In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 22, 2023

TOMMIE HUMBERT, JR.,	*	PUBLISHED
Petitioner,	*	No. 17-360V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; Influenza ("Flu") Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA").
Respondent.	*	

Joseph Alexander Vuckovich, Maglio Christopher and Toale, Washington, DC, for Petitioner.
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

I. INTRODUCTION

On March 17, 2017, Tommie Humbert, Jr. ("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 he suffered a left shoulder injury as the result of an influenza ("flu") vaccination administered on November 21, 2014. Petition at 1

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the 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.

[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 Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

(ECF No. 1). Respondent argued against compensation, stating that "this case is not appropriate for compensation." Respondent's Report ("Resp. Rept.") at 1 (ECF No. 24).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that Petitioner has provided preponderant evidence that his flu vaccine caused his left shoulder injury, satisfying Petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

II. ISSUES TO BE DECIDED

The parties agree that Petitioner received a flu vaccine in his left shoulder on November 12, 2014.[3] Joint Status Rept., filed July 5, 2022, at 1 (ECF No. 114). They also agree that "Petitioner reported 'mild pain in his left shoulder after his flu shot a couple weeks ago. About [two] days after the flu shot [Petitioner] started getting shooting pains around his shoulder and down his forearm,' with numbness in his left index finger."[4] Id. (quoting Petitioner's Exhibit ("Pet. Ex.") 2 at 20 (medical record dated December 8, 2014)).

The parties disagree about the six-month severity requirement under the statute. Joint Status Rept. at 2. Petitioner alleges his injury lasted for at least six months, and Respondent disagrees. Id.

Regarding causation, Petitioner argues that the flu vaccine caused-in-fact his shoulder injury and that he can satisfy all three Althen prongs.[5] Joint Status Rept. at 2. Respondent does not agree that Petitioner has alleged a distinct shoulder injury or that he can satisfy the Althen prongs. Id.

III. BACKGROUND

A. Procedural History

Petitioner filed his Petition on March 17, 2017. Petition. From April 2017 to January 2018, Petitioner filed medical records. Pet. Exs. 1-12. Respondent filed his Rule 4(c) Report on April 25, 2018, recommending against compensation. Resp. Rept. at 1.

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[3] "The parties agree that that the petition was timely filed, and that [P]etitioner received a vaccination manufactured within the United States." Joint Status Rept., filed July 5, 2022, at 1 (ECF No. 114).

[4] The index finger is "the second digit of the hand, the finger adjacent to the thumb." Index, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25095 (last visited Feb. 10, 2023).

[5] Petitioner has not alleged a significant aggravation claim or that the flu vaccine caused-in-fact or significantly aggravated any cervical neck condition. Joint Status Rept. at 2. Additionally, Petitioner is not alleging a Table Injury. Id. at 1.

Thereafter, the case was removed from the special processing unit ("SPU") and reassigned. Notice of Reassignment dated April 27, 2018 (ECF No. 26). From September 2018 to March 2020, Petitioner filed various documentation, including letters and affidavits, horse pull results, social media posts, phone records, and workers compensation documentation.[6] Pet. Exs. 13-145.

On March 16, 2020, this case was reassigned to the undersigned. Notice of Reassignment dated Mar. 16, 2020 (ECF No. 82). The undersigned held a status conference on September 25, 2020 to discuss ongoing discovery issues. Order dated Sept. 25, 2020, at 1 (ECF No. 86). In light of the parties' discussion, the undersigned stayed the matter's discovery dispute pending potential informal settlement negotiations. Id. By February 2021, Respondent indicated he would like to proceed with litigation. Resp. Status Rept., filed Feb. 16, 2021 (ECF No. 93). A status conference was held on March 4, 2021, where the parties indicated they would like to file expert reports. Order dated Mar. 4, 2021 (ECF No. 94). Petitioner filed an expert report from Dr. Benjamin Busfield on May 7, 2021. Pet. Ex. 146. Respondent filed expert reports from Dr. Julie Bishop and Dr. Brian Callaghan on October 15, 2021. Resp. Exs. A, C.

A Rule 5 conference was held on December 7, 2021. Rule 5 Order dated Dec. 8, 2021 (ECF No. 106). The undersigned preliminarily found Petitioner had no history of previous shoulder pain, Petitioner's onset was within two days or 48 hours of his vaccination, Petitioner's pain and reduced range of motion were in the vaccinated shoulder, Petitioner's pain was mild to moderate, and Petitioner's sequela lasted until August 2015. Id. at 2-4. The undersigned also preliminarily found Petitioner's shoulder symptoms are not explained by cervical pathology. Id. at 3-4. Respondent's counsel agreed to speak with her client regarding his position on settlement. Id. at 4. On April 1, 2022, Respondent filed a status report maintaining that he would like to proceed with litigation. Resp. Status Rept., filed Apr. 1, 2022 (ECF No. 110).

A status conference was held on April 19, 2022, where the parties agreed to resolve entitlement through a ruling on the record. Order dated Apr. 19, 2022, at 1 (ECF No. 111). Petitioner filed his motion for a ruling on the record on July 5, 2022. Pet. Motion for a Decision on the Record or a Bench Ruling ("Pet. Mot."), filed July 5, 2022 (ECF No. 115). Respondent filed his response on September 2, 2022, and Petitioner filed a reply on October 3, 2022. Resp. Response to Pet. Mot. ("Resp. Response"), filed Sept. 2, 2022 (ECF No. 118); Pet. Reply Memorandum in Support of Pet. Mot. ("Pet. Reply"), filed Oct. 3, 2022 (ECF No. 119).

This matter is now ripe for adjudication.

[6] Only those exhibits the undersigned finds relevant are discussed in this Ruling.

B. Factual History

1. Medical History[7]

On November 21, 2014, at 49 years of age, Petitioner received a flu vaccine in his left arm. Pet. Ex. 1 at 2. Petitioner's prior medical history was unremarkable. Resp. Response at 2.

On December 8, 2014, Petitioner presented to primary care physician, Dr. Sherman G. Ibarra, with a chief complaint of "pain in left arm." Pet. Ex. 2 at 40. Dr. Ibarra documented, "[Petitioner] had mild pain in his left shoulder after his flu shot a couple weeks ago. About [two] days after the flu shot [Petitioner] started getting shooting pains around his shoulder and down to his forearm." Id. Petitioner reported shooting pain down his arm when he raised his arm and turned his head as well as "mild numbness at the tip of his left index finger." Id. Physical examination revealed "[m]ild decreased sensation at finger pad area of left index finger" and "[m]ild left shoulder pain with impingement testing."[8] Id. at 41. Petitioner's strength in his left shoulder was 5/5 with no pain with supraspinatus[9] and subscapularis testing, but Petitioner did have pain in his left shoulder with abduction and turning his head to the right. Id. There was no tenderness to palpation of the cervical spine, left shoulder, or left upper arm. Id. Assessment was "[l]eft shoulder pain with radiation" and "[l]eft index finger neuralgia." Id. at 42. Petitioner was prescribed a Medrol Dose Pak and declined a neurology referral. Id.

Petitioner returned to Dr. Ibarra on December 12, 2014 and reported he felt better. Pet. Ex. 2 at 44. Specifically, his left arm pain and left finger numbness were better. Id. He felt the pain was stemming from an area between his left shoulder and neck. Id. On physical examination, Petitioner had no pain with testing, had 5/5 strength in left shoulder, and was tender to palpation with muscle spasm in area between shoulder and neck (trapezius). Id. at 45. Diagnosis was "[l]eft shoulder upper extremity pain and finger neuralgia." Id. Petitioner

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[7] Petitioner's medical history from 2016 to 2017 is largely taken from Respondent's brief. See Resp. Response at 4-6.

[8] Impingement testing is done for rotator cuff tendinitis. Impingement Test, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=134132 (last visited Feb. 10, 2023). Impingement sign occurs "when the shoulder is flexed forward with the humerus internally rotated and its greater tubercle against the surface of the acromion," and "pain indicates an overuse injury to the arm muscle." Impingement Sign, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106312 (last visited Feb. 10, 2023).

[9] Supraspinatus muscle originates in the scapula and inserts into the humerus, "the long bone of the arm that articulates with the scapula at the shoulder and with the radius and ulna at the elbow," and is used to abduct the humerus. Musculus Supraspinatus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=90974 (last visited Feb. 10, 2023); Humerus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=23196 (last visited Feb. 10, 2023).

declined any additional testing, referral, specialists, and physical therapy. Id. at 45-46. Dr. Ibarra directed Petitioner to apply hot and cold compresses to his left trapezius area and to follow up in two-to-three weeks. Id. at 46.

At a follow-up visit on December 31, 2014, Petitioner had full range of motion in his left shoulder and no swelling, edema, or tenderness.[10] Pet. Ex. 2 at 48. Assessment was "[left] shoulder pain etio[logy]? Poss[ible] neuropraxia."[11] Id. Petitioner was directed to continue taking Meloxicam[12] and Flexeril,[13] perform shoulder exercises, and apply alternating hot and cold compresses as needed. Id.

Petitioner saw internist Dr. Charles Dinwiddie on January 30, 2015 for a follow-up visit for issues unrelated to his left shoulder. Pet. Ex. 5 at 18. No complaints of pain or numbness in his left shoulder or arm were documented. See id. at 18-19. Physical examination noted full range of motion. Id. at 19.

Petitioner returned to Dr. Ibarra's office on April 14, 2015 for "[l]eft shoulder pain since 11/2014." Pet. Ex. 2 at 49. Petitioner stated that since his flu vaccine in November, he has had continuous pain in his left shoulder. Id. He reported complaints of pain with range of motion of shoulder and left scapular[14] and supraspinatus pain at the visit. Id. Overall, Petitioner "state[d] that [his] shoulder pain [was] improving, however he would 'like something done' because . . . it [was] 'not going away.'" Id. at 51.

Under history of present illness, nurse practitioner ("NP") Michelle L. Myers documented Petitioner's left shoulder pain was moderate, fluctuated in intensity, and was

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[10] This record is handwritten and difficult to read.

