In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 31, 2023

EMON HOLLINS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 18-1313V Special Master Sanders

John L. Shipley, Davis, CA, for Petitioner.
Colleen C. Hartley, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On August 28, 2018, Emon Hollins ("Petitioner"), filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2018),[2] alleging a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered on November 10, 2015. Pet. at 1, ¶ 14, ECF No. 1. After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has failed to provide preponderant evidence that the flu

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

vaccine he received on November 10, 2015, caused him suffer from a SIRVA or an off-Table local shoulder injury consistent with SIRVA. Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed an affidavit, medical records, and a statement of completion on September 10, 2018. Pet'r's Exs. 1–7, ECF Nos. 8-1–8-7, 9. Petitioner filed another medical record on September 25, 2018. Pet'r's Ex. 8, ECF No. 10-1. On February 28, 2019, Petitioner filed a supplemental affidavit and a vaccine administration record. Supp. Aff., ECF No. 14; Pet'r's Ex. 9, ECF No. 15-1. In a status report dated May 29, 2019, Respondent identified several outstanding medical records. ECF No. 21 at 1. Petitioner responded on September 12, 2019, and filed additional medical records and a statement of completion. Pet'r's Exs. 10–12, ECF Nos. 27-1–27-3, 30. Respondent filed a Rule 4(c) report on December 18, 2019. ECF No. 34. The following day, Respondent filed a motion to stay the proceedings in this case "for a period of at least ninety days."[4] ECF No. 36 at 1. The presiding special master granted Respondent's request. Order at 3, ECF No. 37.

Petitioner's counsel filed a stipulation for withdrawal of counsel on February 24, 2020, that was granted on February 26, 2020. ECF Nos. 38–39. Petitioner continued the case, as a *pro se* litigant, and this case was reassigned to me on February 26, 2020. ECF No. 42. On April 6, 2020, Petitioner's former counsel filed a motion for leave to file for attorney's fees. ECF. No. 44. The motion was granted, and the subsequent motion for fees was filed on October 23, 2020, and granted on August 13, 2021. ECF Nos. 52–53, 66. Petitioner acquired new counsel on March 11, 2021. ECF No. 59.

I held a status conference in this case on May 18, 2021, and ordered Petitioner to file an expert report no later than July 20, 2021. Min. Entry, docketed May 18, 2021; Scheduling Order at 1, ECF No. 63. After two motions for extension of time, Petitioner filed a second supplemental affidavit on September 29, 2021, and his expert report with medical literature on October 3, 2021. 2nd Supp. Aff., ECF No. 69-1; Pet'r's Exs. 14–19, ECF No. 70-1–70-7, 71.[5] Respondent filed his expert report on December 6, 2021, along with the expert's curriculum vitae ("CV") and supporting medical literature. Resp't's Exs. A, A Tab 1, B, ECF Nos. 72-1–72-3. Petitioner filed a second supplemental expert report on February 4, 2022. Pet'r's Ex. 20, ECF No. 73-1. Respondent filed his supplemental expert report and medical literature on April 13, 2022. Resp't's Exs. C, C Tab 1, ECF Nos. 74-1–74-2. Petitioner filed his expert's CV on July 9, 2022. Pet'r's Ex. 21, ECF No. 76-1.

On July 15, 2022, Petitioner filed a motion for a ruling on the record. Pet'r's Mot., ECF No. 77. Respondent filed his response on September 12, 2022. Resp't's Resp., ECF No. 78. Petitioner replied on September 26, 2022. Pet'r's Reply, ECF No. 79.

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[4] Respondent noted "twenty-three Vaccine Act petitions filed [between January 1, 2018 and December 19, 2019], alleging [SIRVA] from a vaccine administered at a Wisconsin state prison." ECF No. 36 at 1. He expressed "serious concerns about the veracity of these petitions," given the high number of submission and requested "the opportunity to thoroughly investigate these cases before taking a position on the merits of the instant petition."

[5] Petitioner filed his first expert report twice, both times without an exhibit number. I will thus refer to this expert report as Petitioner's Exhibit 14.1.

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. 300aa § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). Accordingly, this matter is now ripe for resolution.

II. Factual History

A. Medical Records

1. Pre-vaccination Medical Records

Petitioner's pre-vaccination medical history is significant for Graves' disease,[6] rheumatoid arthritis ("RA"),[7] polysubstance abuse, and obesity. Pet'r's Ex. 2 at 5, 8, 16–17, ECF No. 8-2. Petitioner's medical records reflect that at the time of all medical evaluations, treatment, and the vaccination at issue in this case, Petitioner was an inmate at the Waupun Correctional Institution in Wisconsin. Petitioner reported left-sided chest pain to the Wisconsin correctional facility's on-call, registered nurse on January 7, 2015. *Id.* at 433. On May 18, 2015, he complained of "shaking pain in shoulder and [of his] knee 'really hurting[.]'" *Id.* at 52. Nurse progress notes from July 8, 2015, show that Petitioner was seen for "hands, elbows, shoulder, [and] knees pain [at a severity of 6] of 10" and indicated that the pain began in March of 2015. *Id.* The record notes "wrists[,] elbows[,] shoulder[, and] knee [sic] sore to palp[ation with] slight swelling of hands[.]" *Id.* Petitioner was assessed with [rheumatoid factor][8] arthralgias[9] [clinically warranted] rheumatoid arthritis[.]" *Id.* He declined steroids to lower inflammation. *Id.* A July 30, 2015 progress note recorded Petitioner's complaints of pain and burning in his joints but states that he "never took Prednisone.[10]" *Id.* at 48. A follow-up note dated August 6, 2015, describes "marked improvement in joint pain [on] Prednisone." *Id.* at 49.

