In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 12, 2019

MAYA SANDOVAL,	*	PUBLISHED
	*	
	*	No. 16-304V
Petitioner,	*	
v.	*	Special Master Gowen
	*	
	*	Decision on Entitlement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Michael A. Firestone, Marvin Firestone, MD, JD & Associates, San Mateo, CA
Camille M. Collett, Department of Justice, Washington, D.C.

RULING ON ENTITLEMENT[1]

On March 8, 2016, Maya Sandoval ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccination she received on October 18, 2013. Petition at ¶ 1.

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this opinion contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the opinion will be available to anyone with access to the Internet.** Before the opinion is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the court's website without any changes.** *Id.*

[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) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

Based on a full review of all the evidence and testimony presented at the entitlement hearing held in San Francisco, CA on May 2-3, 2019, I found the petitioner is entitled to compensation.[3]

I. BACKGROUND

A. Procedural History

On March 8, 2016, petitioner filed her petition alleging that the flu vaccine was the cause-in-fact of her developing a right shoulder injury. (ECF No. 1). This case was originally assigned to the Special Processing Unit ("SPU"). Petitioner filed medical records associated with the claim on March 18, 2016 and May 31, 2016. (ECF Nos. 8, 11 & 12). On August 8, 2016, petitioner filed an amended petition, adding the alternative pleading that the flu vaccine caused a significant aggravation of a pre-existing shoulder condition "which prior to the October 18, 2013 vaccine, was asymptomatic." Amended Petition at ¶ 17. (ECF No. 17).

On November 7, 2016, respondent filed a Rule 4(c) Report stating that based on the evaluation of the medical evidence it his position that compensation is not appropriate. Respondent's Report ("Resp. Rep.") (ECF No. 24) at 1. Respondent argued that petitioner provided no evidence of a logical sequence of cause and effect supporting her contention that she suffered any injury or condition as a result of the flu vaccine petitioner received on October 18, 2013. *Id.* at 13. Respondent stated that, at the time, no expert report had been filed and petitioner's treating physicians associated her shoulder complaints to her torn rotator cuff. *Id.* at 13. Further, respondent argued that petitioner failed to show a proximate temporal relation between the vaccination and injury. *Id.* Respondent's main contention is that petitioner did not report any shoulder pain until March of 2015. *Id.*

The case was reassigned to the undersigned Special Master for further proceedings. (ECF No. 25). After a status conference held on December 13, 2016, the undersigned ordered petitioner to submit a supplemental affidavit addressing the lack of medical treatment for her shoulder pain for a period of seventeen months and to submit an expert report on how a SIRVA injury may lead to the significant damage or deterioration of the shoulder. Scheduling Order (ECF No. 30).

On February 13, 2017, Dr. John Costouros, a Clinical Assistant Professor of Orthopaedic Surgery at Stanford University Medical Center, submitted an expert report and supporting medical literature for petitioner. Petitioner's Exhibit ("Pet. Ex.") 35 (ECF No. 31). On June 22, 2017, respondent filed an expert report by Dr. Robert Lightfoot, a rheumatologist and currently a Professor of Medicine Emeritus, at the University of Kentucky. Respondent's Exhibit ("Resp. Ex.") A (ECF No. 37).

I held a Rule 5 Status Conference on July 18-19, 2017, at which the petitioner appeared in addition to her counsel and respondent's counsel. Rule 5 Order (ECF No. 38). When petitioner was questioned about the delay in reporting her shoulder pain, petitioner responded

[3] Pursuant to §300aa-13(a)(1), in order to reach my conclusion, I considered the entire record, including all of the medical records, statements, expert reports, medical literature and testimony presented at the entitlement hearing submitted by both parties. This opinion discusses the elements of the record I found most relevant to the outcome.

that she associated the pain with a fibromyalgia flare-up and saw no reason to bring it up to her medical providers as she was uninterested in taking any medication. *Id.* at 2. Respondent requested petitioner file any official records from her former employer to reflect how she had to curtail her teaching duties. *Id.* Respondent further requested medical records relating to petitioner's fibromyalgia diagnosis. *Id.* During this status conference, the parties requested a fact hearing. *Id.* I order petitioner to file a supplemental expert report addressing multiple questions. *Id.* Further, I recommended the parties pursue informal settlement, as this case posed significant litigative risk. *Id.* The parties agreed to pursue both options, still requesting an entitlement hearing date be set for May 2019. *See* Petitioner ("Pet.") Status Report (ECF No. 29).

In January 2018, respondent filed a status report indicating that settlement was not possible, and it was his intention to defend against this claim. Respondent ("Resp.") Status Report (ECF No. 51). An entitlement hearing was scheduled for May 2-3, 2019 in San Francisco, CA. Hearing Order (ECF No. 58).

The parties submitted pre-hearing briefs outlining the relevant factual and legal issues that needed to be resolved. *See* Pet. Prehearing Brief; Resp. Prehearing Brief. (ECF Nos. 63 & 72). A hearing was held on May 2-3, 2019 in San Francisco, CA.

Petitioner submitted fact testimony from herself, Ms. Naheed Farooq, Ms. Summera Farooq, Ms. Kathleen Wit, Ms. Karen Green, and Mr. Seth Dardis. Petitioner also submitted expert testimony from Dr. John Costouros.[4] The respondent submitted expert testimony from Dr. Robert W. Lightfoot.[5]

[4] Dr. John Costouros received his bachelor's degree with honors in biological sciences from Stanford University in 1994 and his M.D. from the University of California, San Francisco in 1998. Pet. Ex. 37 at 1. He completed his general surgery internship, orthopaedic surgery residency, and arthritis research fellowship at the University of California, San Francisco between 1998 and 2004. This was followed by arthroscopic and reconstructive shoulder & elbow surgery fellowships at Harvard Medical School and the University of Zürich in 2004 and 2005. *Id.* Dr. Costouros is board certified in orthopaedic surgery with an added qualification of sports medicine. Pet. Ex. 37 at 2. He was an adjunct professor in the department of kinesiology and biomechanics at San Jose State University from 2006 through 2013. *Id.* He was the medical director of the Graduate School of Athletic Training at San Jose State University from 2008 through 2013. *Id.* Dr. Costouros joined the faculty at Stanford University as an assistant professor of orthopaedic surgery in 2011. *Id.* Dr. Costouros is currently on the Program Committee of Shoulder and Elbow Education Sessions at the American academy of Orthopaedic Surgeons. *Id.* Dr. Costouros is an active practitioner and is the attending surgeon at Stanford University Healthcare and Lucile Packard Children's Hospital. Pet. Ex. 37 at 4. Dr. Costouros has published extensively in the field of orthopaedic surgery. Pet. Ex. 37 at 6-21. Dr. Costouros has served as an expert witness in the Vaccine Program and is qualified as an expert in orthopaedic surgery.