[11] Neuropraxia is the "failure of conduction in a nerve in the absence of structural changes, due to blunt injury, compression, or ischemia." Neurapraxia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=33618 (last visited Feb. 10, 2023).

[12] Meloxicam is "a nonsteroidal antiinflammatory drug used in the treatment of osteoarthritis." Meloxicam, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30286 (last visited Feb. 10, 2023).

[13] Flexeril is "used as a skeletal muscle relaxant for relief of painful muscle spasms." Flexeril, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=18790 (last visited Feb. 10, 2023); Cyclobenzaprine Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=12135 (last visited Feb. 10, 2023).

[14] Scapular includes the region of the back overlying the scapula, the bone behind the shoulder. Regio Scapularis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=103247 (last visited Feb. 10, 2023); Scapula, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=44756 (last visited Feb. 10, 2023).

improving. Pet. Ex. 2 at 49. "The shoulder problem occurred 6.5 month(s) ago." Id. The pain radiated to the neck and down the arm to the left index finger, with numbness in his left index finger. Id. Pain was exacerbated with movement, and relieved with "immobilization, heat application, medication, physical therapy[,] and steroids given in December." Id. On physical examination, Petitioner had full range of motion, normal and equal strength bilaterally, equal grip strength bilaterally, equal sensation bilaterally in hands and fingers, no evidence of impingement, and brachial reflex equal bilaterally. Id. at 50-51. Petitioner tested negative for Neers, Hawkins, Apely, cross shoulder test, and drop arm test. Id. at 51. The "[o]nly abnormal result was [Petitioner's] complaint of tenderness to left trapezius, tenderness at the acromion process with palpation." Id. Diagnosis was "shoulder pain." Id. Petitioner was directed to continue range of motion exercises and was prescribed Flexeril and prednisone. Id.

Petitioner returned to Dr. Dinwiddie's and to Dr. Ibarra's offices in August 2015, February 2016, and March 2016. Pet. Ex. 2 at 52-57; Pet. Ex. 5 at 20-23. Physical examinations conducted during these visits did not indicate issues with Petitioner's left shoulder or arm. See Pet. Ex. 2 at 52-57; Pet. Ex. 5 at 20-23. No complaints of left shoulder pain were documented during these visits. See Pet. Ex. 2 at 52-57; Pet. Ex. 5 at 20-23. But see Pet. Exs. 13-14.

On August 16, 2016, Petitioner sought treatment for a neck and upper arm injury sustained at work on July 23, 2016 while "removing [a] fallen limb from highway." Pet. Ex. 10 at 28. Petitioner was referred to physical therapy, which he started on August 23, 2016. Pet. Ex. 12 at 12. Date of onset was July 23, 2016. Id. Petitioner reported the injury occurred while at work. Id. At his first session, Petitioner denied any prior history of shoulder or neck issues. See id.

A cervical spine magnetic resonance imaging ("MRI") conducted on September 12, 2016 revealed degeneration at multiple cervical levels. Pet. Ex. 12 at 71.

On September 16, 2016, Petitioner saw certified physician assistant ("PA-C") John Hannaford who noted Petitioner's condition was "shoulder related." Pet. Ex. 12 at 54. On September 22, 2016, Petitioner saw orthopedist, Dr. Scott Waterman, for left shoulder pain that began on July 23, 2016. Pet. Ex. 8 at 7. Petitioner explained that when trying to move something out of the road, he felt a pop and then experienced shooting pain from his neck down into his left forearm. Id. He also reported numbness in his left arm and index and middle fingers. Id. On examination, a left shoulder examination was normal, but Petitioner reported numbness in his index and middle fingers with abduction or when he turned his head. Id. Dr. Waterman found Petitioner's symptoms were consistent with a cervical radiculopathy,[15] particularly given that his symptoms were reproduced with cervical spine motion. Id.

[15] Cervical radiculopathy is a "radiculopathy of cervical nerve roots, often with neck or shoulder pain; compression of nerve roots is a common cause in this area." Cervical Radiculopathy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=101392 (last visited Feb. 10, 2023).

Petitioner saw Dr. Joseph C. Duncan, an orthopedic surgeon, on September 27, 2016. Pet. Ex. 8 at 2. Dr. Duncan noted that Petitioner's symptoms began following a work injury on July 23, 2016, and that Petitioner had no prior history of similar issues. Id. Petitioner complained of pain in his left arm, weakness in his left shoulder, and numbness and weakness in his hand. Id. Assessment was cervical radiculopathy. Id. at 3. He recommended a spinal fusion. Id.

On October 5, 2016, Petitioner returned to PA-C Hannaford for a follow up on his left shoulder. Pet. Ex. 10 at 8. Hannaford questioned whether Petitioner's symptoms suggested a left shoulder condition. Id. On October 25, 2016, Petitioner saw Dr. David Schwartz, an orthopedist. Pet. Ex. 12 at 5. Petitioner stated that his symptoms had actually improved over the past three weeks. Id. On examination, Petitioner's left shoulder was normal with the exception of a "positive left Spurling sign to the C7 distribution."[16] Id. at 6. Petitioner was assessed with resolving left C7 radiculopathy associated with a foraminal osteophyte disc extrusion at the C6-7 level. Id.

Petitioner saw Dr. Larry Bumguardner, a primary care provider, on March 22, 2017. Pet. Ex. 9 at 8. Petitioner stated that "[h]e [was] still having some issues with his left shoulder following a flu vaccine approximately 2 years ago. He believe[d] the injection was given to[o] far forward and he had a shooting pain down his left arm to this mid forearm when given the injection." Id. He reported "weakness of the left shoulder and arm as well as atrophy of the muscles and loss of [range of motion] of the shoulder." Id. Petitioner did not mention his intervening work injury. See id. Petitioner stated that his shoulder "ha[d] been getting better over the last year and he [was] wondering what he can do to improve strength of the arm." Id. On examination, Dr. Bumguardner noted some reduced range of motion in the left shoulder, mild atrophy in the left arm and forearm, and mildly reduced strength in the left arm. Id. at 10. Assessment was shoulder-girdle neuropathy. Id. at 11.

On October 17, 2017, Petitioner saw PA Kelly S. Jones at his primary care provider's office. Pet. Ex. 11 at 9. Petitioner reported "increasing pain in his left shoulder." Id. "[Petitioner] state[d] that he got a flu vaccine a few years ago and had an 'injury' and since then he [has] shoulder pain and arm pain . . . ." Id. Petitioner reported he was "diagnosed with a nerve injury and it has to be treated with a steroid to help with the pain." Id. Petitioner stated that his shoulder "usually doesn't bother him but over the past few days it started bothering him." Id. Petitioner did not mention his July 2016 work injury. See id. Diagnosis was left shoulder pain. Id. at 10. PA Jones prescribed a short course of oral steroids. Id.

[16] The Spurling test is used to determine whether an individual has cervical radiculopathy. Spurling Test, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112983 (last visited Feb. 10, 2023). "[T]he examiner presses down on the top of the head while the patient rotates the head laterally and into hyperextension; pain radiating into the upper limb ipsilateral to a rotation position of the head indicates radiculopathy." Id.

2. Affidavits & Letters[17]

a. Petitioner's Affidavit

Petitioner stated he received a flu vaccine on November 21, 2014 in his left arm. Pet. Ex. 6 at ¶¶ 1, 3. Prior to vaccination, Petitioner had no history of left shoulder injury. Id. at ¶ 12. "During the vaccination, blood ran down [his] left arm from the injection site." Id. at ¶ 5. "Within 24 hours of receiving the vaccination, [he] began to experience pain in [his] left shoulder," which "became excruciating in the months following." Id. at ¶¶ 6-7. The pain, which he described as "intense" and "stabbing," was "the most intense pain that [he] had ever experienced." Id. at ¶¶ 7, 9. The pain affected his sleep. Id. at ¶ 8. "Often [he] would wake up screaming in the middle of the night, having moved [his] arm in a manner that aggravated the pain." Id. He eventually "[tied] [his] left arm to [his] torso with a belt" to keep his arm from moving while he slept. Id. He indicated the pain was at its worst about six months after vaccination and persisted until the spring of 2016. Id. at ¶¶ 8, 10. As of April 4, 2017, the date in which his first affidavit was executed, Petitioner averred he "continue[d] to suffer from a lack of strength and muscle tone in [his] left arm as a result of the long period of time during which [he] was unable to use it." Id. at ¶ 11.

At the time of vaccination in the fall of 2014, Petitioner's job was physically demanding. Pet. Ex. 19 at ¶ 2. In the weeks following his shoulder injury, he found work difficult "due to the intense pain in [his] left shoulder." Id. at ¶ 3. Thus, he requested less physical work duties and received a change in job duties around Thanksgiving 2014, shortly after his vaccination. Id.

In his free time, Petitioner enjoyed spending time with his daughter, coaching youth basketball, and participating in horse pulling, which he explained have all been affected by his shoulder injury. Pet. Ex. 19 at ¶ 5. While coaching, Petitioner was unable to demonstrate certain basketball skills and had difficulty carrying equipment at practices and games. Id. at ¶ 6. With competitive horse pulling, he would compete as part of a team as the "hitcher," or "the person who, at the start of the event, actually hitches the team of horses to the pre-measured weight that they are to pull." Id. at ¶ 7. Petitioner explained "[t]his is a physically challenging task because the hitching has to be done quickly, before the horses start to move." Id. "Prior to [his] shoulder injury, [he] was known as a very competent hitcher." Id. Although he writes with his right hand, he would use his left hand and arm to hitch. Id. at ¶ 8. Since his shoulder injury, he has "seldom participated in these events" and "[his] performance in horse pulls has never returned to its pre-injury level." Id.

b. Letters from Dr. Charles B. Dinwiddie's Office

Dr. Dinwiddie provided one letter. Pet. Ex. 13 at 1. He remembered Petitioner stating "[h]e had received a vaccine and that he had some type of reaction from the injection, to his shoulder." Id. Dr. Dinwiddie stated Petitioner first told him of this injury at his appointments in

[17] Only those affidavits and letters that were relevant to the undersigned's Ruling are addressed.