Petitioner had an initial consultation with rheumatologist Dr. Elzbieta Perry on November 5, 2015. Pet'r's Ex. 5 at 140, ECF No. 8-5. Petitioner reported that "he was in his normal state of health until March of [2015] when he started to experience joint pain." *Id.* He described

[6] Graves' disease is "a syndrome of diffuse hyperplasia of the thyroid, with a female predominance; it usually has an autoimmune etiology and has been linked to autoimmune thyroiditis." *Dorland's Illustrated Medical Dictionary* 527 (33rd ed. 2020) [hereinafter "*Dorland's*"].
[7] Rheumatoid arthritis is "a chronic systemic disease primarily of the joints, usually polyarticular, marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefaction of the bones." *Dorland's* at 154.
[8] Rheumatoid factor are "antibodies directed against antigenic determinants . . . these are found in the serum of about 80 percent of persons with classical or definite [RA] . . . ." *Dorland's* at 669.
[9] Arthralgias are joint pains. *Dorland's* at 154.
[10] Prednisone is "a synthetic glucocorticoid derived from cortisone[.]" *Dorland's* at 1486.

> pain [in] shoulders, knees, wrists, right ankle and hand joints. He rates the pain level as 8 out of 10. He feels that the left shoulder gets swollen, and he noticed intermittent swelling of the right knee. He states the pain is worse in the morning. Because of that, he had laboratory workup obtained by his prime physician in July which showed normal markers of inflammation but rheumatoid factor was 40.

Id. Petitioner's exam revealed "mild tenderness along the glenohumeral joints[11] but full range of motion [("ROM")] in these joints." *Id.* at 142. Petitioner also reported "numbness in his hands and feet . . . [and] fatigue since the diagnosis of Graves' disease." *Id.* at 140. Dr. Perry diagnosed Petitioner with arthralgia, Graves' disease, and left shoulder pain. *Id.* at 143. She noted that Petitioner's Graves' disease "is still uncontrolled[, and i]t is possible that joint pain is related to uncontrolled disease." *Id.* Petitioner was referred for a shoulder x-ray to rule out further consideration of synovitis[12] with unremarkable results. *Id.* at 143, 148.

2. Vaccination and Post-Vaccination Medical Records

Petitioner received the flu vaccination at issue in this case on November 10, 2015. Pet'r's Ex. 9 at 1–2, ECF No. 15-1. The next day, on November 11, 2015, Petitioner reported that he was experiencing chest pain and problems with his left arm that may be related to the flu vaccination he received on November 10, 2015. Pet'r's Ex. 2 at 46–47. During an examination, Petitioner complained of left arm pain and axilla[13] pain. *Id.* at 44–45. The treating nurse noted ROM limitations, "warmth at injection site L deltoid" and "[e]nlarged lymph in L axilla[.]" *Id.* The nurse also noted that Petitioner's left upper arm was swollen. *Id.* at 46–47. The medical note includes objective results for the left deltoid and bicep, and the right deltoid and bicep. *See id.* at 44. Pain is also noted at the right deltoid. *Id.* Petitioner was assessed with "acute pain" and provided with a flu vaccine information statement. *Id.*

On November 12, 2015, Petitioner made a request for a pillow, bottom bunk restriction, and physical therapy for his rheumatoid arthritis. *Id.* at 387. The next day, on November 13, 2015, Petitioner sought follow-up treatment for a "possible vaccine reaction 11/10/15." *Id.* at 47. An examination revealed that his left shoulder was no longer swollen, but Petitioner continued to experience tenderness to palpation and pain with movement, flexion, and extension. *Id.*

Petitioner submitted a health request on November 15, 2015, indicating that he was "still having pain in [his] left shoulder where [he] got [his] flu shot[.]" *Id.* at 386. On November 18, 2015, Petitioner was evaluated for shoulder pain, and his left deltoid was noted to be "normal [with] no redness, warm, swelling from flu shot[.]" *Id.* at 47. The medical note also indicated a normal ROM, and Petitioner was assessed with arthralgias. *Id.* Petitioner submitted another request for a pillow, bottom bunk restriction, and ice. *Id.* at 41. Petitioner also noted his continued left shoulder pain. *Id.* He was noted to have "no further swelling of deltoid, no swollen lymph, no redness, no warmth." *Id.* Petitioner's request for accommodations was denied. *Id.*

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[11] The glenohumeral joint, or shoulder joint, is "the joint formed by the head of the humerus and the glenoid fossa of the scapula." *Dorland's* at 960.

[12] Synovitis is "inflammation of a synovial membrane; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within a synovial sac." *Dorland's* at 1826.

[13] The axilla is the armpit. *Dorland's* at 182.

On November 24, 2015, Petitioner submitted another health service request wherein he stated that he was "still having pain in [his] left arm pit and shoulder." *Id.* at 385. He continued that it had "been two weeks since [he] got that flu shot and had a alergical [sic] reaction to." *Id.* A nurse encounter record dated December 1, 2015, documents Petitioner's complaints of spasms in his left breast and sharp pain in his armpit. *Id.* at 42. Petitioner indicated that these episodes occurred randomly and were triggered by strenuous exercise. *Id.* at 43.

Petitioner continued to seek treatment for ongoing left shoulder and armpit pain on December 21, 2015, January 11, 2016, January 22, 2016, January 26, 2016, and February 1, 2016. *Id.* at 41, 381, 372–73, 375. On March 10, 2016, Petitioner was evaluated for left axilla pain and aching/cramping in his left chest wall. *Id.* at 38. An examination revealed a normal ROM in his left upper extremity. *Id.* at 39. Progress notes from a March 15, 2016 medical visit note that Petitioner followed up for arthralgias and reported morning stiffness in his fingers, shoulder, knees, and tingling in his toes. *Id.* Throughout March, Petitioner continued to seek medical attention for his shoulder and armpit pain. *Id.* at 360, 368. On March 22, 2016, Petitioner was evaluated for "spasms" in his left upper chest, shoulder, and axilla, which he reported "started in November" after his flu shot. *Id.* at 37. Petitioner had "[f]ull ROM to [left] arm." *Id.* On April 28, 2016, Petitioner sought treatment for "inflammation" in his "hands and arms[]" and requested an evaluation with a specialist for his arthritis. *Id.* at 357.