[5] Dr. Robert Lightfoot received his bachelor's degree in 1958 and his M.D. in 1961, both from Vanderbilt University. Resp. Ex. B at 1. He completed his internship at Columbia Presbyterian Medical Center in New York in 1962 followed by his residency at Columbia Presbyterian Medical Center and Vanderbilt University Hospital in 1964. *Id.* Dr. Lightfoot then completed his rheumatology fellowship at Columbia University in 1966. He is board certified in internal medicine and rheumatology. *Id.* Over the course of his career, he has had academic positions at Columbia University, Cornell University, the Medical College of Wisconsin, and the University of Kentucky where he is currently the Professor of Medicine Emeritus. Resp. Ex. B at 1-2. He has also been an active practitioner of rheumatology for over 40 years. Resp. Ex. B at 2-3. Dr. Lightfoot is a member of the American College of Physicians, the American College of Rheumatology, and has served on the board of the Arthritis Foundation. Resp.

At the conclusion of the hearing, the I informed the parties that I intended to issue a ruling from the bench. The parties consented. I stated that the ruling would resolve the factual disputes between the parties and whether the petitioner was entitled to compensation.

II. FINDING OF FACT

A. Legal Standard

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *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).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110

Ex. B at 3-4. Dr. Lightfoot has conducted extensive research in the field of rheumatology and arthritis as well as published many original articles in peer-reviewed journals about the subject. Resp Ex. B at 15-26. Dr. Lightfoot has served as an expert witness in multiple Vaccine Program cases and is qualified as an expert in rheumatology.

Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A special master's ruling on entitlement may be delivered from the bench, with no written opinion. *Doe/17 v. Sec'y of Health & Human Servs.,* 84 Fed. Cl. 691, 704 n.18 (2008). A published written decision memorializing a decision from the bench allows the public access to the reasoning underlying the bench decision. *See Heddens v. Sec'y of Health & Human Servs.*, No. 15-734, 2018 WL 5726991 (Fed. Cl. Spec. Mstr. Oct. 5, 2018) (rev. den., 143 Fed. Cl. 193, *Heddens v. Sec'y of Health & Human Servs.* (2019); *Jaafar, on behalf of A.M. v. Sec'y of Health & Human Servs.*, No. 15-267, 2018 WL 4519066 (Fed. Cl. Spec. Mstr. Aug. 10, 2018). Further, issuing a written decision provides an abbreviated recitation for the basis of decision. *See Hebern v. U.S.*, 54 Fed. Cl. 548 (2002) (example of order affirming bench ruling).

This particular written decision is consistent with, but expands upon, the earlier bench ruling. It provides further reasoning as to why I found the petitioner entitled to compensation.

B. Left Arm/Right Arm

The key factual issue to be resolved is whether petitioner received the October 18, 2013 flu vaccine in her right or left arm. *See* Pet. Prehearing Submissions at 6-7; Resp. Prehearing Submissions at 13-14. Petitioner asserted that she received the covered flu vaccine in her right arm. Respondent argued that there is no objective evidence that supports petitioner's contention that she received the vaccines in her right arm. Resp. Rept. at 13.

The medical record from the day of vaccine administration is silent as to which arm the vaccines[6] were given. Pet. Ex. 2 at 32. Three days after the vaccine, on October 21, 2013, petitioner sought treatment from Dr. Lenoir for slurred and garbled speech, altered mental status, balance disturbances, memory disturbances and vomiting. *Id.* at 29. The record also notes "….pt had flu vac on Friday last week and she believes that she had a reaction to vac. Pt *left* shoulder is red and sore, also itching." *Id.* She was assessed with "possible aphasia TIA[7] high on the differential" and the symptoms of stroke were described to petitioner. *Id.*

In petitioner's first affidavit, she states she received the flu vaccine in her right upper arm. Pet. Aff. at ¶ 3. She maintained this position throughout the course of litigation. During the hearing, petitioner testified that she had always received vaccines and blood work in her right arm. Tr. 59. She acknowledged that she is right hand dominant and most people get their blood work and vaccinations in their nondominant arm. Tr.60. However, she "always carried my purse on the left arm and left my good hand-my dominant hand free to get out….my cell phone or a pen or paper." *Id.* She said this was the same for when carrying her children as babies. *Id.* She indicated she "always had a preference…for not having injections in the left." *Id.*

[6] Petitioner also received a non-covered Pneumovax vaccination. Pet. Ex. 2 at 32.

[7] Transient ischemic attack ("TIA").

When questioned where she received the flu vaccination on October 18, 2013, petitioner pointed to an area about an inch below her shoulder on her right arm. Tr. 63. She stated she felt pain almost immediately after the vaccinations that began in one small area and spread to the top of her right shoulder. Tr. 62. She explained that she was in so much pain after receiving her vaccinations, she had trouble driving home and "handling the wheel with my right arm." Tr. 64. When she got to her apartment that evening, petitioner stated she felt achy and fatigued and went to bed until the following day. *Id.*

Petitioner explained that on Saturday, October 19, 2013, she woke up, made a phone call and drank coffee then went back to bed for most of the day. *Id.* That evening she was found in the hallway in her pajamas by her neighbor, Gary, who saw petitioner struggling to get into her apartment. Tr. 67. He phoned Mrs. Naheed Farooq, petitioner's upstairs neighbor, to help her get into her apartment. *Id.*

At the hearing, Mrs. Naheed Farooq testified that when she saw the petitioner on the evening of October 19, 2013, the petitioner was acting peculiar. Tr. 10. Mrs. Farooq said that the petitioner was not speaking coherently or acting in a normal manner. Tr. 11. She explained, "she [Ms. Sandoval] not understand what she's doing." *Id.* Mrs. Farooq stated that she helped petitioner into her apartment and initially left, but then came back to help put the petitioner into bed. *Id.* When Mrs. Farooq returned to the apartment, she observed that the petitioner had thrown up. *Id.* Mrs. Farooq then tried to help the petitioner change her clothes. *Id.* As Mrs. Farooq attempted to pull the petitioner up to change her, petitioner expressed pain in her right arm, so Ms. Farooq had to push the petitioner into a sitting position. Tr. 12. Mrs. Farooq testified that she observed petitioner's right shoulder as "pink and red." Tr. 13. Two days later, on Monday, October 21, 2013, Mrs. Farooq saw petitioner returning from the doctor's office. Tr. 15-16. Mrs. Farooq stated that petitioner complained about her right shoulder after coming back from the doctor's office. *Id.*