January and August 2015.[18] Id. Dr. Dinwiddie stated "[he] did not examine the area of reaction during those appointments." Id.

Licensed practical nurse ("LPN") Debbie Nellen, who works with Dr. Dinwiddie, also provided one letter. Pet. Ex. 14 at 1. She stated "[Petitioner] called the office complaining of pain at an injection site from a [f]lu vaccine administered to him from [a] nurse at work." Id. She informed Petitioner that Dr. Dinwiddie was not in the office and instructed him to return to the clinic he received the vaccine so they could examine him. Id. She also told him that he could apply an ice pack to reduce any swelling, pain, or redness. Id. During the five weeks Dr. Dinwiddie was out of the office, she received multiple phone calls from Petitioner. Id. She "attributed some of this to his anxiety about his arm, but always referred him back to the medical staff at his place of employment." Id. She also suggested Petitioner could go to a walk-in clinic if need be. Id. At his January 2015 appointment, she remembered Petitioner showing her where his injection was given and complaining of "continued . . . problems with pain in his shoulder that he attributed to the injection site." Id. Petitioner reported he was continuing to be followed by the clinic at work. Id. LPN Nellen "[did] not recall discussing this with him after April 2015 other than for him to mention that his shoulder was slowly getting better." Id.

c. Tim Humbert's Affidavit

Petitioner's brother, Tim Humbert, explained that hitching is very difficult and physically demanding. Pet. Ex. 20 at ¶¶ 1, 3, 6. Petitioner began hitching when he was 12 or 13 years of age and began competing at 15 years of age. Id. at ¶ 4. "At the time of [Petitioner's] 2014 shoulder injury, [Petitioner] had been regarded for some time as one of the best hitchers involved in competitive horse-pulling throughout the Midwest." Id. "By late November 2014[,] [Petitioner] had been an essential part of [the] team" and their team faced "a serious setback when [Petitioner] was unable to help with harnessing." Id. at ¶ 6. Mr. Humbert had to take over this job. Id. After Thanksgiving 2014, Petitioner was unable to hitch due to his shoulder injury. Id. at ¶ 7. Mr. Humbert remembered Petitioner was unable to pick up the hitch in June 2015, and thus, they had to find a substitute hitcher. Id. Petitioner was able to practice and compete about one-and-one-half years later, however, Mr. Humbert averred Petitioner has not been the same since his 2014 shoulder injury. Id. at ¶ 8. Additionally, Mr. Humbert noticed no change in Petitioner's performance following his 2016 work-related shoulder and neck strain. Id. at ¶ 9.

d. Andy Wagner's Affidavit

Andy Wagner is a family friend of the Humbert family and has known Petitioner for "many years." Pet. Ex. 23 at ¶ 1. Mr. Wagner is also involved in horse pulling. Id. at ¶ 2. He noted that Petitioner was one of the best hitchers in horse pulling in the Midwest. Id. at ¶ 4. "Hitching is tough, physical work, as is horse pulling in general. There is no way that a person with a serious shoulder injury could harness or hitch horses in competition." Id. at ¶ 6.

Shortly before the 2015 season, which begins in April or May, the Humbert family approached Mr. Wagner about filling in for Petitioner as their team's hitcher. Pet. Ex. 23 at ¶¶ 5,

[18] These appointment occurred on January 30, 2015 and August 14, 2015. Pet. Ex. 5 at 18-21.

7. Mr. Wagner was told "[Petitioner] couldn't hitch because he had hurt his shoulder and the pain made it impossible for him to hitch," which he understood to mean Petitioner's "shoulder injury was a severe physical limitation, not only because of the way it was described to [him] but also because [he] kn[e]w how much [Petitioner] loved pulling horses" and "[i]t would take very severe pain to keep him out of competition for an entire season." Id. at ¶ 7. Mr. Wagner substituted for Petitioner as hitcher for the 2015 competition season, which ended in September. Id. at ¶ 8.

Mr. Wagner has physical therapy training and spoke to Petitioner about his injury. Pet. Ex. 23 at ¶¶ 2, 9. After Mr. Wagner found out Petitioner would not be competing in horse pulling in the summer of 2015, Petitioner told Mr. Wagner "that he had had the pain in his shoulder ever since getting a flu shot in that shoulder the previous fall." Id. at ¶ 9. "[Petitioner] said he remembered this very clearly, there did not seem to be any doubt in his mind about it, and he did not refer to anything else that might have caused the pain." Id.

e. Amanda Dunnuck's Affidavit

Amanda Dunnuck is a family friend of Petitioner. Pet. Ex. 24 at ¶ 1. She is an attorney and municipal judge in Indiana. Id. at ¶ 2. She remembered Petitioner complaining of shoulder pain that began when he received a flu shot during the fall and winter of 2014. Id. at ¶ 4. She explained that she remembered this clearly due to important events in her professional career occurring at the same time. Id.

Ms. Dunnuck attended a variety of community events, including the youth basketball games Petitioner's daughter played in. Pet. Ex. 24 at ¶ 5. During the 2014-2015 season, following a basketball game Ms. Dunnuck did not attend, Petitioner called to complain of shoulder pain that occurred when someone touched his shoulder at the game. Id. Ms. Dunnock found it unusual for Petitioner to complain "because [he] is usually very stoic, and, to [her] it indicated the severity of the pain he was experiencing." Id. She indicated this phone call would have occurred before the end of the basketball season, which was in March 2015. Id.

Ms. Dunnuck also recalled Petitioner's shoulder injury prevented him from participating in competitive horse pulling in the summer of 2015. Pet. Ex. 24 at ¶ 6. During this time, they communicated almost daily. Id. "[Petitioner] often talked about the pain in his shoulder and he mentioned repeatedly that the shoulder pain was the reason he was not pulling." Id. "[Petitioner] also told [Ms. Dunnuck] that he was belting his arm to his body before bed, since this kept the shoulder from moving and waking him up with pain." Id.

f. Tambrea Reeder's Affidavit

Tambrea Reeder lives near Petitioner and sees him frequently. Pet. Ex. 27 at ¶ 2. Ms. Reeder saw Petitioner on the date of his vaccination. Id. She stated she immediately knew something was wrong because "[h]e was clearly in a lot of pain." Id. Petitioner told her that he had had a flu vaccination and his shoulder had been in pain since the vaccination. Id.

Their families spent Thanksgiving 2014 together at Ms. Reeder's house. Pet. Ex. 27 at ¶ 3. Ms. Reeder remembered Petitioner experiencing severe shoulder pain on Thanksgiving, explaining "[Petitioner] complained about [the pain], which was unlike him, and at one point the pain was so bad that he needed to go to [her] spare bedroom to lie down." Id. She found this behavior "completely out of character" and explained "he would not have done this if he had not been in serious pain." Id.

Throughout late fall and winter of 2014 to 2015, Ms. Reeder remembered Petitioner holding his arm in a certain position "because he said it helped with the pain in his shoulder." Pet. Ex. 27 at ¶ 4. She remembered this because she thought it was a "very unusual way for a person to hold [their] arm." Id. Additionally, she found "it [] unlike [Petitioner] to complain about physical pain so the fact that he did so is memorable." Id. During this time, Petitioner told her the shoulder pain began "immediately after he received his vaccine." Id. Ms. Reeder believed Petitioner had no doubts about this timeline. Id.

Ms. Reeder's daughter also plays basketball, so she attended many of the games during the 2014-2015 season. Pet. Ex. 27 at ¶ 5. She remembered seeing Petitioner at these games with his arm in a strange position, close to his chest, which he explained helped with the pain. Id. at ¶ 6.

Ms. Reeder saw or spoke to Petitioner almost daily in 2015. Pet. Ex. 27 at ¶ 8. She stated Petitioner "frequently mentioned the pain" during this time. Id. She saw Petitioner in his home with his arm tied "close to his body and in front of and toward the center of his chest" with a belt, which he indicated would keep his arm from moving while he slept. Id. at ¶ 9.

C. Expert Reports

1. Petitioner's Expert, Dr. Benjamin Busfield

a. Background and Qualifications

Dr. Busfield is a board-certified orthopedic surgeon who works as an orthopedic surgeon at Busfield Orthopedic Clinic, as an Adjunct Assistant Professor at Touro University College of Medicine, and as CEO and Founder of Diablo Orthopedic Consultants. Pet. Ex. 146 at 1; Pet. Ex. 147 at 1. He received a B.A. in physiology from the University of California, Davis, an M.S. in Physiology and Biophysics from Georgetown University, and an M.D. from Georgetown University School of Medicine. Pet. Ex. 147 at 2-3. Thereafter, he completed a surgery internship and orthopedic surgery residency at the University of California, San Francisco and a sports medicine fellowship at the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, CA. Id. at 2. "[His] practice covers a variety of techniques in orthopedic surgery, including shoulder replacement, arthroscopy, and sports medicine." Pet. Ex. 146 at 1. Dr. Busfield has also co-authored numerous publications. Pet. Ex. 147 at 3-5.

b. Opinion

i. Diagnosis

After a review of the records, Dr. Busfield opined Petitioner has two separate diagnoses: left shoulder pain from shoulder injury related to vaccine administration ("SIRVA") and cervical spondylosis with multi-level stenosis. Pet. Ex. 146 at 7. He explained "[s]houlder and neck pathology commonly overlap and overlapping concomitant neck pathology can mask shoulder pathology in non-discerning physicians." Id. at 9. Dr. Busfield opined that Petitioner's "nonspecific shoulder pain" is consistent with a SIRVA, "as it is consistent with inflammation leading to tendinopathy." Id. at 13.

Dr. Busfield also found Petitioner met all four of the following SIRVA criteria in the Vaccine Injury Table:[19] (1) no history of shoulder pathology prior to vaccination that would explain the symptoms; (2) pain onset within 48 hours after vaccination; (3) pain and reduced range of motion limited to the shoulder in which the vaccine was administered; and (4) no concurrent condition or abnormality that would explain the symptoms. Pet. Ex. 146 at 9-10; see also 42 C.F.R. § 100.3(c)(10)(i)-(iv).