Dr. Perry saw Petitioner for a follow-up on May 24, 2016, and Petitioner complained of joint pain and intermittent joint swelling. Pet'r's Ex. 5 at 56–58. Petitioner reported intermittent swelling of the left ankle and pain in the left shoulder. *Id.* at 56. A physical exam revealed swelling in the left ankle and both hands. *Id.* at 57. Dr. Perry's impression was rheumatoid arthritis "[d]eteriorated[.]" *Id.* at 58. Petitioner returned to Dr. Perry on September 27, 2016, and noted that he was feeling much better on Plaquenil[14] and Meloxicam.[15] *Id.* at 17–19. Petitioner's musculoskeletal examination displayed no swollen joints. *Id.* at 18. An October 3, 2016 progress note recorded that Petitioner "was feeling good[,and his] arm swelling and pain resolved." Pet'r's Ex. 2 at 36.

Petitioner resumed his complaints of post-vaccination left shoulder pain and chest spasms on January 30, 2017. *Id.* at 33. Upon examination, Petitioner displayed full ROM in his left shoulder. *Id.* On February 6, 2017, Petitioner had a normal x-ray of his left shoulder. *Id.* at 200.

On February 9, 2017, Petitioner requested physical therapy for rheumatoid arthritis. Pet'r's Ex. 3 at 87, ECF No. 8-3. He was seen by an ophthalmologist for his Graves' disease on March 1, 2017. Pet'r's Ex. 7 at 13–14, ECF No. 8-7. During that visit, Petitioner reported numbness and tingling in his feet and fingers "[s]ometimes[.]" *Id.* at 14. On August 28, 2017, Petitioner sought treatment for rheumatoid arthritis, and he reported pain and polyarthralgias. Pet'r's. Ex. 2 at 35. Petitioner continued to report pain in his joints during a nurse encounter on October 2, 2017. *Id.* at 24–25. Petitioner submitted a health service request on December 11, 2017, for physical therapy

[14] Plaquenil, or hydroxychloroquine sulfate, is used "as an antiinflammatory disease-modifying antirheumatic drug in treatment of rheumatoid arthritis[.]" *Dorland's* at 870, 1434.
[15] Meloxicam is "a nonsteroidal antiinflammatory drug used in the treatment of osteoarthritis[.]" *Dorland's* at 1111.

to treat mobility problems he had suffered for "months, and even over a year[,]" following a November 2015 left arm injury. *Id.* at 313. Petitioner explained that he "never received treatment[,]" and two years later, he still experienced "mobility issues, pain, and weakness in the arm." *Id.* He was told that he would "have to be assessed[, because the facility does not] order [physical therapy] by request." *Id.* Petitioner continued to seek treatment for his left arm injury on December 12, 2017 and January 8, 2018. *Id.* at 312, 309.

Petitioner was seen on February 8, 2018, for his shoulder pain. Pet'r's. Ex. 4 at 1–2, ECF No. 8-4. He was instructed to complete stretches and was given exercises. *Id.* at 2. When Petitioner returned to see the facility nurse for a follow-up on March 8, 2018, he reported improvement with exercises. Pet'r's Ex. 6 at 1–2, ECF No. 8-6. Petitioner exhibited normal strength in his left arm and a "slight" decrease in ROM in horizontal extension. *Id.* at 1.

More than two years after his flu vaccine, on April 26, 2018, Petitioner continued to seek treatment for left shoulder pain. Pet'r's Ex. 8 at 6, 22. He reported paresthesias[16] in the axillary region to the lateral arm and extending to the hand.[17] *Id.* Petitioner was diagnosed with "chronic shoulder pain [from either] underlying [subdeltoid/subacromial bursitis[18] or adhesive capsulitis ("AC")[19]]." *Id*. Petitioner presented for medical encounters on April 28, 2018, May 12, 2018, and June 9, 2018, for blood pressure and dizziness. *Id.* at 5, 7–8. There is no mention of shoulder pain during these encounters. *See id.*

On August 27, 2018, Petitioner was evaluated for "continued left shoulder pain" that he stated "developed after a flu shot in 2015[.]" *Id.* at 90. Petitioner noted that he played basketball. *Id.* Petitioner displayed pain on palpation to the anterior shoulder and full ROM with pain. *Id.* Petitioner's medical provider ordered a nonsteroidal anti-inflammatory to address his symptoms and scheduled a steroid injection. *Id.* at 91.

On August 31, 2018, Petitioner began physical therapy for left shoulder pain with an "insidious onset" and "ROM deficits most consistent with adhesive capsulitis . . . ." *Id.* at 142. The physical therapist noted that Petitioner's transient muscle spasms also contributed to his localized pain. *Id.* By October 30, 2018, Petitioner had "reasonably functional use" of his left upper extremity. Pet'r's Ex. 10 at 45, 70. ECF No. 27-1.

Petitioner presented to a new rheumatologist on May 10, 2019, and reported intermittent left knee pain. *Id.* at 53–54. He stated that "all of his symptoms ha[d] resolved[]" and that "he no longer requires medication therapy." *Id.* at 53. His laboratory tests and physical examination, including both shoulders, were normal. *Id.* at 54. Petitioner's treater indicated an intention to "repeat rheumatoid factor, CCP, ANA, double-stranded DNA, Smith antibodies [ ] to ensure he

[16] A paresthesias is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." *Dorland's* at 1362.
[17] There is mention of Petitioner's range of motion, but the handwritten note is indecipherable.
[18] Bursitis is "inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon[.]" *Dorland's* at 260.
[19] Adhesive capsulitis is "adhesive inflammation between the joint capsule and the peripheral articular cartilage of the shoulder with obliteration of the subdeltoid bursa, characterized by shoulder pain of gradual onset, with increasing pain, stiffness, and limitation of motion." *Dorland's* at 281.

did not have another autoimmune disease such as lupus[20] that was initially misdiagnosed and do [sic] determine if he has any increased risk of RA based on serology." *Id.* Petitioner's May 23, 2019 blood testing revealed positive CCP AB, and the evaluating physician noted that "[a]pproximately 70% of patient with [RA] are positive for CCP AB, while only 2% of random blood donors are positive." *Id.* at 74. Petitioner's Department of Corrections medical records from September 13, 2018 to July 1, 2019, include a clinical diagnosis (history of) rheumatoid arthritis that was last reviewed on May 23, 2019 and confirmed on that date. *E.g., id.* at 2.