Mrs. Naheed Farooq's daughter, Mrs. Sumemra Farooq also testified that petitioner, "not her usual self," on the evening of October 19, 2013. Tr. 26. She testified that petitioner was "walking, stumbling around the house from one end to the other end." *Id.* When Mrs. Summera Farooq saw the petitioner a few days later, she indicated that her right arm was hurting. Tr. 27. Ms. Summera Farooq stated she observed the petitioner's right arm as being "pinkish and a little reddish." *Id.*

The petitioner submitted multiple medical articles that describe the commonality of left/right errors. *See* Pet. Ex. 28; Pet. Ex. 64; Pet. Ex. 65.[8] McKinley et. al, studied the effect of cognitive distraction on medical student's ability to discriminate left from right. Pet. Ex. 28 at 5. The study found that medical students' own perception of their ability to discriminate between right and left are generally inaccurate. *Id.* at 6. It also found that cognitive distraction had a

[8] Sheldon M. Wolfe, *Difficulties in Right-Left Discrimination in a Normal Population*, 29 Neurology 128 (1973) [Pet. Ex. 31]; John McKinley, et. al., *'Sorry, I meant the patient's left side': impact of distraction on left-right discrimination*, 49 Medical Education 427-435 (2015) [Pet. Ex. 28]; Gerard J. Gormley, *Right-left discrimination among medical students: questionnaire and psychometric study*, 337 BMJ a2826 (2008) [Pet. Ex. 65]; and Samuel C. Seiden, MD & Paul Barach, MD, *Wrong-Side/Wrong-site, Wrong-Procedure and Wrong-Patient Adverse Events*, 141 Arch. Surg., 931-939 (2006) [Pet. Ex. 64].

greater negative impact on left-right discrimination test performance. *Id.* at 1. Sheldon M. Wolfe reported that out of a group of physicians and their spouses, 17.5% of women and 8.8% of men self-reported that they experienced frequent confusion in right-left orientation. Pet. Ex. 31 at 1-2.

During cross-examination, the respondent's expert, Dr. Lightfoot, acknowledged that mistakes between left and right occur in medical documentation. Tr. 278. He further stated that "some doctors and I'm assuming some other health professionals, have right/left issues." Tr. 279. He then continued, by describing the time constraints facing many physicians with outpatient settings, stating "what almost everyone will do is they'll finish, they'll take notes and *enter the important part at the end of the clinic or in the evening at home or something like that*." *Id.* [9] (emphasis added). He concluded by saying, "in that setting where your actual documentation becomes sometime after you're seeing the patient, especially if you're a person that has right/left issues, you might dictate that the left shoulder was this or right shoulder was that." Tr. 280.

Respondent argues that the petitioner's affidavits and oral testimony are insufficient to overcome the presumption that her medical records are accurate and complete. Resp. Memo at 13. Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *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). In cases in which a court has based a finding upon lay testimony, there must be corroborating evidence, either medical or otherwise to support the claim. *Epstein v. Sec'y of Health & Human Servs.,* 35 Fed. Cl. 467, 478 (1996).

In this case the medical records are not clear. When petitioner received her flu vaccine, the location of the vaccination was not documented. Pet. Ex. 9 at 187. At the first medical appointment three days after the vaccine, a nursing note states "pt left shoulder is red and sore also having itching, pt. having dizzy spells." Pet. Ex. 2 at 29. This record does not actually say that petitioner received the vaccine in her left shoulder.

In a letter by Dr. Lenoir, petitioner's primary care physician, dated August 16, 2015, she stated that "the office visit mentions left arm as where the shot was administered. In retrospect, it may have been her right arm." Pet. Ex. 3 at 1. She continued by stating, "it is possible that my medical assistant may have entered the wrong side in the electronic medical record (EMR) program, or the system could have reverted to the default setting." Pet. Ex. 3 at 1. Dr. Lenoir

[9] In fact, Dr. Lightfoot's description of medical professionals entering in notes after an appointment is exactly what happened in at least two of the petitioner's medical records. For example, petitioner had her Medical Annual Wellness Exam on May 14, 2014 at 8:30 AM. Pet. Ex. 2 at 17. However, it appears that Dr. Beltran did not actually create the documentation until 9:00 pm that evening and she did not sign it until May 26, 2014. *See* Pet. Ex. 9 at 157. A similar situation happened following petitioner's June 27, 2014 appointment. Pet. Ex. 2 at 12. The medical records show she had an office visit on June 27, 2014 at 10:00 am. *Id.* However, on June 29, 2014, Dr. Beltran entered chart notes at 9:48 PM for the June 27, 2014 visit. Pet. Ex. 9 at 124.

explained that "I do have an independent recollection of her complaining about significant pain in her arm-I just don't remember now, which side it was, because at the time I was focused on ruling out whether her reported symptoms of dizziness and confusion/difficulty speaking were attributed to a potential stroke." *Id.* She further stated that "I have always felt that she was a reliable historian." *Id.*

Petitioner testified credibly that she received her vaccination on her right arm. Other lay testimony also corroborated petitioner's testimony as to the pain petitioner experienced in her right shoulder in the immediate days following the flu vaccine. Additionally, the testimony of Dr. Lightfoot regarding the delayed entry of case notes into medical records by health care professionals and the medical literature submitted by the petitioner regarding the existence of right/left discrimination issues in the medical practice, also make it plausible that the singular notation of the petitioner's left shoulder as the affected shoulder was entered in error.

In light of the lone medical record suggesting that the post-vaccine injury was in the left arm, credible testimony of petitioner and the other lay witnesses that had knowledge of the events immediately following petitioner's vaccinations, the testimony of the experts and the medical literature submitted describing common left/right errors, I made the following finding at the conclusion of the hearing:

> First issue was the right-left discrimination issue. And I have concluded that the history taking in these types of situations often contain errors and the medical practitioners are not nearly so focused on some of the issues of causation and documentation at times as we are in the litigative process after it…. Mrs. Sandoval very credibly explained that issue, and I concluded that the vaccination was given in the right side.
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> Tr. 288.

III. Ruling on Entitlement

A. Legal Standard

The Vaccine Act provides two avenues for petitioners to receive compensation. A petitioner may demonstrate either that she suffered a "Table" injury,[10] or that she suffered a different injury which was caused-in-fact by a vaccine listed on the Vaccine Injury Table. In the present case, petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table Injury. However, my findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims.

The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS,* 418 F.3d 124, 1248 (Fed. Cir. 2005). 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

[10] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 U.S.C. § 100.3, corresponding to the vaccine received within the time-frame specified.

1279. 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. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Under the *Althen* test, petitioner must show, by a preponderance of the evidence the following: 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 the vaccination and the injury. *Althen*, 418 F.3d at 1278.

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires petitioners to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.,* 219 F.3d 1357, 1361 (Fed. Cir. 2000). Expert testimony in the Vaccine Program is usually evaluated according to the factors set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo,* 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Human Servs.,* 195 F.3d 1302, 1316 (Fed. Cir. 1999). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. v. Sec'y of Health & Human Servs.,* 592 F. 3d. 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in *weighing* the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.,* 94 Fed. Cl. 53, 66-67 (2010).

Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder Ex Rel. v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner,* 522 U.S. 146 (1997)). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

B. SIRVA Definition

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, my 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 S. Atanasoff, et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010)).

1. No History of Pain, Inflammation or Dysfunction of the Affected Shoulder Prior to Vaccine Administration

The first criteria for SIRVA is that a petitioner must show that there was no history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration.

Petitioner acknowledged that she was diagnosed with fibromyalgia in 1994. Tr. 38; Rule 5 Order at 1. She described the pain associated with her fibromyalgia as "achy, but in a really deep way," that occurred bilaterally down the back of her neck, down the back of her shoulders to her mid-back. Tr. 42-44; *Id*. However, she also testified that she never experienced any reduced range of motion as a result of her fibromyalgia. Tr. 76. She explained that despite her fibromyalgia, she did yoga every day, cleaned her house independently, and cared for her brother when he was released from the hospital. Tr. 53. She stated, "the fibromyalgia never prevented me from doing anything physical." *Id.* The medical records also confirm that she had no functional shoulder limitations prior to her vaccinations. *See* Pet. Ex. 2 at 33-34, 42-45; Pet. Ex. 13 at 24-26, 29, 74-76.

A month prior to the petitioner's vaccination, she sought treatment from Dr. Beltran for "pain from fibromyalgia." Pet. Ex. 9 at 192. The medical note explains that the petitioner was "seeking medication options, outside of narcotics." Pet. Ex. 9 at 193. A review of systems revealed petitioner was positive for bone/joint symptoms and myalgia. *Id.* The "musculoskeletal" section of the physical exam describes "overview is aches, spasms." *Id.* Notable about this medical record is that there is no reference to pain, inflammation or dysfunction of the petitioner's right shoulder.

Dr. Costorous observed that the petitioner's prior medical history was notable for fibromyalgia, hyperlipidemia, hypothyroidism and osteoporosis. Pet. Ex. 35 at 7. He stated that

he "did not appreciate evidence of a prior history of significant pain or dysfunction of the same [right] shoulder." *Id.*

Dr. Lightfoot described petitioner's past medical history to include fibromyalgia, hyperlipidemia, hypothyroidism, osteoarthritis of the knee and osteoporosis. Resp. Ex. A at 3, 6. Dr. Lightfoot continued, stating that petitioner "had an endocrine condition, hypothyroidism, periodic undertreatment of which prescription refill lapse….could have aggravated any of those prior painful conditions." *Id.* at 6. But notably, Dr. Lightfoot does not describe any pain, inflammation or dysfunction specific to the petitioner's right shoulder.

Based on the petitioner's medical records and credible testimony, I found that the petitioner did not have any prior history of pain, inflammation or dysfunction in her right shoulder prior to the flu vaccine administered on October 18, 2013.

2. Onset of Pain within the Specified Time Frame

The next criteria for SIRVA is that onset of symptoms is within the specified time-period of less than or equal to 48 hours.

Petitioner asserted that her pain began almost immediately after the vaccine. Petition at ¶ 4; Tr. 63. Respondent argues that petitioner's onset of right shoulder symptoms was first documented in March 2015, seventeen months after receiving the vaccination. Resp. Rept. at 11 n.11; Resp. Memo at 14.

Three days after the vaccination, petitioner called her medical provider at 4:45 am on October 21, 2013 to report symptoms of forgetfulness, "as well as flu like symptoms." Pet. Ex. 9 at 184. Later that day, petitioner saw Dr. Lenoir who was "focused on ruling out whether her reported symptoms of dizziness and confusion/difficulty speaking were attributed to a potential stroke." Pet. Ex. 3 at 1. The medical record from that day also includes a notation that "pt left shoulder is red and sore…" Pet. Ex. 2 at 29.

Petitioner testified that the pain in her right shoulder began immediately. Tr. 28, 63, 75. She stated that the feeling of "wet heat" eventually went away, but the pain remained. Tr. 75. She further testified that she had decreased range of motion. *Id.* When asked why she did not raise the pain with her doctor in appointments following the vaccination, she testified that she believed it was a fibromyalgia flare-up. *Id.* Additionally, she stated that there was no point in mentioning shoulder pain to other doctors for "other things" such as the gastroenterologist, the orthopedist for a left hand injury or the gynecologist. Tr. 76.

She explained, however, that after a while she realized the pain and reduced range of motion were different in her right shoulder after the vaccine from the pain associated with her pre-existing fibromyalgia. Tr. 76-77. Her fibromyalgia symptoms were bilateral in the neck and shoulders and never affected her range of motion. Tr. 75-77. However, after the vaccine the pain and reduced range of motion never manifested in her left shoulder, she began to believe it was something other than her fibromyalgia causing her right shoulder issues. Tr. 76-77.

Mr. Seth Dardis, petitioner's son, testified that in the fall of 2013, petitioner complained about pain in her shoulder. Tr. 240. He explained that petitioner asked him what she could use in her classes so she would not have to write on the chalkboard. *Id.* Mr. Dardis suggested an LCD projector to project her notes onto a big screen. Tr. 240-41. He explained that she was unable to figure out the control panel settings and how to change the monitor settings, so that solution did not work for her. Tr. 241. He testified that petitioner had never mentioned difficulties of work before the fall of 2013 when she was looking for alternative ways to "not have to write on the board." Tr. 242.

He explained that around Christmas in 2013 petitioner was having difficulty moving pots and pans and reaching for glasses with her right arm. Tr. 241. He explained that petitioner told him that she was unable to lift her arm very high, her right arm was weak and painful. *Id.*

Respondent argues that petitioner's contemporaneous records do not establish that her injury manifested within the medically appropriate timeframe. Resp. Memo at 13. He observed that there were eighteen (18) medical encounters between her vaccination and when she reported severe pain which she attributed to her vaccination on October 18, 2013, that did not mention any shoulder pain or functional issues. Tr. 13-14. Respondent also notes that petitioner received an additional vaccination the following year, in September 2014. *Id.*

At the first medical appointment following the vaccination, petitioner did report having shoulder pain and soreness to her medical provider. Pet. Ex. 2 at 29. As discussed above, even though the notation implies the left arm was associated with the flu vaccine, I found that petitioner established that she received the vaccination at issue in her right arm. It is also very credible, given the other symptoms that she had experienced during the intervening weekend, that Dr. Lenoir was heavily focused on addressing the possibility of a life threatening or disabling stroke. *See* Pet. Ex. 3.