With regard to the first criterion, Dr. Busfield opined that the medical records support a finding that Petitioner had no history of pre-existing shoulder symptoms. Pet. Ex. 146 at 8, 10. For the second criterion, onset, he opined the medical records and affidavits, taken together, show "[Petitioner's] symptoms began within 24 hours of vaccination," as described in more detail below. Id. at 10.

For the third and fourth criteria, Dr. Busfield found Petitioner's cervical spondylosis was aggravated by Petitioner's work injury in July 2016. Pet. Ex. 146 at 10. Cervical spondylosis is an age-related degenerative condition, and thus, he argued Petitioner could have been suffering from cervical spondylosis prior to July 2016, but the work injury aggravated the symptoms. Id. None of the medical records prior to July 2016 note this condition, nor do they note complaints consistent with this condition. Id. Petitioner's complaints prior to July 2016 focused on his shoulder. Id. Dr. Busfield noted "[i]t is very common to have overlapping radicular and shoulder pathology." Id. Thus, "the presence of radicular pain would not in any way mean that the vaccine had not caused [Petitioner's] shoulder injury," but it could mean Petitioner's "pain was not limited to the shoulder in which the vaccine was administered." Id. (emphasis omitted).

ii. Causation

Dr. Busfield opined that if a vaccine is injected into the shoulder joint, shoulder pathology of inflammation and pain can occur due to "mechanical trauma and/or directly related

[19] Petitioner is not alleging a Table injury. Joint Status Rept. at 1.

immune response from the injection placed into the subacromial space or shoulder joint."[20] Pet. Ex. 146 at 11-12.

He explained a flu vaccine is commonly given in the intra-muscular deltoid, which overlays the shoulder, with the subacromial space and rotator cuff just under the muscle. Pet. Ex. 146 at 11. When a vaccine is injected higher in the deltoid, the needle "can enter the subacromial space, causing mechanical injury or inflammation," which can lead to various shoulder injuries. Id.

Dr. Busfield cited Hexter et al.,[21] who "report[ed] a case of shoulder pain and functional limitation resulting from inadvertent administration of [a flu] vaccination into the bursal tissues underlying the deltoid muscle." Pet. Ex. 149 at 4. Their patient received a flu vaccine in her left deltoid. Id. at 1. She had no relevant past medical history. Id. "During administration of the vaccine, she felt severe pain in the left shoulder radiating down the upper arm. The patient and her general practitioner[] agreed that the vaccination had been given 'too high.'" Id. The patient's findings were consistent with glenohumeral synovitis and inflammatory bursitis. Id. at 1-3.

Hexter et al. cited studies that discussed the mechanisms posited by Dr. Busfield, explaining an inadvertent injection of a vaccine into the subdeltoid bursa can lead to inflammation, dysfunction, and pain of the shoulder. Pet. Ex. 149 at 3. One study cited by Hexter et al. was authored by Atanasoff et al.,[22] and noted pain onset generally occurs within 24 hours of vaccination, similar to the onset in their patient. Id. Additionally, six of the 13 cases in that study stated the vaccine was administered "too high," similar to the patient in Hexter et al. Id. Of the five studies Hexter et al. examined, clinical presentation in all patients included shoulder pain, and some patients also had weakness or limited range of motion. Id. at 3 tbl.1.

The Hexter et al. authors concluded their findings "reinforce the previous hypotheses that vaccine injection into the subdeltoid bursa leads to a local inflammatory response." Pet. Ex. 149 at 4. "[U]ndoubtedly, vaccines can be unintentionally injected into structures underlying deltoid muscle." Id. Hexter et al. hypothesized that "[w]hen a vaccine is injected into the subdeltoid bursa, a prolonged inflammatory process results from an immune response to a vaccine antigen, to which the recipient has previously been sensitised either naturally or via previous vaccination." Id.

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[20] Dr. Busfield also opined, "based on [his] clinical experience[,] that injury to small blood vessels in the deltoid can cause an intra-muscular hematoma and pain, that can subsequently lead to overhead pain and adhesive capsulitis." Pet. Ex. 146 at 11. "[T]his injury to the subacromial space and/or deltoid muscle can simply be caused by mechanical trauma from the needle injection," and "it would not [] be necessary for the needle to enter the subacromial space." Id.

[21] Adam T. Hexter et al., Management of Glenohumeral Synovitis Secondary to Influenza Vaccination, 7 Shoulder & Elbow 100 (2015).

[22] This study was not filed by either party.

Messerschmitt et al.[23] described the case of a patient who presented with three weeks of shoulder pain and limited range of motion following flu vaccination in the left deltoid. Pet. Ex. 148 at 2. The patient reported no recent trauma and the shoulder had been asymptomatic prior to vaccination. Id. The patient's left shoulder discomfort began "a few days" following vaccination. Id. "The pain was localized to the anterior shoulder joint and was exacerbated with overhead activities." Id. They determined the patient developed progressive osteolysis and surface chondrolysis of the proximal humerus following flu vaccination, and the injury was attributed to the flu vaccine. Id. at 2-3.

The Messerschmitt et al. authors hypothesized that their patient's injury was due to intraarticular and intraosseous vaccination placement. Pet. Ex. 148 at 3. They found the patient had no underlying disorder or condition that could have caused his injury other than flu vaccination. Id. at 4. Messerschmitt et al. concluded "[t]he [flu] immunization caused inflammatory changes in the shoulder joint as confirmed with arthroscopic visualization and histopathologic examination, which likely induced humeral head chondrolysis or converted an asymptomatic chondrolytic process to a symptomatic shoulder condition with limited [range of motion] and function." Id.

With regard to Petitioner's case, Dr. Busfield opined Petitioner's left shoulder injury was caused by mechanical trauma and/or immune response from the flu vaccination, which would have passed through the deltoid into the subacromial space. Pet. Ex. 146 at 12. He explained this mechanism is consistent with Petitioner's medical records and clinical course. Id. at 12-13. "[Petitioner] even disclosed, albeit later in the medical record, that he thought the injection was placed incorrectly." Id. at 12 (citing Pet. Ex. 9 at 8). Additionally, the lack of an alternative cause "make[s] the vaccine the most likely cause of the pathology." Id. at 13.

Dr. Busfield found Petitioner's medical records showed no evidence of pre-existing shoulder symptoms. Pet. Ex. 146 at 2, 8, 10. Petitioner received his flu vaccination on November 21, 2014, and Petitioner's symptoms, based on the medical records and affidavits, show "[Petitioner's] symptoms more likely than not began within 24 hours of vaccination." Id. at 10, 13-14. Dr. Busfield noted the medical records from December 8, 2014, April 14, 2014, and March 22, 2017 and the affidavits consistently placed onset immediately after vaccination. Id. at 12, 14.

To summarize, on December 8, 2014, Petitioner reported his "pain in his left shoulder [began] after his flu shot a couple weeks [prior]." Pet. Ex. 2 at 40. Petitioner also stated "shooting pains around his shoulder and down to his forearm" began within two days after the flu vaccine. Id. Petitioner returned to Dr. Ibarra's office on April 14, 2015 for "[l]eft shoulder pain since 11/2014." Id. at 49. When Petitioner saw Dr. Bumguardner on March 22, 2017, he reported "[h]e [was] still having some issues with his left shoulder following a flu vaccine approximately 2 years ago. He believe[d] the injection was given to[o] far forward and he had a shooting pain down his left arm to this mid forearm when given the injection." Pet. Ex. 9 at 8.

[23] Patrick J. Messerschmitt et al., Progressive Osteolysis and Surface Chondrolysis of the Proximal Humerus Following Influenza Vaccination, 35 Orthopedics e283 (2012).

Dr. Busfield noted that at all three of these visits, Petitioner asserted his shoulder pain began immediately after flu vaccination. Pet. Ex. 146 at 12. Dr. Busfield opined this "consistent pattern of attribution of the injury to the shot" supports the finding that "the most medically reasonable and probable conclusion" is that Petitioner's shoulder pain immediately followed vaccination and the vaccination caused his pain. Id. at 12-13

For additional support of an onset within 24 hours, Dr. Busfield cited to Petitioner's affidavit and Dr. Dinwiddie's letter. Pet. Ex. 146 at 8-14. Petitioner, in his affidavit, explained intense and stabbing pain began in his left shoulder "[w]ithin 24 hours" of vaccination and persisted for over six months. Pet. Ex. 6 at ¶¶ 6-10. Dr. Busfield found Petitioner "reported pain in his shoulder starting after the 2014 vaccination and continuing through 2014 and 2015." Pet. Ex. 146 at 9.

Additionally, in a letter, Dr. Dinwiddie stated Petitioner first told him of this injury in 2015, at his appointments in January and August 2015, although the records from these visits do not mention any complaints of shoulder pain. Pet. Ex. 146 at 8-9, 13; see Pet. Ex. 13 at 1; Pet. Ex. 5 at 18-21. Dr. Busfield acknowledged Dr. Dinwiddie's and LPN Nellen's letters "documented clear recollections of [Petitioner's] shoulder complaint in later 2014-2015 despite lack of any documentation" in the medical records, and argued any lack of documentation should not be evidence of a lack of shoulder pathology at that time given that Dr. Dinwiddie's care was focused on Petitioner's mental health and not his shoulder. Pet. Ex. 146 at 8. Dr. Busfield found it was "not [] surprising" that Dr. Dinwiddie's records do not mention Petitioner's shoulder pain and Dr. Dinwiddie admitted he did not examine Petitioner's shoulder. Id. at 9.

Thus, he found Petitioner's "onset of pain immediately after flu vaccination and certainly within 24 hours." Pet. Ex. 146 at 13-14. Given that Petitioner's "shoulder pathology is a known . . . complication of vaccination, this timing is unlikely to have been coincidental, particularly given the lack of other possible causal factors." Id. at 13.

With regard to Petitioner's cervical pathology, Dr. Busfield opined Petitioner's 2016 work injury aggravated his cervical spondylosis, and prior to this work injury in 2016, there was no evidence of cervical pathology. Pet. Ex. 146 at 10-13. Because cervical spondylosis is an age-related degenerative condition, he acknowledged Petitioner could have been suffering from cervical spondylosis prior to his work injury in 2016. Id. at 10. However, his symptoms only presented after Petitioner's work injury in 2016. Id. Petitioner's medical records consistently focused on Petitioner's shoulder prior to July 2016. Id. Thus, there is no evidence in the medical records that this condition was present in 2014 following vaccination. Id.

