, 2017; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321, Feb. 22, 2017 (delaying the effective date of the final rule until March 21, 2017).

A fact hearing was held on August 15, 2017, after which the undersigned made a factual finding regarding the onset of petitioner's shoulder injury. Ruling on Facts dated Feb. 21, 2018 (ECF No. 62). The early procedural history (from 2015 through 2017) was set forth in the Ruling on Facts and will not be repeated here. See id. at 1-2. After the undersigned issued her Ruling on Facts, she ordered petitioner to file updated medical records and an expert report by April 20, 2018. (ECF No. 63). Petitioner subsequently sought and was granted several extensions of time in which to file her expert report and was ultimately ordered to file it by August 13, 2018. (ECF Nos. 67, 70, 72). In the interim, petitioner filed updated medical records. See Petitioner's Exhibits ("Pet. Exs.") 23-26 (ECF Nos. 65, 68).

On August 10, 2018, petitioner filed an expert report by Dr. G. Russell Huffman. Pet. Ex. 27. Petitioner also filed Dr. Huffman's CV and a number of medical journal articles. Pet. Exs. 28-28.10. On September 13, 2018, respondent filed a status report, stating he was not

interested in settlement negotiations and wished to file a responsive expert report. (ECF No. 76). Respondent was ordered to file an expert report by November 13, 2018. (ECF No. 77). After two motions for an extension of time were requested and granted, respondent filed an expert report by Dr. David Ring on December 21, 2018, along with his CV and medical journal articles. Respondent's Exhibits ("Resp. Exs.") A-B. Petitioner filed a responsive supplemental expert report by Dr. Huffman on March 18, 2019. Pet. Ex. 29.

On April 16, 2019, the undersigned held a status conference in which she shared her preliminary evaluation of the case. Rule 5 Order dated Apr. 17, 2019 (ECF No. 88). After sharing her preliminary findings and opinions, the undersigned encouraged the parties to resolve the case through settlement negotiations. Id. at 2.

On May 31, 2019, respondent filed a status report stating that his position on settlement was unchanged, and he wanted to continue to litigate the case. (ECF No. 91). Respondent filed his supplemental expert report by Dr. Ring and additional medical literature on August 9, 2019. Resp. Ex. C. Petitioner was given the option of requesting an entitlement hearing or filing a ruling on the record and opted to file a motion for a ruling on the record, which she filed on September 16, 2019. (ECF No. 101). Respondent filed his response on October 21, 2019, along with an exhibit. (ECF Nos. 104-05).[3] Petitioner filed a reply on November 5, 2019. (ECF No. 108).

The case is now ripe for adjudication.

II. Factual History

The Ruling on Facts sets forth a summary of petitioner's medical records relative to her left shoulder and a summary of the testimony by petitioner and fact witness Michael Valasky from the fact hearing. See Ruling on Facts dated Feb. 21, 2018, at 3-4. Those summaries will not be repeated here. After the fact hearing, petitioner filed additional medical records relating

[3] Respondent's Exhibit D is a position statement published by the American Academy of Orthopaedic Surgeons/American Association of Orthopaedic Surgeons in 2017. (ECF No. 105-1). The document includes the following caveat and disclosure: "This Position Statement was developed as an education tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions." Resp. Ex. D at 1. The authors of the statement are not identified. The position taken in the statement, that vaccine administration in the shoulder cannot cause shoulder injury, is in direct contrast with the Qualifications and Aids to Interpretation ("QAI") relative to SIRVA in the Vaccine Injury Table and the medical literature filed in this case. See 42 C.F.R. § 100.3(c)(10)(i)-(iv); Pet. Exs. 28.1-28.2. Moreover, the statement appears to take issue with the goal of the Vaccine Act, which was created by Congress to identify and compensate those persons injured by vaccine administration. Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996). The paper was not discussed by either expert in the case. For all the above reasons, the undersigned did not find the statement to be persuasive evidence applicable to this case.

to her 2007 surgery of her left shoulder. See Pet. Exs. 23-26. These records include an MRI report dated July 27, 2007, which interpreted the study as showing supraspinatus tendon and infraspinatus tendon tears and acromioclavicular ("AC") joint arthropathy. Pet. Ex. 25 at 2. Petitioner also filed her operative report dated August 3, 2007, for rotator cuff repair surgery of the left shoulder, performed by Dr. Scott Alpert. Pet. Ex. 23 at 2. Additionally, MRI images were filed as Exhibits 24 and 26.