While respondent is correct to point out there are multiple medical records between the vaccination at issue and when she reported the right shoulder pain to a medical professional, a close examination of these records reveal that these medical appointments included exams focused on petitioner's other health issues and full musculoskeletal exams were not performed. For example, she sought treatment on January 13, 2014 for an ongoing cough. Pet. Ex. 2 at 21. On May 27, 2014, petitioner sought a referral for a gastrologist for GERD symptoms. Pet. Ex. 9 at 134. In June 2014, petitioner saw Dr. Corey, for fatigue swollen lymph nodes and heart burn. Pet. Ex. 13 at 51. Dr. Corey performed a targeted exam focusing on petitioner's head, oral cavity, neck and nose. *Id.* In September 2014, petitioner had a colonoscopy. *Id.* at 56-57. On January 6, 2015, petitioner met with Dr. Lenoir to review her thyroid labs. Pet. Ex. 2 at 5. Petitioner met with an orthopedic hand surgeon regarding left hand injury and it appears the exam focused solely on her left hand. Pet. Ex. 12 at 1-3. It is also important to point out that while petitioner received an annual flu vaccine in the fall of 2014, the location of the vaccine was not documented for this date either. Pet. Ex. 9 at 116-18. Petitioner testified that after the vaccines administered in the fall of 2013, she requested that all bloodwork and subsequent vaccines be administered to her left arm, "because the right one was too painful." Tr. 170.

Additionally, Mrs. Naheed Farooq and Mrs. Summera Farooq's testimonies support the petitioner's onset of symptoms was within 48 hours. Mrs. Naheed Farooq saw the petitioner the day immediately following the vaccination. Tr.10. Mrs. Naheed Farooq testified that petitioner expressed having pain in her right shoulder while she was helping the petitioner change clothes. Tr. 13. Additionally, Mrs. Farooq saw the petitioner three days after the vaccination and again, she complained about pain in her right shoulder. Tr. 16. Mrs. Summera Farooq testified that she observed petitioner's right upper arm as being "pinkish and a little reddish." Tr. 27. She also testified that the petitioner complained of right arm pain a few days after the vaccination. *Id.*

In this case, the petitioner was able to provide clear, cogent and consistent testimony about the onset of her symptoms. She presented corroborating testimony from witnesses, Mrs. Naheed Farooq and Mrs. Summera Farooq, who interacted with the petitioner in the three days immediately following the vaccination.

At the conclusion of the hearing, I found that the petitioner's onset of symptoms was within the required timeframe provided in the Table for a SIRVA. I stated:

> Mrs. Sandoval presented very credible testimony and all of her witnesses were entirely supportive and sufficiently consistent in describing what they knew of her and the onset and nature of the pain that she was suffering. So, I have concluded that she has credibly demonstrated that the pain started very shortly after the vaccine was administered….You had an onset within 48 hours that remained painful and continued on into the present time.

Tr. 289.

3. Pain and Reduced Range of Motion are Limited to the Shoulder in which the Intramuscular Vaccine was Administered

The third criteria for SIRVA is that pain and reduced range of motion are limited to the shoulder in which the vaccine was administered. As discussed above, I found the petitioner received the flu vaccine in the right shoulder.

During the hearing, the petitioner described the pain and the location of the pain she felt following the flu vaccine. Tr. 62. She indicated that the pain immediately after the vaccine was a "burning" sensation that was located around the top two inches of her acromion and then down the humerus about four to five inches. Tr. 62-63.

After receiving the vaccine, her decreased range of motion limited her daily activities, such as cleaning- including walls, windows, and vacuuming. Tr. 52. She also described that her shoulder pain and symptoms made it more difficult to perform the functions of her job. Tr. 88-93. Petitioner explained that she taught English as a second language at Mills Laney Community College. Tr. 36. She testified that she frequently used the classroom board to write examples of words for the classes she taught, but after the vaccine it became difficult. Tr. 88-90. She also stated that she had difficulty maintaining pace when writing or grading papers. *Id.*

Ms. Kathleen Witt, a former colleague of the petitioner, testified that in the fall of 2013 the petitioner expressed that she was experiencing a lot of pain in her shoulder. Tr. 126. Ms. Witt recalled that the petitioners described having difficulty grading papers, tests, preparing for classes and writing on board in the classrooms. Pet. Ex. 75 at 2. Ms. Witt observed that in the late fall of 2013 or by the beginning of the spring 2014 semester, the petitioner switched from using a rolling briefcase to carry her books and her personal computer, to a rolling metal cart due to shoulder pain. Pet. Ex. 75 at 2; Tr. 127.

Ms. Karen Green, a friend of the petitioner, also testified that the petitioner's pain was localized in her right shoulder area and upper arm following the vaccination. Tr. 115. Ms. Green stated that she met the petitioner in 2008 and was aware of her existing fibromyalgia. Tr. 106. She testified that they spoke at least once a day. *Id.* She stated that since she knew the petitioner, her pain related to her fibromyalgia was symmetric, but petitioner was describing pain that "was localized just in the, you know, right shoulder area and the upper arm, and a little around the back." Tr. 115. Ms. Green testified that the pain the petitioner had previously described to her was different from the pain she described after receiving the vaccine. Tr. 117.

As discussed above, Ms. Sandoval was able to distinguish between the pain and location associated with her fibromyalgia from the pain she experienced in her right shoulder after receiving the vaccination. Tr. 75-77. She testified that there was not a corresponding pain or reduced range of motion in her left side. Tr. 76.

In March of 2015, the petitioner was evaluated by Dr. Whitley. Pet. Ex. 2 at 3. Dr. Whitley noted Ms. Sandoval reported pain in the right upper arm that is aggravated by movement. *Id.* at 1. A musculoskeletal exam revealed right arm pain with movement and Dr. Whitley recommended Ms. Sandoval seek an evaluation with an orthopedic specialist. *Id.* at 3.

Dr. Cohen, an orthopedic surgeon, evaluated the petitioner on October 7, 2015. Pet. Ex. 7 at 4. He performed a focused exam of her right upper extremity that revealed reduced range of motion in her right shoulder. *Id.* An x-ray of her right shoulder revealed "right shoulder rotator cuff arthropathy with proximal migration of the humeral head and acetabularization of the acromion. *Id.* Dr. Alwattar assessed the petitioner with a right shoulder arthropathy due to chronic rotator cuff tear, described as "massive." *Id.* He also noted that Ms. Sandoval's pain was "manageable according to patient." *Id.*

The petitioner underwent an MRI on October 21, 2015. Pet. Ex. 8 at 1. Dr. Alwattar concluded the petitioner had a "chronic massive rotator cuff tear with proximal migration of the humeral head; degenerative changes to the gleno humeral joint; rupture of the long head of the biceps." Pet. Ex. 7 at 2.