B. Petitioner's Affidavits

Petitioner filed three affidavits in this case. The affidavit dated August 23, 2018, provided a general summary of events and symptoms following Petitioner's November 10, 2015 flu vaccination. *See generally* Pet'r's Ex. 1, ECF No. 8-1. Petitioner stated that he "woke up at approximately 1:30 a.m. [the night he received his vaccine,] experiencing pain in [his] left arm and axilla region." *Id.* ¶ 3. He complained of the pain and arm stiffness to the facility's staff, including a nurse from the health services unit, and was given Tylenol. *Id.* The next morning, on November 11, 2015, the on-call physician "observed swollen lymph nodes in [Petitioner's] axial region[,] and [his] upper arm was warm to the touch." *Id.* ¶ 4. Petitioner stated he was again given Tylenol and told to exercise his arm "to increase mobility." *Id.* ¶¶ 4–5.

Petitioner continued to detail arm pain through 2015 into October of 2016. *See id.* ¶¶ 6–9. He stated that "[f]rom October 2016 to the present, [he has] experienced continuing pain, weakness and discomfort as well as severe spasms on about a weekly bases [sic] together with pain in [his] shoulder and arm pit into [his] left chest." *Id.* ¶ 10. He also noted continued "lack of mobility and range of movement." *Id.* ¶ 11. Petitioner averred that "other than Graves' Disease, [he] was in [his] normal state of good health[]" when he received the flu vaccine. *Id.* ¶ 12.

In Petitioner's first supplemental affidavit, dated February 26, 2019, he noted that the vaccine administration record "is not complete in full and does not contain the location of the vaccine." Supp. Aff. ¶ 2. Petitioner explained that he is right-handed and requested his vaccination in his left arm. *Id.* He also corrected a mistake in a November 11, 2015 medical record that noted pain in his right deltoid. *Id.* ¶ 3. He "did not have pain in [his] right arm or shoulder." *Id.*

Petitioner also sought to clarify his pre-vaccination joint pain. He described achiness in his "shoulders, elbows, and knees" in July of 2015. *Id.* ¶ 4. Petitioner was diagnosed with arthritis, and he stated that his "symptoms from the flu shot were completely different from the arthritic ache in [his] shoulders." *Id.* ¶¶ 4, 6. Petitioner asserted that his pre-vaccination achiness began at night, and his "joints would be achy in the morning . . . ." *Id.* ¶ 4. Following his vaccination, Petitioner stated he "had stabbing pain in [his] shoulder and armpit." *Id.* ¶ 6. He also reported complete loss of motion in his shoulder and spasms in his "left chest muscle." *Id.*

The second supplemental affidavit, filed on September 29, 2021, provided a much more detailed explanation of Petitioner's course of treatment. Petitioner reiterated the difference

[20] Lupus erythematosus is "a group of connective tissue disorders primarily affecting women aged 20 to 40 years, comprising a spectrum of clinical forms in which cutaneous disease may occur with or without systemic involvement." *Dorland's* at 1066.

between his pre-vaccination achy joint pain and the sharper pain he felt, specifically in his left shoulder, post vaccination. *See* 2nd Supp. Aff. ¶¶ 4–10. He stated that he reported "achy joint pain in [his] shoulders, knees, wrists, right ankle, and hand joint[,]" as well as finger joint pain, on November 5, 2015. *Id.* ¶ 8. He continued that he "explained [to his provider] that [he] usually experienced the achy pains after playing basketball." *Id.* He further explained that "the swollen joints, [ ] could have come from falling on the ground and having physical contact with people during the games though pick and rolls, rebounding, driving to the basket, and playing defense." *Id.* Petitioner noted that his bloodwork done in November of 2015 came back with no inflammatory markers and was negative for rheumatoid factor. *Id.* ¶ 9.

Following his vaccination, Petitioner stated that he complained of post-vaccination shoulder pain. *Id.* ¶ 10. Petitioner described experiencing "a pinching, sharp pain in [his] left shoulder/left inner arm pit area" and chest spasms on November 11, 2015. *Id.* During his examination, Petitioner needed assistance with removal of his shirt. *Id.* He stated that the ROM test was so "excruciating" that the nurse did not continue to push him. *Id.* On November 13, 2015, three days post vaccination, Petitioner was "evaluated for a possible reaction to the flu vaccination." *Id.* ¶ 11. Petitioner recounted pain that continued during November and December of 2015 and January through March of 2016. *Id.* ¶¶ 12–19. He also complained of stiffness and achy pain in his other joints during this time but asserted it "was different from the pain [he] was experiencing in [his] left shoulder." *Id.* ¶ 17. Petitioner attributed this pain to "cardio exercise that [he] did after being told by the nursing staff that exercising is [how] to remedy [his] left shoulder pain and mobility issues . . . ." *Id.*

In April through July of 2016, Petitioner asserted that he "continued to submit health service requests to seek treatment for the pain [he] was experiencing in [his] left shoulder." *Id.* ¶ 20. Petitioner stated that he did "not see these request [sic] in any of the medical records[,]" and he did not get any response or "receive additional treatment[.]" *Id.* Eventually, Petitioner stated that he stopped submitting requests. *Id.*

Petitioner stated that he reported feeling much better during a September 27, 2016 medical examination. *Id.* ¶ 21. By this point, Petitioner noted that he had been diagnosed with rheumatoid arthritis, and his improved condition was with respect to the achiness and swelling only. *Id.* On December 25, 2016, Petitioner noted that he "once again requested medical attention as a result of the achiness [he] was experiencing with [his] joints." *Id.* ¶ 22. He was unsure of the cause of this pain, but he characterized it as different from his shoulder pain. *Id.*