2. Respondent's Expert, Dr. Julie Y. Bishop

a. Background and Qualifications

Dr. Bishop is a board-certified orthopedic surgeon, specializing in shoulder surgery. Resp. Ex. A at 1; Resp. Ex. B at 2. After obtaining her M.D. from Cornell University, she completed a surgery internship and orthopedic residency at George Washington University, a shoulder surgery fellowship at Mt. Sinai Hospital in New York, and a sport medicine visiting

fellowship at the University of Pittsburgh Medical Center. Resp. Ex. B at 1-2. Dr. Bishop currently works as a Professor of Orthopaedics in the Department of Orthopaedic Surgery, Chief of the Division of Shoulder Surgery, and Vice Chair of Finance for the Orthopaedic Department at The Ohio State University. Resp. Ex. A at 1; Resp. Ex. B at 2, 6-7. "As a shoulder specialist," she has focused her over 100 publications on the treatment of shoulder pathology. Resp. Ex. A at 1; see Resp. Ex. B at 8-20. Dr. Bishop has treated multiple SIRVA patients and has published in this area. Resp. Ex. A at 1.

b. Opinion

Dr. Bishop opined, to "a reasonable degree of medical certainty," that there is no evidence that Petitioner's symptoms are consistent with SIRVA or due to vaccination. Resp. Ex. A at 13. She opined "there is overwhelming evidence [Petitioner] [] suffer[ed] from cervical radiculopathy and this is the most likely cause of his symptoms in late 2014/early 2015." Id.

Dr. Bishop found Petitioner's complaints of pain radiating down into the arm, hand, and finger with numbness in a finger to be consistent with a cervical radiculopathy, not a shoulder pathology. Resp. Ex. A at 9. A "cervical radiculopathy can result in pain, paresthesias (numbness), dysesthesias, and weakness" due to compression of cervical nerve roots. Id. (citing Resp. Ex. A, Tab 2 at 1).[24] She explained "a diagnosis of cervical radiculopathy secondary to cervical spine degenerative dis[c] disease should be strongly considered in the presence of neck pain ([P]etitioner had trapezius pain) or radicular symptoms of pain, paresthesia, or numbness in the arm extending to the hand," which mirror Petitioner's complaints. Id. (citing Resp. Ex. A, Tab 3 at 3).[25] Petitioner's "most persistent symptoms," according to Dr. Bishop, were pain and numbness radiating down his arm to the finger, consistent with a cervical radiculopathy. Id.

Dr. Bishop explained, "[f]rom an objective medical perspective, [P]etitioner had 'mild pain' after his vaccination, and two days after vaccination, he experienced 'shooting pains around his shoulder and down to his forearm,' and 'numbness in his left index finger.'" Resp. Ex. A at 10. She opined the "mild pain" could be explained by the vaccination, but Petitioner's symptoms that began two days after vaccination "are far more likely consistent with unrelated cervical radiculopathy." Id. Dr. Bishop argued that even if Petitioner's mild left shoulder pain with positive impingement testing on December 8, 2014 was vaccine-related, there was no evidence of any distinct shoulder pathology after December 8, 2014. Id. Specifically, "no impingement or reduced range of shoulder motion was seen four days later on December 12, 2014, or at any visit thereafter." Id. Additionally, no shoulder imaging was ever ordered that could confirm a distinct shoulder condition. Id. at 8. Nor did Petitioner receive a specific shoulder diagnosis. Id. Dr. Bishop noted Petitioner was only given non-specific diagnoses of left shoulder pain with radiation, left upper extremity pain, left shoulder pain of questionable

[24] Ravi K. Ponnappan et al., Clinical Differentiation of Upper Extremity Pain Etiologies, 23 J. Am. Acad. Orthopaedic Surgeons 492 (2015).

[25] K. J. Hippensteel et al., A Comprehensive Review of Physical Examination Tests of the Cervical Spine, Scapula, and Rotator Cuff, 27 J. Am. Acad. Orthopaedic Surgeons 385 (2019).

etiology and possibly neuropraxia, left shoulder pain, and left finger neuralgia. Id. at 8-9. Therefore, Dr. Bishop concluded it was "very clear that [P]etitioner's symptoms were stemming from an area between left shoulder and neck, and were otherwise entirely consistent with a cervical radiculopathy." Id. at 10 (internal quotations omitted).

Dr. Bishop determined Petitioner's cervical radiculopathy symptoms largely resolved by April 2015 due to lack of complaints in the medical records until Petitioner's work-related injury in July 2016. Resp. Ex. A at 10. She "conclude[d], with a reasonable degree of medical certainty[,] that any complaints the [P]etitioner presented with after his work-related injury [in] 2016 are not in any way related to a flu vaccination in November 2014." Id. Dr. Bishop noted that although Petitioner related his left shoulder and arm issues to his flu vaccine during an appointment in March 2017, "[t]hese findings had clearly developed after his work-related injury as they were not even present during the treatment for that injury." Id. at 11. And, "[a]t best, these findings may suggest further progression of his underlying cervical radiculopathy, which is not related to the vaccination." Id. Thus, Dr. Bishop opined that "although [P]etitioner suspected his symptoms in March 2017 were vaccine-related, his clinical course prior to that date contradicts that claim." Id.

Dr. Bishop found Petitioner's complaints following his work-related injury in 2016, for which he was diagnosed with cervical radiculopathy, to be "very similar" to Petitioner's complaints following the 2014 vaccination. Resp. Ex. A at 10. For example, she noted Petitioner complained of trapezius pain, pain throughout his forearm, and tingling into his index finger on August 23, 2016. Id. On September 22, 2016, Petitioner complained of pain down his arm into the dorsal forearm as well as numbness and tingling into his index/middle finger and forearm with arm abduction. Id. Petitioner then reported stabbing pain down the arm with hand numbness and tingling. Id. Then, on October 25, Petitioner reiterated pain down his left arm into the forearm with numbness in the hand and fingers. Id. In late 2014 to 2015 and again in 2016, Petitioner complained of "pain down the back of his arm, pain down the arm into the forearm and hand, and numbness into the fingers and index finger." Id. Thus, she concluded Petitioner symptoms remained consistent with a cervical radiculopathy during both periods. Id.

Additionally, Dr. Bishop emphasized that all physical examinations of Petitioner following his work-related injury found Petitioner had full range of motion and full shoulder strength. Resp. Ex. A at 10. "[Petitioner] was never noted to have a strength deficit, any muscle atrophy, or a [range of motion] deficit during this timeframe" in 2016 nor in 2014 through April 2015. Id.

Dr. Bishop acknowledged the "diagnostic dilemma" that occurs for a general physician when differentiating between cervical and shoulder pathology. Resp. Ex. A at 9 (citing Resp. Ex. A, Tab 2 (discussing distinguishing characteristics between neurologic and musculoskeletal causes of upper extremity and shoulder pain). She noted "[i]t is not surprising" that "[P]etitioner did not have a clear shoulder diagnosis . . . as his complaints [were] not consistent with a pure shoulder pathology." Id.

Regarding SIRVA, Dr. Bishop opined that "[g]iven the lack of any objective and supportive evidence that [P]etitioner had a distinct shoulder injury after his vaccination,"

Petitioner did not develop a shoulder injury nor did he meet the SIRVA criteria. Resp. Ex. A at 12. Dr. Bishop does not dispute that Petitioner met the first criterion—no history of shoulder pathology that might explain post-vaccination symptoms. Id. Regarding onset, she agreed Petitioner developed shooting pain that radiated down his arm with numbness in his finger within two days of vaccination, but opined these "symptoms [were] most likely attributable to cervical radiculopathy, and were not specific to the shoulder," as described above. Id.

For the third criterion (pain and reduced range of motion limited to the shoulder in which the vaccine was administered), Dr. Bishop opined Petitioner did not meet this criterion because his complaints were more radicular than they were related to the shoulder. Resp. Ex. A at 13. According to Dr. Bishop, "[t]here is no condition in the shoulder that would cause pain radiating into the neck and then down past the elbow, into the hand with numbness in the index finger." Id. Additionally, no reduced range of motion in the shoulder was documented. Id. Even though Petitioner complained of arm pain, Dr. Bishop stressed this symptom is "a common radicular symptom." Id. Lastly, Dr. Bishop opined Petitioner cannot meet criterion four (no other condition or abnormality is present that would explain Petitioner's symptoms). Id. She explained Petitioner was diagnosed with C7 radiculopathy in 2016, and the symptoms that supported this diagnosis "are nearly identical to [Petitioner's] symptoms in later 2014 and 2015." Id. Furthermore, she found "the degree of arthritic change seen in the cervical spine MRI in 2016 [to be] quite advanced, [and] was undoubtedly present in 2014." Id. She concluded Petitioner's findings on MRI are "the most obvious and likely underlying reason for the symptoms in 2014 and 2015, especially as the reported symptoms were very consistent with cervical radiculopathy." Id.

Lastly, with regard to Dr. Busfield's proposed medical theory, Dr. Bishop opined that because Petitioner was not diagnosed with any specific shoulder condition, and did not have and objective radiographic imaging done to support a specific diagnosis, Dr. Busfield's theory is "not relevant." Resp. Ex. A at 13.

Darnley et al.,[26] an article Dr. Bishop co-authored, discussed a case of a 32-year-old patient who developed shoulder pain soon after receiving a flu vaccination. Resp. Ex. A, Tab 1 at 1, 3. The patient was diagnosed with septic arthritis and rotator cuff tear. Id. at 2. "Due to a lack of another cause and the time course in which her symptoms began, [the authors] believe[d] . . . "[t]he vaccine was the inciting event." Id. at 3. Darnley et al. stressed "the importance of a diagnostic work-up in a patient presenting with shoulder pain after a vaccine" because "[s]houlder pain after a vaccination could often have a benign presentation." Id.