III. Expert Reports

A. Petitioner's Expert, Dr. G. Russell Huffman

Dr. Huffman is a shoulder and elbow surgeon, and an Associate Professor of Orthopaedic Surgery and Director of the Shoulder and Elbow Surgery Fellowship at the University of Pennsylvania Medical Center. Pet. Ex. 28 at 1. Dr. Huffman attended medical school at Duke University School of Medicine, completed his surgical internship and orthopaedic surgery residency at the University of California, San Francisco, and completed shoulder and elbow fellowships at the University of Southern California and the Mayo Clinic. Id. Dr. Huffman "oversee[s] 3,000 patient office visits a year and perform[s] over 450 surgeries per year." Pet. Ex. 27 at 1. He has authored over 100 publications, and lectures nationally and internationally. Id. He researches shoulder and elbow issues and has diagnosed and treated patients with SIRVA for eight years. Id. Dr. Huffman is currently investigating a SIRVA protocol at the University of Pennsylvania. Id.

Dr. Huffman opines that "within a reasonable degree of medical certainty" the records in this case document that petitioner sustained a SIRVA injury. Pet. Ex. 27 at 7. Before reaching his opinions, Dr. Huffman reviewed petitioner's medical records, MRIs, respondent's Rule 4(c) Report, and a transcript from the fact hearing held on August 15, 2017. Id. at 2-5. He also reviewed and cited supporting medical literature. Id. at 5-8.

Petitioner filed two expert reports by Dr. Huffman. In his first expert report, Dr. Huffman began by noting petitioner's prior history of left shoulder rotator cuff injury occurring after a fall in 2007, which required surgery. Pet. Ex. 27 at 5. Dr. Huffman explains that Dr. Alpert's records show that within three to four months after petitioner's 2007 shoulder surgery, "she had good strength and had regained full range of motion." Id. at 6. After this surgery, and prior to the vaccination in 2013, there is no reference in the records to suggest that petitioner had any further problem associated with the 2007 left shoulder injury. Id. at 5-7. Dr. Huffman states, "[w]hile it is clear that [petitioner] has a prior history of a left shoulder traumatic rotator cuff tear, there was no repeated trauma to her shoulder or other inciting event other than the vaccination to explain her pain, dysfunction and need for surgery in 2014." Id. at 7. Dr. Huffman concludes that petitioner's left shoulder was "asymptomatic for 7 years until the time of flu vaccination in December 2013." Id.

Dr. Huffman next opines that there is a temporal association between the flu vaccine petitioner received on December 30, 2013 and her left shoulder injury. Pet. Ex. 27 at 5-6. Petitioner testified that she had left shoulder pain two hours after receiving the vaccine, and that subsequently her symptoms worsened. Id. at 5. Dr. Huffman states that petitioner's complaints

were corroborated by Mr. Valasky, who testified that petitioner had pain after her vaccination. Id. at 6. Dr. Huffman concludes that petitioner's clinical history "of left shoulder symptoms occurring within two hours [is] within the requisite 48-hour window" for the temporal criteria for SIRVA causation. Id. at 7.

Dr. Huffman opines that "[petitioner's] injury fits within the established SIRVA criteria," as reported by Dr. Tom Ryan in a 2011 Institute of Medicine ("IOM") report presented on behalf of the Injection-Related Work Group. Pet. Ex. 27 at 6 (citing Pet. Ex. 28.2).[4] Dr. Ryan states:

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

Pet. Ex. 28.2 at 9. In his report, as Dr. Huffman notes, "Dr. Ryan expanded SIRVA to include, but not be limited to deltoid bursitis and other conditions that cause a 'prolonged restriction of [shoulder] function.'" Pet. Ex. 27 at 6 (quoting Pet. Ex. 28.2 at 7).