From February through December of 2017, Petitioner "did not specifically complain about [his continuing left shoulder] pain at this time." *Id.* ¶ 26. He believed, "[b]ased on [his] previous complaints, and the treatment [he] received, [he] honestly felt that requesting treatment would be futile." *Id.* Petitioner said that in December of 2017, his shoulder pain was getting worse. *Id.* ¶ 27. In response for his request for physical therapy, the facility nurse told Petitioner that his "needs are being addressed." *Id.* Petitioner stated that he submitted a separate request later in December for his achy joints, which he believed were separate from his shoulder pain. *Id.* Noting that the record documenting a February 8, 2018 exam noted Petitioner's limited participation, Petitioner explained that "the record fail[ed] to convey [his] participation was limited because of the pain

[he] was experiencing." *Id.* ¶ 30. He stated that he was given an exercise worksheet for frozen shoulder and told to return in a month or sooner if his symptoms worsened. *Id.*

Petitioner detailed his attempts to receive treatment in April of 2018 and noted that he was "finally prescribed physical therapy [ ]." *Id.* ¶ 34. After more than three months of waiting to begin his therapy, Petitioner submitted another request and was told there was "a long waiting list . . . ." *Id.* ¶ 36. Petitioner recounted an examination on August 27, 2018, and noted that he experienced pain when the provider tested his ROM. *Id.* ¶ 39. He noted that "[t]his was consistent with the other times [he] displayed full range of motion[]" in that he experienced pain despite demonstrating full ROM. *Id.* He received a steroid injection on August 27, 2018, and began physical therapy on August 31, 2018. *Id.* ¶¶ 39–40. Petitioner continued physical therapy through October of 2018. *Id.* ¶ 40.

Finally, Petitioner explained the gaps in his medical treatment. He stated that he did not always mention his shoulder pain in every health request but that it was continuous. *See id.* ¶ 42. He further stated that he "became extremely frustrated with the treatment [he] received, or more accurately did not receive." *Id.* The major component of his treatment was exercise, and his request for physical therapy was initially denied and then delayed for months. *Id.* His physical therapy request was only approved after he filed an inmate complaint for treatment. *Id.* ¶ 43. The complaint was filed on August 24, 2018, and "despite the fact [his] complaint was rejected, [he] actually did begin receiving physical therapy treatment a few days after [his] complaint was submitted and rejected." *Id.* Petitioner believes "the limited resources and treatment for inmates explains why [he] did always receive consistent treatment for [his] left shoulder injury, despite the fact [he] was always in pain and suffered from adhesive capsulitis as a result of the vaccination." *Id.* ¶ 44.

III. Expert Reports

A. Petitioner's Expert, John G. Costouros, M.D.

John G. Costouros, M.D., is a board-certified orthopedic surgeon with an additional certificate of added qualification in orthopaedic sports medicine. Pet'r's Ex. 14.1 at 2, ECF No. 71. He received his undergraduate degree from Stanford University and his medical degree from the University of California, San Francisco. Pet'r's Ex. 21 at 1. Dr. Costouros' postdoctoral training includes an internship in general surgery and residency in orthopaedic surgery at the University of California, San Francisco and shoulder and elbow surgery fellowships with Harvard Medical School and the University of Zurich, Balgrish Hospital in Switzerland. *Id.* The entirety of Dr. Costouros' career "which includes clinical practice and research since 2004 has been focused exclusively on the comprehensive treatment of shoulder disorders." Pet'r's Ex. 14.1 at 2. Dr. Costouros served as an assistant professor of orthopaedic surgery for "nearly [ten] years" at Stanford University Medical Center. *Id.* He is currently the Chief of Shoulder Surgery at the Institute for Joint Restoration and Research in Menlo Park, California. *Id.* Dr. Costouros has written extensively on shoulder related medical topics including, the need for ultrasound guidance for shoulder injections. *See* Pet'r's Ex. 21 at 8–11.

Dr. Costouros concluded in his initial expert report "that the [flu] vaccination that [Petitioner] received to the left shoulder on November 10, 2015, more likely than not, led to the

current condition of the left shoulder and specifically the development of adhesive capsulitis." Pet'r's' Ex. 14.1 at 6. Dr. Costouros noted that Petitioner "had no prior history of left shoulder adhesive capsulitis prior to injection . . . ." *Id.* Petitioner's pre-vaccination, November 5, 2015 complaints of diffuse joint pain were not characteristic of adhesive capsulitis in Dr. Costouros' opinion. *Id.* at 7. Additionally, Petitioner's "initial [SIRVA] symptoms of shoulder pain, redness, burning, swelling and loss of motion began developing within 48 hours of the vaccination." *Id.* at 6. Dr. Costouros asserted that Petitioner's' pain and loss of ROM "were isolated to the left shoulder" and that "there is no other condition or abnormality which would explain the constellation findings demonstrated in [Petitioner's] left shoulder . . . ." *Id.* at 6–7. Dr. Costouros did not believe that Petitioner's post-vaccination clinical presentation was consistent "with a pre-existing inflammatory condition such as rheumatoid arthritis which is characterized by morning pain and stiffness that improves later in the day, joint swelling and effusions, and progressive and [sic] loss of motion over time." *Id.* at 9. However, Dr. Costouros noted that during Petitioner's November 5, 2015 evaluation by Dr. Perry, Petitioner displayed "no effusion, full range of motion, and mild tenderness at the joint line." *Id.* at 6. While Dr. Costouros questioned whether Petitioner was accurately diagnosed with RA, he acknowledged that Petitioner suffered from diffuse joint pain, pre vaccination. *Id.* at 11. Dr. Costouros opined that Petitioner's pre-vaccination and post-vaccination symptoms are distinguishable and unrelated. *Id.* The former affected multiple joints, while the latter was acute, limited to his shoulder, and temporally related to Petitioner vaccination in the affected arm. *See id.* at 11–12. Dr. Costouros also noted the Petitioner's shoulder injury was alleviated by a steroid injection and physical therapy. *Id.* at 11. Petitioner's "pre-existing inflammatory condition, which is characterized by morning pain and stiffness that improves later in the day, joint swelling and effusions, and progressive and loss of motion over time" are separate, unrelated symptoms. *Id.*