Dr. Howard Cohen evaluated the petitioner on October 28, 2015. Pet. Ex. 11 at 1. He performed a physical exam that again revealed reduced range of motion in her right shoulder and stated the petitioner demonstrated "severe pain" at roughly 110 degrees forward elevation." *Id.* He stated that petitioner's MRI revealed "severe longstanding massive rotator cuff tear with apparent atrophy in the supraspinatus and infraspinatus." *Id.* He recommended she consider a reverse shoulder arthroplasty. *Id.*

Petitioner then sought a second opinion from Dr. Tom Norris. Pet. Ex. 21 at 1, 6-7; Tr. 81. A physical exam again revealed reduced range of motion of her right shoulder. Pet. Ex. 21 at 6. Dr. Norris noted that the petitioner reported that after the flu and Pneumovax vaccine two years ago she had severe pain. *Id* at 7. Dr. Norris agreed that the petitioner was a candidate for reverse shoulder arthroplasty. Pet. Ex. 11 at 2.

At the conclusion of the hearing, I stated that petitioner "was able to explain the difference in the presentation of the shoulder injury that she attributed to the vaccine from those types of pains that come with fibromyalgia. She was able to…adequately and clearly explain the difference that the right shoulder injury…caused a significant change in her pain…" Tr. 290.

Therefore, I conclude that the petitioner was able to adequately demonstrate that the pain and reduced range of motion she experienced after the vaccination was limited to her right shoulder.

4. No other condition or abnormality is present that would explain the petitioner's symptoms

The final criteria for petitioners to establish a SIRVA is to show that no other condition or abnormality is present that would explain the petitioner's symptoms.

The petitioner's past medical history includes a history of fibromyalgia, hyperthyroidism, and degenerative changes in her shoulder. Additionally, the parties agree that petitioner had an asymptomatic pre-existing rotator cuff tear prior to the vaccination. Pet. Prehearing Memo at27; Rule 5 Order at 2; Resp. Ex. A at 8. Each of these conditions will be considered in turn.

a. Hyperthyroidism

In his first report, Dr. Lightfoot opined that the petitioner's hypothyroidism is an important factor in her past medical history and "possibly intermittently untreated hypothyroidism may have clouded the clinician's ability to discern the presence of intrinsic shoulder pathology." Resp. Ex. A at 3, 8. He stated that "anything that hurts would hurt worse if your thyroid is underactive or not being treated properly." Tr. 255. He testified that if a patient does not take their medicine for hyperthyroidism, it can lead to vast muscle breakdown, the protein blocks the kidneys, resulting in rhabdomyolated renal failure. *Id.* He suggested that the petitioner's undertreated hyperthyroidism could have resulted in some type of pain that made it difficult to diagnose an underlying shoulder injury. Resp. Ex. A at 6. When questioned whether there was evidence of the above described process, Dr. Lightfoot responded "no." *Id.*

Dr. Costorous acknowledged petitioner's hyperthyroidism and stated that prior to vaccination in October 2013, "…she was relatively functional with respect to her shoulder." Tr. 199. He stated that hyperthyroidism can be linked to other conditions that affect the shoulder, such as adhesive capsulitis or frozen shoulder. Tr. 209. He also acknowledged that lapses in medication for hyperthyroidism can lead to shoulder conditions but stated "it presents very differently on examination and patients typically have a loss of active motion or passive motion

in combination and it tends to be self-limiting." Tr. 210. Dr. Costouros stated that these symptoms were different from the ones the petitioner was experiencing. *Id.*

Based on the testimony of Dr. Lightfoot and Dr. Costouros regarding her history of hyperthyroidism, I find that this pre-existing condition does not explain her shoulder symptoms.

b. Degenerative Changes

Respondent's expert Dr. Lightfoot opined that the petitioner's osteoarthritis of the right acromioclavicular joint indicated some form of repetitive, chronic subtle trauma to the right shoulder, possibly leading eventually to asymptomatic tearing, which led to eventual symptomatology. Resp. Ex. A at 8.

He stated that the presence of degenerative arthritis "suggests some form of repetitive trauma to the shoulder area, which may have been the mechanism for petitioner's rotator cuff tear." *Id.* at 7.

However, when he testified, he stated osteoarthritis is more common in older individuals as a result of continued wear and tear over the decades, but it does not have anything to do with an inflammatory response to a vaccine or tissues under the acromion, which is down the shoulder joint. Tr. 258. Dr. Lightfoot conceded that the degenerative arthritis in the acromion-clavicular ("AC") joint was "irrelevant" to the petitioner's additional shoulder issues and could be classified as a coexisting condition. *Id.*

Dr. Costouros testified that the petitioner's pre-existing degenerative changes in her AC joint was not a significant factor in leading to her dysfunction. Tr. 207. He stated that when patients have AC joint arthritis it is often ignored as "not clinically relevant." *Id.*

Based on the testimony and explanation of both experts, I find that the degenerative changes in petitioner's AC joint would not explain her symptoms of pain or reduced range of motion in her right shoulder.

c. Fibromyalgia

Respondent's expert Dr. Lightfoot attempted to link petitioner's fibromyalgia to her right shoulder pain. Resp. Ex. A at 3. He stated that in a patient with "widespread pain of fibromyalgia….it can be difficult, if not impossible to delineate what is hurting on physical exam, as everything palpated hurts on palpation." Resp. Ex. C at 2. He concluded that it would be "impossible" to determine in any given encounter whether petitioner's fibromyalgia or other conditions were largely responsible for her symptoms. *Id.* at 3.

However, as described in greater detail above, petitioner was able to clearly articulate the difference between her fibromyalgia pain and the pain she experienced after receiving the flu vaccine in October 2013. Therefore, respondent's assertion that petitioner's pre-existing fibromyalgia was responsible for her symptoms was easily rebutted.

At the end of the hearing, I concluded that because of the petitioner's underlying fibromyalgia she had prior symptoms that affected her neck, back, shoulder and hips, but she was able to explain the difference in the presentation of the shoulder injury that she attributed to the vaccine from those types of pains that come with fibromyalgia. Tr. 290. Therefore, her fibromyalgia would not explain the petitioner's symptoms of shoulder pain or reduced range of motion.

d. Pre-Existing Rotator Cuff Tear

Both experts agreed that petitioner may have had an asymptomatic rotator cuff tear prior to receiving the vaccination. Resp. Ex. A at 8; Pet. Ex. 35 at 7.

Dr. Costouros opined that the vaccination petitioner received led to a significant exacerbation and aggravation of the pre-existing, asymptomatic condition of her right shoulder. Pet. Ex. 35 at 7. He continued, by stating, "I do not believe that the injection caused the massive rotator cuff tear which was evident on the MRI." *Id.* He noted that many patients with massive and chronic rotator cuff tears, especially older individuals, are often completely asymptomatic-free of pain or subjective dysfunction. *Id.*; Tr. 201. However, patients that are asymptomatic can become symptomatic after additional trauma, which in Ms. Sandoval's case, was the influenza vaccination. *Id.* at 6-7.