Dr. Huffman opines that the above criteria are met here, assuming petitioner's left shoulder was asymptomatic from 2007 until her 2013 vaccination, as the records indicate and as he concludes. Pet. Ex. 27 at 6-7. Further, Dr. Huffman opines that petitioner's 2014 MRI shows "significant bursitis," consistent with the inflammation noted and described by Dr. Michael Schwartz when he performed petitioner's arthroscopic surgery in 2015. Id.; see Pet. Ex. 2 at 11-12. Dr. Huffman asserts that petitioner's bursitis "is consistent with bursitis observed in SIRVA cases" described in medical journal articles by Cross et. al. (subdeltoid bursitis)[5] and Cook (subacromial/subdeltoid bursitis).[6] Pet. Ex. 27 at 6-7. In his clinical practice, Dr. Huffman has seen patients "with bursal-sided changes in the rotator cuff associated with bursitis after vaccinations into the subacromial space." Id. at 7.

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[4] Tom Ryan, Injection-Related Work Grp., Dep't of Health & Human Servs., 2011 Institute of Medicine (IOM) Report Generated Proposals for Updates to the Vaccine Injury Table (VIT) (2011).

[5] Gail B. Cross et al., Don't Aim Too High: Avoiding Should Injury Related to Vaccine Administration, 45 Australian Fam. Physician 303 (2016).

[6] Ian F. Cook, Subdeltoid/Subacromial Bursitis Associated with Influenza Vaccination, 10 Hum. Vaccines & Immunotherapeutics 605 (2014).

Additionally, Dr. Huffman states that there is literature to explain petitioner's injury and to support his proposed causal mechanism. He opines as follows:

> The proposed mechanisms range from direct injection into the bursa with a resultant inflammatory response, injury from the needle and a regional immunogenic response causing bursitis, synovitis or neuritis. In [petitioner's] case, the left shoulder rotator cuff tearing, bursitis and biceps tear are related to the vaccination. In cases such as [petitioner's], these injuries are the result of an inflammatory bursal response from vaccination itself.

Pet. Ex. 27 at 7 (internal citations omitted).

In support of his opinions, Dr. Huffman cites several articles related to shoulder injuries following vaccine administration, some of which discuss proposed mechanisms of causation in detail. See Pet. Ex. 27 at 8. Of these, articles by Bodor and Montalvo ("Bodor")[7] and Atanasoff et al. ("Atanasoff")[8] are illustrative. In Bodor, the authors discuss two patients who had shoulder pain and weakness following vaccines administered high in the deltoid muscle.[9] Pet. Ex. 28.6 at 1-2. The authors hypothesized that the "vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response." Id. at 2. "Given that the subdeltoid bursa is contiguous with the subacromial bursa, this led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule," as well as "adhesive capsulitis." Id. The authors also noted that in both patients, multiple structures within the shoulder were involved, including the "subacromial space, the bicipita tendon and the glenohumeral joint," which suggested "a primary inflammatory etiology rather than a mechanical overuse problem." Id. at 3. The authors recommended against using the upper third of the deltoid for vaccine administration to prevent injury. Id. They concluded that "the diagnosis of vaccination-related shoulder dysfunction . . . [should] be considered in patients presenting with shoulder pain and weakness following a vaccine injection." Id.

In Atanasoff, the authors searched the database of claims submitted to the Vaccine Program for injuries related to shoulder pain or dysfunction, adhesive capsulitis, or shoulder bursitis and identified thirteen cases filed from 2006 to 2010 where "vaccine administration led to significant shoulder pain and dysfunction." Pet. Ex. 28.1 at 1-2. Based on their investigation, the authors proposed that the "mechanism of injury is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." Id. at 1.

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

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

[9] Here, petitioner testified that her flu vaccine was administered "high in [her] deltoid area." Transcript ("Tr.") 50.

The authors also stated that "[a]lthough shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response" as seen in the patients they studied. Id. at 3. Of interest, the authors noted that "some of the MRI findings in [their] case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." Id. They also observed that "[o]ther findings such as fluid collections, localized tendon inflammation, and bursitis are more consistent with the vaccine needle over-penetration mechanism." Id. at 3-4. Moreover, six patients reported that their vaccines were administered "too high," which suggests that improper injection technique may have caused or contributed to the injury. Id. at 4. Many of the patients in their case study (62%) were "overweight or obese" and no patient was underweight, suggesting that "needle length alone" was not the problem. Id.

In his second expert report, Dr. Huffman expresses disagreement with some of the opinions set forth by respondent's expert, Dr. Ring. First, Dr. Huffman responds to petitioner's pre-existing history of bilateral rotator cuff problems. He notes that only the petitioner's left shoulder "has remained persistently symptomatic with an onset after her vaccination" with the only distinguishing "difference being vaccination administration with an adverse SIRVA incident." Pet. Ex. 29 at 1.