Dr. Costouros explained that Petitioner's SIRVA manifested as adhesive capsulitis "due to an inflammatory effect from vaccine administration into the subdeltoid bursa or over-insertion into a tendon." *See id.* at 5–6. He conceded that that vaccine component responsible for the inflammatory response is unknown and "may be [ ] either [ ] the antigenic or non-antigenic components of the vaccine . . . ." *See id.* at 5. Dr. Costouros continued that "[t]his reaction may be exacerbated if the injection is placed directly into the glenohumeral joint and the synovial tissue of the shoulder capsule." *Id.* at 6. In Petitioner's case, "the injection communicat[ed] with the glenohumeral joint, either by direct communication with the needle or in the presence of a small rotator cuff tear, [and] trigger[ed] the development of adhesive capsulitis or a 'frozen shoulder[]' . . . ." *Id.*

In a supplemental report filed on February 4, 2022, Dr. Costouros addressed Dr. Cagle's contention that Petitioner's injury does not fulfill the Table's requirement that there be no history of pain, inflammation, or dysfunction of the affected shoulder. Pet'r's Ex. 20 at 2. Dr. Costouros noted the legal SIRVA criteria for entitlement in the Program but stated that his "opinion regarding this point is purely a medical one." *Id.* at 2–3. In determining whether an injury could be vaccine-caused, Dr. Costouros stated that he looks "to see if the vaccination caused a new and unrelated injury, or potentially exacerbated an existing injury." *Id.* at 3. In Petitioner's case, Dr. Costouros reviewed the findings within the November 5, 2015 medical record and concluded that they "are not consistent with a pre-existing adhesive capsulitis and entirely different from the findings one would see as a result of SIRVA-induced adhesive capsulitis." *Id.* Plainly, Dr. Costouros does "not

believe [Petitioner's] pre-existing shoulder condition could have caused his post-vaccination shoulder condition." *Id.* He "defer[ed] to the legal experts as to whether, from a legal standpoint, Petitioner's SIRVA injury is precluded based on what [he] believe[s] to be an unrelated pre-vaccination medical condition." *Id.* at 4.

Dr. Costouros reiterated his assertion that there is clear evidence of a 48-hour injury onset. *Id.* He noted Petitioner's immediate complaint within twenty-four hours of the injection of an acute, sharp pain. *Id.* (citing Pet'r's Ex. 3 at 4–5). He further noted a medical record the day after the injection that described Petitioner's left upper arm as "hot to touch and swollen." *Id.* (citing Pet'r's Ex. 3 at 17–18). Dr. Costouros conceded that he relied heavily on Petitioner's consistent and continuous complaints of mobility issues to find evidence of limited ROM, in contrast to documented physical evaluations. *See id.* at 5–6. Dr. Costouros also noted that Petitioner exhibited limited ROM during physical therapy and that his injury was improved by steroid injections and therapy. *Id.* at 6 (citing Pet'r's Exs. 8 at 141–142; Pet'r's Ex. 10 at 45–47). Dr. Costouros again noted that these treatments are not effective against RA. *Id.* at 8. In conclusion, Dr. Costouros also summarized his general causation theory for a shoulder injury caused by vaccination. *See id.*

B. Respondent's Expert, Paul J. Cagle, M.D.

Paul J. Cagle, M.D. is a board-certified orthopaedic surgeon and assistant professor and associate program director in the department of orthopaedic surgery at the Icahn School of Medicine at Mount Sinai. Resp't's Ex. A at 1. He received his undergraduate degree from St. Ambrose University in Davenport, Iowa and his medical degree from Loyola University Chicago Stritch School of Medicine. Resp't's Ex. B at 1. Dr. Cagle completed his orthopaedic surgery residency at the University of Minnesota Academic Health Center and Medical School followed by a shoulder and elbow fellowship at Mount Sinai Hospital and a shoulder fellowship at Private Hospital Jean Mermoz/Center Orthopaedic Santy in Lyon, France. *Id.* Currently, Dr. Cagle's practice "focuses on the shoulder, representing approximately 95% or more of the patients and pathology [he] treat[s]." Resp't's Ex. A at 2. His professional memberships include the American Shoulder and Elbow Surgeons, the American Academy of Orthopaedic Surgeons, and the American Orthopaedic Association. *Id.* at 1. Dr. Cagle has authored numerous publications on the shoulder and other joint related injuries. *See* Resp't's Ex. B at 3–7. He submitted two written reports in this case.

In his initial export report, Dr. Cagle identified Petitioner's "clear and well-documented pain in the left shoulder that predated the vaccination event[]" as "substantial and reliable evidence that the criteria for a SIRVA are not met." Resp't's Ex. A at 5. Focusing on Petitioner's November 5, 2015 complaint of shoulder pain and swelling, Dr. Cagle noted that "an identical presentation [that] predates the vaccination event by [five] days[]" casts doubt on Petitioner's assertion that he experienced acute pain and swelling post vaccination. *Id.* Although Dr. Costouros relied on Petitioner's descriptions of limited shoulder mobility as evidence of loss ROM, Dr. Cagle found "no clear evidence of loss of range of motion immediately following the alleged vaccination event." *Id.* He noted that Petitioner's physical exam on March 22, 2016, revealed "[f]ull ROM to [left] Arm[.]" *Id.* (citing Pet'r's Ex. 2 at 37). Dr. Cagle conceded that Petitioner complained of ROM limitations in March of 2017, but Dr. Cagle stated that notes from earlier, post-vaccination

visits in January and February of 2016 describe no "no physical examination, no diagnosis, and no range of motion assessment." *Id.* at 6.

Dr. Cagle also noted Petitioner's history of rheumatoid arthritis and saw "no evidence that any of the alleged shoulder pain experienced following the subject vaccination differed in any way from prior pain or what could be subsequently expected with a diagnosis of arthritis." *Id.* In his supplemental report, Dr. Cagle reiterated the points he made in his initial report and argued that Dr. Costouros' conclusions are based on subjective complaints from the Petitioner and not objective findings. *See* Resp't's Ex. C at 1–2. Dr. Cagle noted that "[i]n medicine, opinions are based on evidence and evaluations." *Id.* at 2. Dr. Cagle could identify no objective evidence that Petitioner suffered from loss of ROM, or that his symptoms post vaccination are distinguishable from the pain and swelling he experienced five days before his injection. *Id.* at 1–2.