[26] James E. Darnley et al., Septic Arthritis of the Glenohumeral Joint Following Influenza Vaccination: Case Report and Review of the Literature, 30 Current Orthopaedic Practice 1 (2019).

3. Respondent's Expert, Dr. Brian C. Callaghan

a. Background and Qualifications

Dr. Callaghan is board certified in neurology and electrodiagnostic medicine. Resp. Ex. D at 1. After receiving his M.D. from the University of Pennsylvania Medical Center, he completed a preliminary medicine internship and neurology residency at the University of Pennsylvania Medical Center and a neuromuscular fellowship at the University of Michigan Health System. Id. He currently works as an Associate Professor of Neurology at the University of Michigan and as "a neuromuscular specialist with a primary interest in patients with neuropathy such as cervical radiculopathy." Resp. Ex. C at 1. Dr. Callaghan "ha[s] published more than 100 articles with most focusing on neuropathy including the appropriate diagnostic evaluation and treatment." Id.; see also Resp. Ex. D at 10-17. He estimates that he has seen over 200 patients with cervical radiculopathy throughout his career. Resp. Ex. C at 1.

b. Opinion

Dr. Callaghan opined, "more likely than not," Petitioner's correct diagnosis was a cervical radiculopathy based on Petitioner's history, examinations, and MRI results, and consistent with the findings of orthopedist Dr. Waterman and orthopedic spine specialists Dr. Duncan and Dr. Schwartz. Resp. Ex. C at 5-7. A cervical radiculopathy occurs when there is "[c]ompression of the nerve roots in the neck by arthritic changes and/or disc herniation." Resp. Ex. C at 6 (citing Resp. Ex. C, Tab 2 at 1).[27] "Patient presentations can range from complaints of pain, numbness, and/or tingling in the upper extremity to electrical type pains or even weakness." Resp. Ex. C, Tab 2 at 1. "C7 pain radiates down the dorsal aspect of the arm, through the elbow and into the third digit." Id. at 3.

According to Dr. Callaghan, Petitioner's symptoms of radiating pain, numbness, tingling, and neck pain coupled with examination findings of numbness in Petitioner's left index finger and a positive Spurling test were "more consistent with a cervical radiculopathy." Resp. Ex. C at 6. Dr. Callaghan acknowledged that a Spurling test was not conducted prior to Petitioner's work injury in July 2016, but reasoned that symptoms consistent with a positive Spurling test (pain when moving head to right side) were present in December 2014. Id. Additionally, Dr. Callaghan opined Petitioner's cervical spine MRI confirmed the diagnosis of cervical radiculopathy "as it demonstrate[d] narrowing which would be expected to compress the left C7 nerve root, which is compatible with the [P]etitioner's symptoms of pain radiating into the left arm," as well as "degenerative changes in his neck that could compress left C5 and C6." Id.

Because the symptoms reported by Petitioner in December 2014, which Petitioner associated with his flu vaccine, are "almost entirely identical" to the symptoms following Petitioner's July 2016 work-related injury, Dr. Callaghan opined "[the symptoms] are most likely from the same underlying cause." Resp. Ex. C at 5. For support, he noted "[Petitioner] consistently reported radiating pain from his neck and down into his arm and numbness in his

[27] John M. Cardidi et al., Cervical Radiculopathy: A Review, 7 Hosp. for Special Surgery J. 265 (2011).

left hand" in 2014. Id. Petitioner also reported his symptoms were replicated when he turned his head to the right in 2014, which Dr. Callaghan found consistent with symptoms stemming from the cervical region. Id. Even though Petitioner's symptoms following his 2016 work-related injury were "more severe," Dr. Callaghan emphasized Petitioner continued to report pain in his neck, that radiated down his arm, with numbness in his left hand as well as arm symptoms that were reproduced when he turned his head. Id.

Dr. Callaghan noted no provider diagnosed Petitioner with a "distinct shoulder condition." Resp. Ex. C at 5. "[O]ther than a reference to impingement-related pain in his left shoulder during a visit in 2014, [Petitioner's] shoulder joint examinations were largely normal." Id. Petitioner's primary care provider, in 2014, thought Petitioner's symptoms were related to a nerve issue and diagnosed neuropathy and neuropraxia. Id. Dr. Callaghan also noted that examinations of Petitioner's left shoulder and neck were conducted by Dr. Waterman, Dr. Duncan, and Dr. Schwartz, and none found Petitioner suffered from a "distinct and separate shoulder condition." Id. at 5-6. Instead, all three doctors determined Petitioner's symptoms and examination findings were consistent with a cervical radiculopathy. Id. at 6. Dr. Waterman, in September 2016, found Petitioner's symptoms "consistent with a cervical radiculopathy." Id. at 5 (citing Pet. Ex. 8 at 7). Dr. Duncan, later in September 2016, assessed Petitioner with a cervical radiculopathy. Id. (citing Pet. Ex. 8 at 3). And Dr. Schwartz diagnosed Petitioner with a resolving left C7 radiculopathy in October 2016. Id. (citing Pet. Ex. 12 at 6).

In response to Dr. Busfield's opinion that there is evidence of both a cervical radiculopathy and SIRVA, Dr. Callaghan opined Dr. Busfield provided no evidence to support a finding of shoulder pathology in Petitioner. Resp. Ex. C at 6. Dr. Callaghan also noted a shoulder MRI and EMG, which could have aided in diagnosing Petitioner's condition, were not done. Id.

With regard to the Vaccine Injury Table criteria for SIRVA, Dr. Callaghan opined Petitioner did not meet the third and fourth criteria. Resp. Ex. C at 6-7. Criterion three, or pain and reduced range of motion limited to the shoulder in which the vaccine was administered, was not met because (1) Petitioner reported radiating pain down the arm and hand and (2) Petitioner reported neck pain, "which would not be expected in a shoulder condition." Id. at 6. Dr. Callaghan opined the symptom of neck pain is expected with cervical radiculopathy. Id. He added that physical examinations did not note "any objective findings consistent with a distinct shoulder pathology." Id. Criterion four—no other condition or abnormality present that would explain Petitioner's symptoms—was not met "because all of his symptoms can be explained by the diagnosis of cervical radiculopathy." Id. Additionally, Dr. Callaghan cited to the cervical spine MRI as evidence of "clear findings consistent with a cervical radiculopathy." Id.

Dr. Busfield also argued the cervical spondylosis was age-related and could have already been present prior to his work injury in July 2016. Pet. Ex. 146 at 10. In response, Dr. Callaghan opined that although "cervical spondylosis was likely already present before the left upper extremity symptoms started, this does not mean that these changes were not the cause of any [of] the symptoms." Resp. Ex. C at 7. He explained that "[d]egenerative changes in the neck accumulate over time and patients often have a period without symptoms prior to causing enough nerve root injury to elicit symptoms." Id. He found "[P]etitioner's symptoms reported

after his vaccination were entirely consistent with a cervical condition, but they were more mild." Id. Petitioner's symptoms progressed over time and then became more severe following his work injury in July 2016. Id.

Lastly, Dr. Callaghan found Dr. Busfield's case reports "only suggest[]" a proximal temporal relationship between vaccination and injury. Resp. Ex. C at 7. Additionally, they discussed injuries that Petitioner did not develop. Id. "[W]hile case reports are valuable tools in flagging areas for future study, they are anecdotal and provide low-level evidence compared to other study designs." Id.

Dr. Callaghan concluded Petitioner's correct diagnosis is cervical radiculopathy, which is "the most likely cause" of Petitioner's left shoulder and arm pain symptoms. Resp. Ex. C at 5-7. He found "no evidence a vaccine can cause, or does cause, cervical radiculopathy."[28] Id. at 7.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 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 & Hum. 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. § 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 & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

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 & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. 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

[28] Dr. Callaghan noted he "performed a literature search investigating the association of vaccines and SIRVA," but he did not file the medical literature he found pursuant to this search. Resp. Ex. C at 1.

can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 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 & Hum. 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, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such

testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

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

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege he suffered a Table Injury, he must prove a vaccine he received caused his injury. 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, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. 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 & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 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." § 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 his 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).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and

noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

V. ANALYSIS

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury[,]" determining facts relating to the claimed injury can be significant in a case like this, where Petitioner's diagnosis is in dispute. Id. Thus, before determining if Petitioner has met each prong of Althen, the undersigned addresses whether Petitioner has established, by a preponderance of the evidence, that Petitioner suffers from SIRVA.

Dr. Busfield opined Petitioner developed a SIRVA following his November 21, 2014 flu vaccination, and a cervical spondylosis after a work injury in July 2016. He explained that Petitioner had no pre-existing shoulder pathology prior to vaccination, that Petitioner developed pain in his shoulder and arm within 24 hours of vaccination, and that there is no alternative cause for Petitioner's symptoms. Dr. Busfield acknowledged Petitioner's cervical pathology, but opined there was no evidence of cervical pathology prior to July 2016.

Dr. Bishop and Dr. Callaghan opined Petitioner suffered from cervical radiculopathy, not SIRVA, and that the cervical radiculopathy is the most likely cause of Petitioner's symptoms that began in November 2014. Resp. Ex. A at 13; Resp. Ex. C at 5-7. Both Dr. Bishop and Dr. Callaghan agreed that Petitioner's symptoms of pain and numbness radiating down his arm to the finger were consistent with a cervical radiculopathy. Resp. Ex. A at 9; Resp. Ex. C at 6. They also asserted that because the symptoms Petitioner complained of in 2014/2015 matched those symptoms in 2016, when Petitioner received the cervical radiculopathy diagnosis from his treating physicians, Petitioner's symptoms during both periods of time were likely due to the same underlying condition—cervical radiculopathy. Resp. Ex. A at 10; Resp. Ex. C at 5.

Dr. Bishop and Dr. Callaghan both argued that even if Petitioner's left shoulder pain with positive impingement testing on December 8, 2014 was vaccine-related, there was no evidence of any distinct shoulder pathology after December 8, 2014. Resp. Ex. A at 10; Resp. Ex. C at 6. Additionally, they also asserted that no shoulder imaging was ever ordered that could confirm a distinct shoulder condition, nor did Petitioner receive a distinct shoulder diagnosis. Resp. Ex. A at 8; Resp. Ex. C at 5-6.