Dr. Huffman also disagrees with Dr. Ring's factual assertion that "short small needles are used for vaccinations." Pet. Ex. 29 at 1. Dr. Huffman explains that there has been a trend over the last ten years towards using one-and-a-half- to two-inch length needles for vaccine administration. Id. According to Dr. Huffman, this length "far exceeds the mean width of the middle deltoid." Id. Moreover, he asserts that "it is well established that iatrogenic needle placement in the bursa is common." Id.

The next point of disagreement is Dr. Ring's position that vaccines administered into the bursa cause no adverse effects. Dr. Huffman opines that vaccines contain "proinflammatory antigens that are designed to be placed in inert intramuscular positions" not in the bursa or intrarticular portion of the shoulder. Pet. Ex. 29 at 1-2. Lastly, Dr. Huffman disagrees with Dr. Ring's opinion that "rotator cuff tendinopathy is not caused by vaccination." Id. at 2. Dr. Huffman emphasizes the fact that there are multiple case reports and government experts (Atanasoff) who have provided "specific SIRVA criteria based on the understanding and knowledge of adverse effects when the vaccination is placed in or around the shoulder joint." Id.

B. Respondent's Expert, Dr. David Ring

Dr. Ring is an orthopedic surgeon who specializes in the care and treatment of upper limb disorders. Resp. Ex. A at 1. He attended medical school at the University of California, San Diego, and completed his internship in surgery at Massachusetts General Hospital. Resp. Ex. B at 1. Dr. Ring completed his residency in orthopaedic surgery at Harvard and was Chief Resident in orthopaedic surgery at Beth Israel Deaconess Medical Center. Id. Dr. Ring also completed a fellowship in hand and microvascular surgery at Massachusetts General Hospital. Id. Dr. Ring worked at Massachusetts General Hospital for thirty-three years and in 2016 joined the Dell Medical School at the University of Texas at Austin as the Associate Dean for

Comprehensive Care. Resp. Ex. A at 1. Dr. Ring has special expertise in "the psychological and social determinants of illness." Id. In his clinical practice, Dr. Ring has treated patients with shoulder problems since 2000. Id.

Respondent filed two expert reports by Dr. Ring. In his initial expert report, Dr. Ring opines that petitioner's 2007 MRI showed infraspinatus and supraspinatus tendinopathy requiring surgery. Resp. Ex. A at 1-2. Dr. Ring does not mention any symptoms or treatment relative to petitioner's left shoulder from 2007 until after her 2013 vaccination. See id. He agrees that petitioner attributed the left shoulder pain she experienced in 2014 to her vaccination. Id. at 2. Dr. Ring opines that petitioner's 2014 MRI showed evidence of her prior 2007 rotator cuff surgery as well as a "small defect in the supraspinatus" tendon. Id. He states that on January 19, 2015, Dr. Schwartz conducted surgery on petitioner's left shoulder, and later that year, petitioner's shoulder pain returned, and she had a steroid injection for it. Id.

In his expert report, Dr. Ring discusses rotator cuff tendinopathy, and describes the tendons that surround the top of the humerus, which make up the shoulder joint. See Resp. Ex. A at 2. The "tendons belong to muscles that rotate the shoulder, thus they are the rotator cuff of tendons." Id. He also explains the effects of aging on these tendons and asserts that "[m]ost small defects are part of the aging process." Id.

Next, Dr. Ring opines that needles used for vaccine administration are "too short to enter the subacromial space" or bone and asserts that it would be "extremely unlikely" for a short needle to accidently enter the joint space or bursa. Resp. Ex. A at 2. He further opines that there is no evidence that the flu vaccine can injure tissues. Id. He asserts that the likelihood of a flu vaccine causing shoulder injury is "essentially zero." Id. at 2-3. Dr. Ring states that "[g]iven the remarkable number of vaccinations administered each year, such damage, if it existed would have been recognized by now."[10] Id. at 2.

With regard to petitioner's left shoulder injury, Dr. Ring opines that "[petitioner] suffered no shoulder injury as a result of her December 2013 vaccination . . . [and] that it is far more likely than not that her left shoulder rotator cuff tendinopathy . . . and mild arthritis . . . are expected age-related changes in the shoulder." Resp. Ex. A at 3.