Dr. Costouros testified that some patients with multiple tendon tears can compensate by leveraging other muscles, such as the deltoid muscle, to compensate for the some of the functions that the torn muscles used to perform. *Id.* Dr. Costouros cited to an article by Atanasoff et. al[11]., which stated that a review of ultrasound and MRI studies of persons past middle age that were asymptomatic "found partial or complete rotator cuff tears in 39% of those individuals." Pet. Ex. 15 at 3. The article states that common shoulder conditions including impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis may cause no symptoms until provoked by trauma or other events. *Id.* at 4.

The respondent's expert, Dr. Lightfoot stated that he agreed with the literature that some people with fairly significant rotator cuff tears can be asymptomatic. Tr. 266. Dr. Lightfoot stated that "if there are a group of people out there who have torn rotator cuffs and don't know about it, it's possible that [they are] predispose[d] to developing SIRVA when you get an injection at the right time at the right place." Tr. 275.

I found Dr. Costouros to be credible when describing the likelihood of a pre-existing asymptomatic rotator cuff tear. Tr. 290. Particularly the Atanasoff article, that states, "In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions, including…rotator cuff tear…*In many cases, these conditions may cause no symptoms until provoked by trauma or other events."* Pet. Ex. 15 at 3 (emphasis added).

[11] S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010). Pet. Ex. 15.

Therefore, the petitioner's pre-existing asymptomatic rotator cuff tear did not explain the petitioner's symptoms of shoulder pain or reduced range of motion she experienced immediately after receiving the vaccination.

1. *Althen* Prong One: Petitioner has established a reliable and reputable theory of how the flu vaccine can cause the significant aggravation of SIRVA.

Under *Althen* prong one, the petitioner must present a theory explaining how the relevant vaccine can cause the petitioner's injury. *Althen*, 418 F.3d at 1278. In this case, the petitioner's theory of causation is SIRVA. The Federal Circuit has held that recognition of a link between vaccine and injury on the Vaccine Injury Table supports petitioner's burden under *Althen* prong one. *Doe 21 v. Sec'y of Health & Human Servs.*, 527 Fed. Appx. 875 (Fed. Cir. 2013). The respondent added SIRVA to the Vaccine Injury Table for the influenza vaccine. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132. The respondent does not dispute that the flu vaccine can cause SIRVA. *See* Resp. Rept. at 11 n. 11. Additionally, the Vaccine Program has a well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program. *See, e.g.*, *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) (rev. den., 142 Fed. Cl. 329 (2019)); *Loeding v. Sec'y of Health & Human Servs.*, No. 15-740V, 2015 WL 7253760 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (noting that "respondent 'has concluded that petitioner's injury is consistent with SIRVA; that a preponderance of evidence establishes that her SIRVA was caused in fact by the flu vaccination she received on October 14, 2014; and that no other causes for petitioner's SIRVA were identified."); *Johnson v. Sec'y of Health & Human Servs.*, No. 16-165V, 2016 WL 3092002 (Fed. Cl. Spec. Mstr. Apr. 13, 2016) (awarding compensation for a SIRVA caused-in-fact by the influenza vaccine).

Petitioner, through Dr. Costouros, established a theory of causation. He opined that the flu vaccine led to the significant exacerbation and aggravation of an asymptomatic right shoulder condition. Pet. Ex. 35 at 7. He stated that the subacromial and subdeltoid bursa communicate with one another and an injection into this rough area can generate the SIRVA response. *Id.* Further, this reaction may be exacerbated in the setting of a massive rotator cuff tear in that the injection will directly communicate with the glenohumeral joint and synovial tissue of the shoulder capsule, *which may also increase pain, stiffness and overall dysfunction. Id* (emphasis added).

Dr. Costouros opined that the flu vaccine injection triggered the decompensation of petitioner's right shoulder. Tr. 212. Dr. Costouros explained that some patients with massive rotator cuff tears (that include multiple tendons of the four main shoulder tendons) are able to compensate. Tr. 201. Compensation occurs with the retraining of the residual non-torn muscles around the rotator cuff or leveraging other muscles, such as the deltoid muscle, to compensate for some of the functions that the torn muscles used to perform. *Id.* Dr. Costouros stated that in SIRVA, the injection does not go into the muscle itself, but into the shoulder joint, leading to decompensation. Tr. 204. He concluded that that the localized inflammatory response reaction or the needle injection was the beginning of Ms. Sandoval's decompensation in her right shoulder. Tr. 204-205.

The Atanasoff article cited by Dr. Costouros provides support for his theory that the flu vaccine caused the petitioner's rotator cuff tear to become symptomatic. As noted above, the Atanasoff article cites a Reilly et al. study which reviewed ultrasounds and MRIs of persons past middle age who were considered asymptomatic and found partial or complete rotator cuff tears in 39 percent of those individuals. Pet. Ex. 15 at 3. The article continues, stating, "Therefore, some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and those *became symptomatic as a result of vaccination-associated synovial inflammation." Id.*

Dr. Lightfoot agreed that some individuals with "fairly significant rotator cuff tears," can be asymptomatic. Tr. 266. He testified that "there are a group of people out there who have torn rotator cuffs and don't know about it,-- it's possible that that [sic] could predispose developing SIRVA when you get an injection at the right time and right place. Tr. 275. When directed to the Atanasoff article on cross-examination he confirmed his answer, stating that "many people have that and it may well be that they are more predisposed to SIRVA that others…" Tr. 277.

Dr. Costouros did not attempt to attribute the flu vaccine to her degenerative arthritis or to be the cause of her underlying rotator cuff tear. Pet. Ex. 35 at 5; Tr. 290. Dr. Costouros indicated that he thought the flu vaccine may have contributed to the decompensation of the tendons and/or muscles in the rotator cuff, which I found credible based on the medical literature, as well as, the volume of SIRVA claims before the court. *Id.* Respondent's expert also recognized that pre-existing tendon tears can be asymptomatic in some individuals and more importantly, conceded that it is possible that they are predisposed to developing SIRVA. Tr. 275.

Therefore, the petitioner met her burden by showing by a preponderance of the evidence that the flu vaccine she received on October 18, 2013 could cause and was the cause in fact of her SIRVA.

2. *Althen* Prong Two: Petitioner Established a Logical Sequence of Cause and Effect Showing the Flu Vaccine was the Cause of Her Injury

Under *Athen* Prong Two the petitioner must demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury.