For the following reasons, the undersigned finds preponderant evidence that Petitioner suffered from shoulder pain following flu vaccination. First, Petitioner's treating physicians documented complaints of shoulder pain following vaccination. On December 8, 2014, Petitioner reported his "pain in his left shoulder [began] after his flu shot." Pet. Ex. 2 at 40. Petitioner also stated "shooting pains around his shoulder and down to his forearm" began within two days after receiving the flu vaccine. Id. Physical examination revealed "[m]ild decreased sensation at finger pad area of left index finger" and "[m]ild left shoulder pain with impingement testing." Id. at 41. Dr. Ibarra's assessment was "[l]eft shoulder pain with radiation" and "[l]eft index finger neuralgia." Id. at 42. Petitioner was prescribed a Medrol Dose Pak. Thus, 17 days after vaccination, Petitioner's physician made an assessment of left shoulder pain.

Petitioner returned to Dr. Ibarra on December 12, 2014. Diagnosis was "[l]eft shoulder upper extremity pain and finger neuralgia." Pet. Ex. 2 at 43. Petitioner was directed to apply hot and cold compresses to his left trapezius area. Again, Dr. Ibarra assessed Petitioner with left shoulder pain.

At a follow-up visit on December 31, 2014, Petitioner's physical examination was normal; however, assessment remained "[left] shoulder pain etio[logy]? Poss[ible] neuropraxia." Pet. Ex. 2 at 48. Petitioner was directed to continue taking Meloxicam and Flexeril, perform shoulder exercises, and apply alternating hot and cold compresses as needed.

Petitioner saw Dr. Dinwiddie on January 30, 2015 for an issue unrelated to his left shoulder. Although the records do not document that Petitioner complained of shoulder pain, Dr. Dinwiddie submitted a letter stating that Petitioner complained of his shoulder injury during this appointment. LPN Nellen also recalled Petitioner complaining of his "continued . . . problems with pain in his shoulder." Pet. Ex. 14 at 1.

On April 14, 2015, Petitioner returned to Dr. Ibarra for "[l]eft shoulder pain since 11/2014." Pet. Ex. 2 at 49. Petitioner stated that since his flu vaccine in November, he has had continuous pain in his left shoulder. Id. Dr. Ibarra's diagnosis was "shoulder pain." Id. at 51. Petitioner was directed to continue range of motion exercises and was prescribed Flexeril and prednisone.

Petitioner returned to Dr. Dinwiddie in August 2015, again for issues unrelated to his left shoulder. Although the records do not document shoulder complaints, Dr. Dinwiddie recalled Petitioner complaining of his shoulder injury during this visit. LPN Nellen likewise recalled Petitioner mentioning his shoulder injury and indicating "his shoulder was slowly getting better." Pet. Ex. 14 at 1.

Thus, from December 2014 to April 2015, Dr. Ibarra consistently diagnosed Petitioner with left shoulder pain and/or left shoulder upper extremity pain. Additionally, Dr. Ibarra continually treated Petitioner for his shoulder pain by prescribing steroids, a muscle relaxant, a nonsteroidal anti-inflammatory drug, alternating hot and cold compress, and at-home shoulder exercises. Dr. Dinwiddie and LPN Nellen recalled Petitioner complaining of shoulder pain at his appointments in January 2015 and August 2015. Petitioner's treating physician in 2014 through

August 2015 continually documented Petitioner's complaints of shoulder pain and assessed him with shoulder pain.

Here, the undersigned gives deference to the statements of Petitioner's treating physicians as they are "in the best position" to determine Petitioner's injury and the cause of such injury. See Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326; Cucuras, 993 F.2d at 1528 (noting contemporaneous medical records, "in general, warrant consideration as trustworthy evidence"). Therefore, the undersigned finds Petitioner has proven by preponderant evidence that he suffered from shoulder pain following his flu vaccination in November 2014.

Dr. Ibarra also diagnosed Petitioner with left index finger numbness and/or neuralgia. However, this diagnosis does not negate the primary diagnosis of shoulder pain.

Second, the undersigned disagrees that Petitioner's clinical course and symptoms were the same after vaccination in 2014 and after Petitioner's work injury in 2016. After vaccination, Petitioner's pain was characterized as shoulder pain. Petitioner did not present with neck pain. Nor did he have numbness in his shoulder radiating down the arm. Petitioner exhibited shoulder pain with impingement testing. And he had pain with range of motion of the shoulder. After his work injury in 2016, Petitioner's injury occurred to his neck, with shooting pain originating from the neck. He had numbness in the arm, index, and middle fingers.[29] An MRI confirmed diagnosis of cervical pathology. Petitioner's symptoms were also consistent with cervical radiculopathy, leading to a diagnosis of cervical radiculopathy. Therefore, the undersigned is not persuaded by Respondent's experts' arguments on this point.

B. Six-Month Severity Requirement

To be entitled to compensation, Petitioner must show he

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 11(c)(1)(D). Here, Petitioner must prove by preponderant evidence that he "suffered the residual effects or complications of [his] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." Id. at § 11(c)(1)(D)(i).

Petitioner argues his symptoms that began on November 21, 2014 continued through the summer of 2015, and at least until August 2015, satisfying the six-month severity requirement. Pet. Mot. at 9-18; Pet. Reply at 15-16. Petitioner acknowledges that his medical records do not note his shoulder condition after April 2015, but asserts the affidavits provide evidence that Petitioner's shoulder pain continued until at least August 2015. Pet. Mot. at 10.

[29] See Resp. Ex. C, Tab 2 at 3 (noting a C7 radiculopathy radiates down the arm into the third digit, or middle finger).

Respondent argues Petitioner does not meet the six-month severity requirement under the statute because he did not provide preponderant evidence that he "suffered the residual effects or complications of [his alleged injury] for more than six months after the administration of the vaccine." Resp. Response at 23-24 (citing § 11(c)(1)(D)(i)). Respondent, quoting his expert Dr. Bishop, argued "[P]etitioner did have one positive shoulder exam finding, a positive impingement test on December 8, 2014," that resolved by December 12, 2014, and thereafter "there [was] no supporting evidence for any distinct shoulder pathology." Id. at 24 (quoting Resp. Ex. A at 9). "While [P]etitioner submitted an affidavit, and those from numerous affiants, stating that his shoulder pain persisted over six months after vaccination," Respondent argued "those opinions cannot be given any weight[] because . . . it can be difficult to differentiate shoulder pain caused by an issue specific to the shoulder joint, and a medical examination and medical history are needed to differentiate those condition." Id. And "none of the affiants can state whether [P]etitioner's symptoms were due to a specific shoulder condition rather than cervical radiculopathy." Id.

The undersigned finds preponderant evidence that Petitioner suffered from shoulder pain for more than six months. Petitioner first saw a provider on December 8, 2014, and reported his pain in his left shoulder and arm began after flu vaccination. "About [two] days after the flu shot [Petitioner] started getting shooting pains around his shoulder and down to his forearm." Pet. Ex. 2 at 40. On December 12 and December 31, 2014, Petitioner returned to Dr. Ibarra for his left shoulder pain.

On January 30, 2015, Petitioner saw Dr. Dinwiddie, for a follow-up visit for unrelated issues. In his letter, Dr. Dinwiddie wrote Petitioner reported shoulder pain following flu vaccination at this visit. And in LPN Nellen's letter, she recalled Petitioner showing her where he received his flu vaccination and complaining of "continued . . . problems with pain in his shoulder." Pet. Ex. 14 at 1.

Petitioner returned to Dr. Ibarra's office on April 14, 2015 for "[l]eft shoulder pain since 11/2014." Pet. Ex. 2 at 49.

Petitioner's next visit was on August 14, 2015, when he returned to Dr. Dinwiddie for issues unrelated to his left shoulder. Dr. Dinwiddie noted, in a letter, Petitioner complained of shoulder pain following flu vaccination during this visit. LPN Nellen's letter noted Petitioner "mention[ed] that his shoulder was slowly getting better" at this visit. Pet. Ex. 14 at 1. The Federal Circuit has made clear that medical records are not presumed "accurate and complete as to all the patient's physical conditions." Kirby, 997 F.3d at 1382 (rejecting the presumption); see also Shapiro, 101 Fed. Cl. at 538 ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy, 23 Cl. Ct. at 733)).

The above timeline established by preponderant evidence that Petitioner suffered from shoulder pain from November 2014 until August 2015, which is more than six months of

sequela.[30] Thus, Petitioner has shown, by preponderant evidence, that he "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." § 11(c)(1)(D)(i).

C. Causation Analysis

1. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d 1339 at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The mechanism for a SIRVA injury is well-described in the medical literature. For example, Hexter et al. explained that an inadvertent injection of a vaccine into the subdeltoid bursa can lead to inflammation, dysfunction, and pain of the shoulder. Pet. Ex. 149 at 3. "[U]ndoubtedly, vaccines can be unintentionally injected into structures underlying deltoid muscle." Id. at 4. Thus, "[w]hen a vaccine is injected into the subdeltoid bursa, a prolonged inflammatory process results from an immune response to a vaccine antigen, to which the recipient has previously been sensitised either naturally or via previous vaccination." Id.

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 added SIRVA after receipt of an intramuscularly administered 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 & Hum. Servs., 88 Fed. Cl. 178, 193 (2009), rev'd on other grounds, 527 F. App'x. 875 (Fed. Cir. 2013)

[30] The undersigned does not find evidence of continued shoulder pain from flu vaccination after August 2015, and thus, Petitioner may not recover damages for any pain or injury after August 2015.

Moreover, Petitioner submitted the expert opinions of Dr. Busfield, who provided a sound and reliable medical and scientific theory of causation supported by medical literature. In summary, Dr. Busfield explained that the injection of a vaccine into the shoulder joint can lead to shoulder pathology of inflammation and pain due to "mechanical trauma and/or directly related immune response from the injection placed into the subacromial space or shoulder joint." Pet. Ex. 146 at 11-12. Respondent's experts do not dispute Petitioner's theory generally, nor do they argue the theory is not sound or reliable. Respondent's experts opine that because Petitioner was not given a specific shoulder diagnosis, and that Petitioner was diagnosed with a cervical radiculopathy, albeit almost two years post-vaccination, that this theory is not relevant. However, for the reasons described above, the undersigned does not find these arguments persuasive, and finds "shoulder pain" is a sufficient diagnosis.