In his first expert report, Dr. Ring provides five references. See Resp. Ex. A at 4. None of the references relate specifically to shoulder injuries following vaccine administration. Generally, the articles relate to rotator cuff disease, misperception of disease onset, and the effect of financial compensation on disease outcome. See id.

In his second expert report, Dr. Ring expounds on the changes that occur to the rotator cuff tendons with aging. Resp. Ex. C at 1. He also discusses the "common error of equating new symptoms with new pathophysiology." Id. at 2. Dr. Ring suggests that "more rigid experimentation . . . is lacking in the current concept of 'SIRVA'" and that case reports are

[10] It is not clear from Dr. Ring's expert reports whether he reviewed the medical literature filed by petitioner that reference or discuss shoulder injuries related to vaccine administration.

scientifically inadequate to establish causation. Id. He references a post-licensure study related to the hepatitis A vaccine as an example of a more rigorous and appropriate approach to discern a causal association. Id. (citing Resp. Ex. C-12).[11] He also discusses his philosophy on causation and the perils of "assumption of harm" versus the merits of "the default position . . . that there is no causation." Id. Dr. Ring concludes that there is a "high probability" that the symptoms at issue here are "related to . . . age-appropriate changes [that] are just coincident with an annual vaccination in the shoulder region." Id. at 2-3.

At the end of his second report, Dr. Ring provides a list of references that generally discuss shoulder pathology seen on MRI and at autopsy in asymptomatic patients, rotator cuff changes associated with aging, comparisons of asymptomatic and symptomatic shoulders, a post-licensure study related to the hepatitis A vaccine, and an article on how intra-articular immunization can stimulate a positive immune response. See Resp. Ex. C at 3-4. None of the references discuss shoulder injuries related to vaccine administration.

IV. Factual Issues

A. Applicable Legal Standard

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her 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 testimony, 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)).

B. Factual Findings

Respondent does not dispute that petitioner received the vaccination at issue intramuscularly in her left deltoid on December 30, 2013. Rather, the primary disagreements in this case involve two of the SIRVA criteria: (1) onset of petitioner's left shoulder injury and (2) petitioner's pre-existing left shoulder injury which required surgery in 2007.

The undersigned resolved the issue of petitioner's onset of pain in the Ruling of Facts issued February 21, 2018, in which she found the onset of petitioner's symptoms occurred within

[11] Steven Black et al., A Post-licensure Evaluation of the Safety of Inactivated Hepatitis A Vaccine (VAQTA®, Merck) in Children and Adults, 22 Vaccine 766 (2004).

forty-eight hours of her flu vaccine administered on December 30, 2013.[12] That Ruling is incorporated herein by reference as if fully set forth.

The second issue, relating to petitioner's pre-existing shoulder injury, is addressed below in the context of the Althen v. Secretary of Health and Human Services analysis.

V. Legal Standard for Entitlement

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

To receive compensation through the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 300aa-13(a)(1)(A), 11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner's claim predates the inclusion of SIRVA on the Table, she must prove her claim by showing that her injury was caused-in-fact by the vaccination in question. § 300aa-11(c)(1)(C)(ii). To do so, petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

[12] In the concluding paragraph of the Ruling on Facts, the undersigned erroneously stated the date of petitioner's flu vaccination as December 13, 2013, instead of December 30, 2013. Ruling on Facts dated Feb. 21, 2018, at 6. Therefore, the undersigned restates her finding here with the correct date, so that there is no confusion.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 300aa-13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 300aa-13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

VI. Ruling on Entitlement

As described above, in order to receive compensation under the Vaccine Act, petitioner must prove causation by satisfying the three-pronged test set forth in Althen by a preponderance of evidence. 418 F.3d at 1278. In Althen, the Federal Circuit described this standard "as one of proof by a simple preponderance, of 'more probable than not' causation." Id. at 1279.

Although the first and second prongs of Althen appear to be similar, these analyses involve different inquiries. See Doe 93 v. Sec'y of Health & Human Servs., 98 Fed. Cl. 553, 566-67 (2011). The first prong focuses on general causation, whether the administered vaccine *can* cause the particular injury suffered by the petitioner, and the second prong focuses on specific causation, whether the administered vaccine *did* cause the injury. Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). This distinction "has been described as the 'can cause' vs. 'did cause' distinction." Stapleford v. Sec'y of Health & Human Servs., No. 03-234V, 2009 WL 1456441, at *18 (Fed. Cl. Spec. Mstr. May 1, 2009).