IV. Ruling on the Record

A. Petitioner's Motion

Petitioner argues in his motion for a ruling on the record that the record contains preponderant evidence of a Table SIRVA and that he is entitled to compensation. Pet'r's Mot. at 23. Petitioner relies on his affidavit, in which he stated that his left shoulder began within hours of his flu vaccination, at approximately 1:30 a.m. *Id.* at 24 (citing Pet'r's Ex. 1 ¶ 2). A November 11, 2015 medical note recorded Petitioner's armpit pain and that upon examination, his arm was hot to the touch and swollen. *See id.* (citing Pet'r's Ex. 2 at 44–45). Although Petitioner admits that he had a history of diffuse joint pain, he argues that his "rheumatoid arthritis was a separate and distinct injury from the injury he suffered following the flu shot." *Id.* at 25. He describes the former pain as achy, while the newer post-vaccination pain "was sharp, throbbing, and painful with movement." *Id.* at 25–26. Petitioner contends that his receipt of a steroid injection and physical therapy referral is consistent with adhesive capsulitis, a common SIRVA. *See id.* at 26.

Petitioner further argues that Respondent's assertion that Petitioner's additional pain disqualifies a Table SIRVA award is "erroneous and overly restrictive." *Id.* at 27. The "complain[ts] of pain to other parts of [Petitioner's] left arm or areas adjacent to his shoulder" is "simply evidence that he suffered a serious musculoskeletal injury." *Id.* Furthermore, despite this condition, "Petitioner's nurses, physical therapists, and doctors did not identify the presence of any condition or abnormality that would explain Petitioner's left shoulder symptoms." *Id.* at 29.

Alternatively, Petitioner argues that he has established that he suffered from a causation-in-fact shoulder injury pursuant to *Althen*. *Id.* at 31. He notes that "[a]ccording to Dr. Costouros, SIRVA can be the result of an 'inflammatory effect from the vaccine administration into the subdeltoid bursa over insertion into a tendon.'" *Id.* at 33–34 (quoting Pet'r's Ex. 14.1 at 5). Petitioner further relies on Dr. Costouros' explanation that adhesive capsulitis can result if the injection comes into contact with the glenohumeral joint, "as was the case with [Petitioner]." *Id.* at 34 (citing Pet'r's Ex. 14.1 at 6). Petitioner reiterates that he experienced symptoms consistent with SIRVA, including swelling and limited ROM, immediately after vaccination. *Id.* at 38 (citing Pet'r's Ex. 2 at 44–47). Furthermore, he consistently "complained of having pain and mobility issues of the left shoulder" for three years following his vaccination. *Id.* at 35.

Petitioner asserts that Respondent's expert misconstrues medical records and fails to consider the additional evidence from Petitioner's affidavits that fully explain the nature of his symptoms. *Id.* at 39–40.

B. Respondent's Response

In response to Petitioner's motion, Respondent recounts Petitioner's relevant medical history and notes Petitioner's rheumatoid arthritis diagnosis. *See* Resp't's Resp. at 2–9. Respondent also notes that five days prior to the vaccination, Petitioner complained of left shoulder pain and "self-reported that 'he feels that the left shoulder gets swollen.'" *Id.* at 15 (quoting Pet'r's Ex. 5 at 140). Respondent acknowledges that Petitioner complained of shoulder pain immediately after his vaccination but notes that Petitioner also complained of chest and armpit pain. *Id.* (citing Pet'r's Ex. 2 at 44–47).

Respondent argues that "[p]ain in the chest is outside the shoulder and axillary pain is not a feature of SIRVA." *Id.* Consistent with Respondent's argument that Petitioner's pain was not limited to his shoulder, Respondent further argues that Petitioner cannot assert a Table claim because rheumatoid arthritis is another condition present that "can explain his symptoms." *Id.*

In tandem with his contention that Petitioner has not established Table SIRVA, Respondent further asserts Petitioner has not provided preponderant evidence that his vaccine is the but-for cause of Petitioner's shoulder pain. *Id.* at 16. Respondent argues that Petitioner has not set forth a reliable medical theory of causation, illustrated a logical sequence of cause and effect, or described an appropriate temporal relationship in support of his claim. *Id.* at 16–17. Respondent argues that Petitioner has not presented evidence of a biological mechanism, and aside from a "vague proposition, Dr. Cagle has pointed out there is no evidence of an inappropriate injection technique or need [sic] length in this case." *Id.* at 16. Further, Respondent notes that Petitioner's reported limited ROM self-resolved within eight days of vaccination. *Id.* at 15 (citing Pet'r's Ex. 2 at 47). Respondent argues that Petitioner cannot establish causation-in-fact because Petitioner had "prior complaints of left shoulder pain, . . . his pain was not limited to his left shoulder, and . . . [he] had pre-existing arthritis." *Id.* at 16. Lastly, Petitioner complained of left shoulder swelling and pain five days before his vaccination. *See id.* at 17.

Nearly every aspect of Petitioner's claim is disputed by Respondent. Respondent asserts that Petitioner's injury is not consistent with SIRVA, and that unrelated, contemporaneous complaints of pain in other areas preclude a Table claim. Furthermore, Respondent contends that Petitioner has not presented preponderant evidence of a general causation theory, nor has he provided preponderant evidence that his causation theory is consistent with the facts in his case. Respondent requests dismissal of Petitioner's claim. *See id.*

V. Applicable Statutory Scheme

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred

within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); § 13(a)(1)(B).

The Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 CFR § 100.3. Table injury cases are guided by statutory "Qualifications and Aids in Interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. *See* 42 CFR § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited [ROM] occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced [ROM] are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if a petitioner is unable to establish a Table claim, she may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table," or causation-in-fact, claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 300aa-13(a)(1)(A); *see* § 11(c)(1)(C)(ii)(II). A 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 ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citations omitted).