For all of the above reasons, the undersigned finds Petitioner has provided by preponderant evidence a sound and reliable theory that the flu vaccine administered intramuscularly can cause SIRVA, and therefore, Petitioner has satisfied the first Althen prong.

2. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

With regard to the second Althen prong, the undersigned finds there is preponderant evidence in the record to support a logical sequence of cause and effect showing the November 21, 2014 flu vaccination to be the cause of Petitioner's left shoulder pain.

First, Petitioner's clinical course is consistent with the mechanism purported for a SIRVA following flu vaccination. Overall, Petitioner's pain began within two days after vaccination, the pain worsened with movement, Petitioner experienced pain with range of motion, and Petitioner's pain interfered with his ability to perform activities.

Petitioner received the flu vaccine at issue on November 21, 2014. Petitioner first complained of his shoulder pain to a treating physician on December 8, 2014. Dr. Ibarra documented Petitioner reported pain began "[a]bout [two] days after the flu shot." Pet. Ex. 2 at 40. When Petitioner returned to Dr. Ibarra's office on April 14, 2015, he stated that since his flu vaccine in November, he has had continuous pain in his left shoulder. Petitioner averred that "[w]ithin 24 hours of receiving the vaccination, [he] began to experience pain in [his] left shoulder." Pet. Ex. 6 at ¶¶ 6-7.

Petitioner also reported shoulder pain since his flu vaccination to friends. Mr. Wagner recalled Petitioner reporting "that he had had the pain in his shoulder ever since getting a flu shot." Pet. Ex. 23 at ¶ 9. Mr. Wagner stated "there did not seem to be any doubt in his mind" regarding pain onset. Id. Ms. Dunnuck remembered Petitioner complaining of shoulder pain that began when he received a flu shot. Pet. Ex. 24 at ¶ 4. Ms. Reeder saw Petitioner on the date of his vaccination and observed "[h]e was clearly in a lot of pain." Pet. Ex. 27 at ¶ 2. Petitioner told her that he had pain in his shoulder since his flu vaccination. Id. ¶¶ 2, 4. Ms. Reeder believed Petitioner had no doubts about the timeline of his symptoms. Id. at ¶ 4.

Throughout Petitioner's course, he reported his pain worsened with movement and he had pain with range of motion. On December 8, 2014, Petitioner reported left shoulder pain when he raised his arm. On April 14, 2015, Petitioner complained of pain with range of motion of shoulder and left scapular and supraspinatus pain. At this visit, NP Myers documented Petitioner's pain was exacerbated with movement and relieved with "immobilization." Pet. Ex. 2 at 49.

To prevent his arm from moving, Petitioner would tie his arm to his torso with a belt. In 2014 and 2015, Ms. Reeder remembered Petitioner holding his arm in a certain position "because he said it helped with the pain in his shoulder." Pet. Ex. 27 at ¶ 4. Ms. Reeder also saw Petitioner at basketball games holding his arm in a strange position to help with the pain. Id. at ¶ 6. She also recalled seeing Petitioner in his home with his arm tied to his body with a belt. Id. at ¶ 9.

Additionally, Petitioner's pain interfered with his ability to perform activities. Petitioner found work difficult due to his shoulder pain, and requested less physical work duties shortly after vaccination. In his free time, Petitioner enjoyed spending time with his daughter, coaching youth basketball, and participating in horse pulling, which he explained were all affected by his shoulder injury. Petitioner was unable to demonstrate certain basketball skills and had difficulty carrying equipment at basketball practices and games.

With horse pulling, Petitioner was unable to participate because of the physically demanding nature of hitching and horse pulling. Mr. Wagner stepped in for Petitioner as hitcher during the summer of 2015. Ms. Dunnock communicated with Petitioner almost daily during the summer of 2015, and "[Petitioner] often talked about the pain in his shoulder and he mentioned repeatedly that the shoulder pain was the reason he was not pulling." Pet. Ex. 24 at ¶ 6.

Moreover, the undersigned finds Dr. Busfield's opinions persuasive regarding the importance of a patient's recollection. Specifically, he opined "the trigger of sudden-onset

orthopedic pain is highly likely to be correct when it is offered just a few weeks after the fact." Pet. Ex. 146 at 12. He noted Petitioner asserted the flu shot as the trigger of his pain on December 8, 2014, 17 days after vaccination, and on April 14, 2015, which he found to be "a consistent pattern of attribution of the injury to the shot, with pain immediately following the shot." Id. Thus, "the most medically reasonable and probable conclusion is that the pain in fact immediately followed the shot and the shot caused it." Id. at 13.

Thus, based on all of the evidence, the undersigned finds Petitioner developed shoulder pain consistent with SIRVA following flu vaccination. See Shyface, 165 F.3d at 1352-53 (the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury"). The undersigned also finds the medical records, affidavits, and letters illustrate Petitioner's shoulder pain began within two days of flu vaccination, and continued throughout the summer of 2015, until August 2015, almost 10 months after vaccination. This finding is also consistent with the evidence presented by Petitioner, Dr. Dinwiddie, and his expert, Dr. Busfield.

Next, the undersigned does not agree that Petitioner's shoulder pain can be attributed to an alternative factor unrelated to vaccination from November 2014 to August 2015. Respondent's experts opine Petitioner's symptoms can be explained by cervical radiculopathy. However, this opinion ignores the fact that Petitioner's physicians gave him two distinct diagnoses, left shoulder pain and finger neuralgia/numbness. Further, Petitioner was not diagnosed with cervical radiculopathy by his treating physicians after vaccination, in 2014, or in 2015. He did not have any diagnostic studies that revealed cervical pathology after vaccination, in 2014, or in 2015. He did have index finger numbness that was attributed to finger neuralgia. However, nerve pathology causing finger numbness is not pathognomonic for cervical radiculopathy or cervical pathology. Additionally, for the reasons described above in the diagnosis section, the undersigned found Petitioner's presentation in 2014 following vaccination different than his presentation in 2016 following his work-related injury. Moreover, as explained by Dr. Busfield, it is "common to have overlapping radicular and shoulder pathology" but "the presence of radicular pain [does] not . . . mean that the vaccine [did] not cause[] [Petitioner's] shoulder injury."[31] Pet. Ex. 146 at 10.

The undersigned agrees with Respondent's experts with respect to the injury that he sustained on July 23, 2016. On August 16, 2016, Petitioner sought treatment for a neck and upper arm injury sustained at work on July 23, 2016 while "removing [a] fallen limb from highway." Pet. Ex. 10 at 28. On September 12, 2016, a cervical spine MRI revealed degeneration at multiple cervical levels. Dr. Waterman, an orthopedist, diagnosed Petitioner with cervical radiculopathy on September 22, 2016. Petitioner saw Dr. Duncan, an orthopedic surgeon, on September 27, 2016. Assessment was cervical radiculopathy. And on October 25, 2016, Petitioner saw Dr. Schwartz, an orthopedist, whose assessment was left C7 radiculopathy after Petitioner's examination revealed a "positive left Spurling sign to the C7 distribution." Pet. Ex. 12 at 6. Respondent's experts, Dr. Bishop and Dr. Callaghan, agreed with Petitioner's

[31] See, e.g., Gurney v. Sec'y Health & Hum. Servs., No. 17-481V, 2019 WL 2298790, at *6 n.12 (Fed. Cl. Spec. Mstr. Mar. 19, 2019) (noting Respondent's expert explained "patients often have overlap of shoulder, neck and nerve complaints").

treating physicians and opined Petitioner suffered from cervical radiculopathy. Dr. Bishop and Dr. Callaghan also opined the cervical radiculopathy was not caused by Petitioner's 2014 flu vaccination.

Further, the undersigned finds there is not preponderant evidence that Petitioner's shoulder pain persisted after August 2015. Petitioner's medical records and letters from Dr. Dinwiddie and LPN Nellen establish complaints of shoulder pain until August 2015. There is no medical record evidence of shoulder pain between August 2015 and July 2016, when Petitioner suffered a work-related injury. And Petitioner conceded that his shoulder pain continued at least until August 2015. Pet. Mot. at 9-18; Pet. Reply at 15-16.

For the reasons described above, the undersigned finds that Petitioner has provided preponderant evidence of a logical sequence of cause and effect required under Althen prong two for a SIRVA after his flu vaccination on November 21, 2014 until August 2015.

3. Althen Prong Three

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 defined as a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. 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 & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury"), aff'd, 475 F. App'x 765 (Fed. Cir. 2012).

Dr. Busfield opined Petitioner's "onset of pain [was] immediately after flu vaccination and certainly within 24 hours." Pet. Ex. 146 at 13-14. Dr. Bishop agreed Petitioner developed symptoms within two days of vaccination, although she found these symptoms more consistent with a cervical radiculopathy. Resp. Ex. A at 10. Dr. Callaghan did not dispute Petitioner's symptoms began within two days. See Resp. Ex. C at 6-7.

The undersigned finds Petitioner's shoulder pain began within two days of his flu vaccination, consistent with the experts' opinions, medical records, and affidavits and letters. This timing is medically acceptable given the Petitioner's mechanism. Therefore, the undersigned finds the temporal association is appropriate given the mechanism of injury and Petitioner has satisfied the third Althen prong.

4. Alternative Causation

Because the undersigned concludes that Petitioner has established a prima facie case, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence "that [Petitioner's] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to Althen prong two, the undersigned found Respondent failed to establish evidence to show that Petitioner's SIRVA was caused by a source other than vaccination. Thus, Respondent did not prove by a preponderance of evidence that Petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

VI. CONCLUSION

For the reasons discussed above, the undersigned finds that Petitioner has established by preponderant evidence that his November 21, 2014 flu vaccine caused his left shoulder injury, which began in November 2014, and continued until August 2015. Therefore, Petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master