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

A. First Althen Prong

The mechanism for a SIRVA injury is well described in medical literature filed in this case. Specifically mentioned as supporting this causal association are the Atanasoff and Bodor articles. To summarize, the authors in Atanasoff stated that "[a]lthough shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination . . . is consistent with a robust and prolonged immune response." Pet. Ex. 28.1 at 3. They further noted that some of their MRI findings showing tears in shoulders "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." Id. In Bodor, the authors discussed two patients with shoulder pain and weakness following the administration of a vaccine high in their deltoid muscles and found multiple structures within the shoulder to be involved, suggesting "a primary inflammatory etiology rather than a mechanical overuse problem." Pet. Ex. 28.6 at 1-3. They concluded that "the diagnosis of vaccination-related shoulder dysfunction . . . [should] be considered in patients presenting with shoulder pain and weakness following a vaccine injection." Id. at 3.

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

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

Additionally, the undersigned notes that, prior to the adoption of the revised Table, which is effective for petitions filed on March 21, 2017 and later, respondent conceded entitlement in numerous SIRVA cases alleging causation by an intramuscularly administered flu vaccine. See, e.g., Cothern v. Sec'y of Health & Human Servs., No. 14-574V, 2014 WL 6609687 (Fed. Cl. Spec. Mstr. Oct. 15, 2014); MacLaughlin v. Sec'y of Health & Human Servs., No. 17-57V, 2018 WL 3030269 (Fed. Cl. Spec. Mstr. Mar. 16, 2018). Even after the revised Table became effective, respondent continued to concede cases which may not have met the Table criteria, but in which respondent, nevertheless, believed causation had been established. See, e.g., Buras v. Sec'y of Health & Human Servs., No. 17-1012V, 2018 WL 4042194 (Fed. Cl. Spec. Mstr. Apr. 13, 2018).

Moreover, petitioner submitted the expert opinion of Dr. Huffman who provided a sound and reliable medical and scientific theory of causation supported by medical literature. The proposed mechanisms include direct injection into the bursa with a resultant inflammatory response and a regional immunogenic response causing bursitis.

The undersigned finds petitioner provided preponderant evidence that the seasonal flu vaccine administered intramuscularly can cause SIRVA. General causation is established, and therefore, petitioner satisfied the first Althen prong.

B. Second Althen Prong

With regard to the second Althen prong, the undersigned finds there is a preponderance of evidence in the exhibits filed and testimony given to support a logical sequence of cause and effect showing the December 30, 2013 flu vaccination to be the cause of petitioner's left shoulder pain. See Althen, 418 F.3d at 1278. First, Dr. Ryan's report and the medical literature provide a framework for evaluating whether petitioner's claim is consistent with SIRVA. The criteria are as follows:

- No history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration;
- Pain occurs within the specified time frame;
- Pain and reduced range of motion are limited to the shoulder in which the vaccine was administered; and
- No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Pet. Ex. 28.2 at 9. A vaccinee is considered to have suffered from a SIRVA injury if she manifests all four of the above criteria. Id.

1. Prior Condition

There is no question that petitioner had prior history of left shoulder problems in 2007 that required surgery. The issue here is whether she had any history of pain, inflammation, or dysfunction of her left shoulder prior to her December 2013 vaccination to explain her symptoms of shoulder pain and decreased range of motion that occurred after vaccine administration. On August 3, 2007, petitioner had rotator cuff repair surgery and subacromial decompression of her left shoulder. Pet. Ex. 9 at 18-19. On November 19, 2007, at her post-operative appointment, petitioner had full range of motion and was doing well. Id. at 2. There is no evidence that petitioner had any continuing pain, problems with range of motion, or any other problems with her left shoulder until after she received the flu vaccine at issue in this case.