Dr. Costouros opined that the petitioner's underlying tissue damage in her shoulder was asymptomatic prior to receiving the flu vaccination on October 18, 2013. Pet. Ex. 46 at 2. He explained that a vaccination can act as an irritant to someone with an existing rotator cuff tear. Tr. 215. The elements of the vaccine, including the preservative or simply the immune response, can trigger an "inflammatory or painful condition in the fluid that communicates not only with the joint, but the area of a rotator cuff" causing a previously asymptomatic torn rotator cuff to become symptomatic. Tr. 215-16. In other words, since petitioner had a pre-existing rotator cuff tear, she was more susceptible to an inflammatory injury from a vaccine administered in her shoulder area. She was essentially "primed" for an "increased inflammatory reaction," eventually resulting in the deterioration of function and increased pain. Pet. Ex. 46 at 2.

This is in fact what happened to petitioner. Initially, petitioner attributed her pain to her fibromyalgia but noticed that there was not a corresponding pain on the other [left] side. Tr. 75; Rule 5 Order at 1. She began to experience a reduced range of motion in her right shoulder that made it difficult to perform certain aspects of her job and limited her activities of daily living. Tr. 76, 95-96. For example, she had difficulty maintaining pace while grading papers or writing homework assignments for her students. Tr. 89-90. She also had difficulty writing on the board in the classrooms. Tr. 166. As a result of these difficulties, she reduced her workload for the spring 2014 semester, choosing classes that did not require as much writing. Tr. 93.

On March 30, 2015, petitioner sought treatment from Dr. Whitley for right upper arm pain. Pet. Ex. 2 at 1-3. Petitioner reported the onset of pain to be "two years ago." A note from that appointment indicates that petitioner's symptoms included decreased mobility and severe pain with movement of arm. *Id.* at 1. Petitioner expressed difficulty dressing. *Id.* On physical exam, it was observed that petitioner had pain in her arm with movement. *Id.* at 3. She was referred to an orthopedist for an evaluation of "tendinitis vs. myopathy." *Id.*

In October 2015, petitioner saw Dr. Alwatter, an orthopedist, for right shoulder pain. Pet. Ex. 7 at 1. She reported that "pain has been present for chronic worse over last few months," and stated that specific movement overhead and behind her back are aggravating factors. *Id.* Dr. Alwatter performed a focused physical exam that showed decreased range of motion on forward elevation, external rotation and internal rotation. *Id.* at 2. Dr. Alwatter assessed her with right shoulder rotator cuff arthropathy due to a chronic rotator cuff tear and recommended an MRI. *Id.*

An MRI on October 21, 2015 showed a "massive chronic cuff tear, intracapsular long head of biceps torn, and degenerated acromioclavicular joint." Pet. Ex. 8 at 1. Dr. Howard Cohen, an orthopedic surgeon, wrote a letter referring the petitioner to Dr. Tom Norris, stating, "In my office, she was found to have profound rotator cuff weakness and limited abduction and forward elevation to roughly 110 degrees where she had severe pain." Pet. Ex. 11 at 1. He continued, stating, "Her MRI revealed a severe longstanding massive rotator cuff tear with apparent atrophy in the supraspinatus and infraspinatus." *Id.* He wrote, "In October of 2013 after receiving a pair of vaccinations in her right proximal shoulder, her pain worsened." *Id.*

Petitioner saw Dr. Norris on November 11, 2015 for pain in her right shoulder. Pet. Ex. 21 at 1, 6, 7. He noted that petitioner attributed her symptoms to a vaccination she received on October 19, 2013. *Id.* A physical exam revealed a reduced range of motion in her right shoulder and decreased strength. *Id.* at 7. Dr. Norris recommended a reverse shoulder arthroplasty. *Id.* at 6. Dr. Howard reiterated to petitioner that she is a candidate for shoulder reconstruction on November 23, 2015. Pet. Ex. 7 at 2.

After moving to southern California, petitioner saw Dr. Youderian for treatment of her shoulder pain. Pet. Ex. 10 at 1. Again, the petitioner attributed the onset of her pain to the vaccination in the fall of 2013. Dr. Youderian reviewed the MRI and again recommended a reverse shoulder arthroplasty. *Id.* at 3.

In *Tenneson v. Sec'y of Health & Human Servs.,* Chief Special Master Dorsey found that the QAI criteria for SIRVA to be persuasive regarding the factors necessary to demonstrate a logical sequence of events. *Tenneson,* WL 3083140 at *7 (Mar. 30, 2018).

As discussed above, the undersigned found that petitioner met the Table's criteria for SIRVA by a preponderance of the evidence. The undersigned found that the individuals that testified about the petitioner's range of motion and pain in her right shoulder before and after the vaccine were credible. Additionally, Dr. Costouros was able to explain how many individuals with existing rotator cuff tears that do not demonstrate symptoms could develop symptoms and dysfunction following an injection into the already damaged tissue of a shoulder. *See* Pet. Ex. 35 & Pet. Ex. 49. Further, I found the petitioner testified credibly about the onset of her pain within the specified timeframe of less than or equal to 48 hours after the vaccination. Finally, the alternative causes for pain or shoulder dysfunction proposed by respondent were not supported by the medical records or expert opinions.

The petitioner testified at the hearing that she still had not undergone the recommended surgery and was waiting for the time to be right. Tr. 176, 180. She said that she still experiences pain in her right shoulder. Tr. 176.

For these reasons, the petitioner has met her burden to show a logical sequence of events by a preponderance of the evidence as required by *Althen* prong two.

3. *Althen* Prong Three: Petitioner has established a medically acceptable temporal relationship between the flu vaccine and SIRVA.

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen,* 418 F.3d at 1281. Respondent stated that the vast majority of SIRVAs begin within a day of the vaccine. Resp. Brief at 20. Respondent cited to the Atanasoff article as providing a timeframe of one to four days as being medically appropriate for onset of SIRVA. *Id.* at 20. Then respondent argued that petitioner only reported shoulder soreness and that her arm was red and itchy three days after the vaccine and petitioner did not show that it was more than a simple transient site reaction that resolved. *Id.* at 20.

As discussed above, petitioner testified credibly that her onset of pain was within 48 hours after receiving the flu vaccine on October 18, 2013. She described continuous and ongoing pain and reduced range of motion in her right shoulder. Dr. Lenoir signed a letter stating that she recalled petitioner complaining of "significant pain in her arm," at the first medical appointment three days after receiving the vaccination. Pet. Ex. 3. In light of the finding above that petitioner's shoulder pain began within 48 hours of her October 18, 2013 flu vaccination, petitioner has satisfied *Althen* Prong Three.

IV. CONCLUSION

Thus, for all the foregoing reasons, I find that petitioner established by a preponderance of the evidence that her October 18, 2013 flu vaccination was the cause-in-fact of her SIRVA. Tr. 289. She is entitled to compensation. A separate damages order will be issued.

IT IS SO ORDERED.

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master