Further, petitioner filed a supportive expert opinion regarding this issue. Dr. Huffman explains that Dr. Alpert's records show that "[petitioner] had good strength and . . . full range of motion" three to four months after her shoulder surgery in 2007. Pet. Ex. 27 at 6. Dr. Huffman reviewed petitioner's medical records and agrees that "[t]here is no record or indication of symptoms in [petitioner's] shoulder" to suggest petitioner had any further problems associated with her 2007 injury. Id. While there is no question that petitioner had a prior history of left shoulder rotator cuff tear and surgical repair, Dr. Huffman opines that "there was no repeated trauma to her shoulder or other inciting event other than the vaccination to explain her pain, dysfunction and need for surgery in 2014." Id. at 7. Dr. Huffman concludes that petitioner's

"left shoulder was asymptomatic for [seven] years until the time of flu vaccination in December 2013." Id. Like Dr. Huffman, Dr. Ring does not mention any symptoms or treatment relative to petitioner's left shoulder from 2007 until after her 2013 vaccination. See Resp. Ex. A, C.

Based upon a review of the record as a whole, including the medical records, factual testimony, and expert reports, the undersigned finds there is no evidence that petitioner experienced any issues with her left shoulder for approximately seven years prior to vaccination. Petitioner's history of a remote left rotator cuff injury should not preclude her from recovering for an injury sustained as a result of her flu vaccination in 2013.

2. Scope of Pain and Limited Range of Motion

Based on the petitioner's testimony and medical records, petitioner's vaccine-related symptoms were limited to her left shoulder. Petitioner had problems with her right hip and back in 2014, but she did not allege that these problems were related to vaccination. In the records from petitioner's May 10, 2014 visit to her chiropractor, Dr. Deborah Weinstock, petitioner complained of shoulder pain. Pet. Ex. 8 at 2. She saw Dr. Schwartz in July 2014, complaining of left arm pain for seven months, and he found petitioner had limited range of motion. Pet. Ex. 2 at 1. A July 2014 MRI showed a rotator cuff tear. Pet. Ex. 4 at 1-2. Relative to the left shoulder injury alleged in the petition, there is no indication that petitioner experienced pain or limited range of motion in any area other than her left arm and shoulder.

3. Other Condition or Abnormality

Dr. Huffman identifies no other condition or abnormality to explain petitioner's symptoms. He concludes that while "[petitioner] ha[d] a prior history of a left shoulder traumatic rotator cuff tear, there was no repeated trauma to her shoulder or other inciting event other than the vaccination to explain her pain, dysfunction and need for surgery in 2014." Pet. Ex. 27 at 7. In contrast, Dr. Ring opines that petitioner's shoulder injury is not a result of her December 2013 vaccination, but caused by aging. Resp. Ex. A. at 3.

Based upon the medical literature filed by respondent, it appears that it is not uncommon for people of petitioner's age to have age-related changes and arthritis in their shoulders. Given her age, which at the time of the 2013 vaccination was sixty-four,[13] and her medical history, it would not be surprising for petitioner to have age-related shoulder pathology. However, she did not have left shoulder symptoms for approximately seven years prior to her vaccination. In Atanasoff, the authors stated that a "rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis . . . may cause no symptoms until provoked by trauma or other events." Pet. Ex. 28.1 at 3. The authors concluded that some of the injuries shown in their MRI findings "may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation." Id. Here, petitioner may have had pre-existing pathology, but she was not symptomatic until after vaccination. Thus, but for her vaccination in December 2013, she would not have suffered a symptomatic shoulder injury. See Shyface, 165 F.3d at 1352-53.

[13] See Pet. Ex. 1 at 11 (noting petitioner's date of birth as September 22, 1949).

The undersigned finds there is nothing in the medical records filed or testimony given that points to another condition or abnormality as the cause of petitioner's symptoms.

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

C. Third Althen Prong

As stated in the earlier fact ruling and above, the undersigned finds the onset of petitioner's left shoulder pain occurred within forty-eight hours of vaccination. The timing of onset shows a proximate temporal relationship between vaccination and injury. See Althen, 418 F.3d at 1278.

The undersigned finds the evidence discussed in this ruling qualifies as preponderant evidence to show the flu vaccine caused petitioner's shoulder injury within the time frame required. The temporal association is appropriate given the mechanism of injury. Thus, petitioner has satisfied the third Althen prong.

VII. Conclusion

Based on the record as a whole, including the testimony of petitioner and her witnesses, and the petitioner's expert opinions, the undersigned finds there is preponderant evidence to satisfy Althen and to establish petitioner's December 30, 2013 flu vaccination caused her left shoulder pain and limited range of motion, resulting in the need for surgery. **The undersigned finds petitioner entitled to compensation.**

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master