In the seminal case of *Althen v. Sec'y of of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test to determine whether a petitioner has established a causal link between

a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is also unnecessary. *Althen*, 418 F.3d at 1278–81; *Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id.* at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See* 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Id.* at 1278; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that [the] vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *See* 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* This is because "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.'" *Id.* (quoting *Althen*, 418 F.3d at 1280). In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Once a petitioner has established her *prima facie* case, the burden then shifts to Respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B). The Vaccine Act requires Respondent to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. *Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Such a showing establishes that the factor unrelated, not the vaccination, was "principally responsible" for the injury. *See* § 300aa-13(a)(2)(B). The factor unrelated must be the "sole substantial factor[;]" therefore, Respondent must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan*, 539 F.3d at 1354.

VI. Discussion

In the present case, the parties are unable to agree on any material fact or legal conclusion, save that Petitioner's flu vaccination occurred on November 10, 2015. Petitioner maintains that he suffered a left-sided shoulder injury that satisfies the QAI criteria for a SIRVA. Pet'r's Mot. at 23. Alternatively, Petitioner asserts that he "has established entitlement under an *Althen*/Causation Analysis." *Id.* at 31. Respondent, however, disputes the characterization of the claim as on-Table, the timing of onset, and the nature of Petitioner's symptoms. *See generally* Resp't's Resp. Respondent also argues that Petitioner has not presented preponderant evidence of general or specific causation. *Id.* After a thorough review of the record, I find that Petitioner has not presented preponderant evidence of a Table claim. Petitioner has submitted evidence of a theory of causation, a logical sequence of cause and effect, and an appropriate temporal relationship for an off-Table, shoulder injury. However, Petitioner cannot establish that his condition was vaccine-caused.

A. Table Claim

i. History of Pain, Inflammation, or Dysfunction

It is undisputed in this case that Petitioner had a pre-vaccination history of pain and inflammation in his left shoulder within a week of receiving his flu vaccination. Petitioner argued that his pre-vaccination shoulder pain is distinguishable and therefore not relevant to the alleged SIRVA. This interpretation of the QAI criteria belies a plain reading of the text: "No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration *that would explain* the alleged signs, symptoms . . . occurring after vaccine injection." 42 CFR §100.3(c)(10) (emphasis added). Petitioner noted that he had no history of adhesive capsulitis pre vaccination. However, Petitioner described his shoulder months prior to his vaccination as "really hurting." Pet'r's Ex. 2 at 52. He also complained of swelling and tenderness in his left shoulder five days prior to his vaccination. Pet'r's Ex. 5 at 140. The day after his vaccination, Petitioner again complained of swelling and pain in his left shoulder. Pet'r's Ex. 2 at

46–47. Given the striking similarities between the symptoms Petitioner experienced five days pre vaccination and one day post vaccination, his pre-existing history of joint pain would explain the continued symptoms, and Petitioner cannot satisfy the first QAI criterion. His medical history also prevents him from meeting the remaining QAI criteria.

ii. 48-Hour Symptom Onset

Petitioner complained of chest pains and left shoulder pain on November 11, 2015, the day after his vaccination. Pet'r's Ex. 2 at 44–45. He also immediately attributed his injuries to his vaccination, and his pain was assessed as acute. *Id.* at 44–47. Upon examination, Petitioner exhibited range of motion limitations and warmth at the injection site. *Id.* at 44–45. Petitioner clearly experienced symptoms within 48 hours. However, Petitioner's history of: (1) left-sided chest pain in January of 2015; (2) joint pain, including his left shoulder, beginning in March of 2015; and (3) left shoulder swelling as recent as five days pre vaccination is persuasive evidence that Petitioner's symptom onset predated his vaccination. *See* Pet'r's Ex. 2 at 52, 433; Pet'r's Ex. 5 at 140. Petitioner did not report that his symptoms were continuous, but he had complained of all these post-vaccination symptoms pre vaccination, except the injection-site warmth and ROM limitations. A November 13, 2015 medical record revealed that the swelling had subsided two days post vaccination, but the injection site warmth remained. Pet'r's Ex. 2 at 47. This localized warmth and temporary swelling is preponderant evidence of new symptoms that occurred within 48 hours of vaccination. These symptoms, however, are evidence of an acute, elevated immune response commonly seen immediately after vaccination. Indeed, the CDC website lists mild flu vaccine side effects that usually subside within a few days.[21] These symptoms include redness and swelling at the injection site. *Id.* This is preponderant evidence that Petitioner suffered a mild reaction to the flu vaccine. However, the left shoulder symptoms Petitioner asserts developed into adhesive capsulitis were detailed in previous medical complaints along with chest pain. Petitioner has not presented preponderant evidence that the initial onset of his left shoulder pain occurred post vaccination.

iii. Nature of Symptoms

Petitioner's expert, Dr. Costouros described Petitioner's pre-vaccination, diffuse joint pain as "[in]consistent with adhesive capsulitis." Pet'r's Ex. 14.1 at 6. Dr. Costouros further attempted to distinguish Petitioner's multiple joint pain from his "initial [SIRVA] symptoms of shoulder pain, redness, burning, swelling and loss of motion." Pet'r's Ex. 14.1 at 6. However, as previously noted, Petitioner complained of shoulder pain and swelling immediately prior to his vaccination. Petitioner also complained of burning in his joints in July of 2015, more three months before his vaccination. Pet'r's Ex. 2 at 48. Dr. Costouros did not persuasively explain how Petitioner's later symptoms are different. He simply noted Petitioner's earlier complaints of pain included other joints and that Petitioner's post-vaccination shoulder symptoms continued until his physical therapy. *See* Pet'r's Ex. 14.1 at 11. Petitioner continued to report mobility limitations, but he also reported continued chest pain and other joint pain into 2017. *See* Pet'r's Ex. 2 at 33, 35. Dr. Costouros did not explain how armpit and chest pain are indicators of SIRVA. Petitioner has not

[21] Centers for Disease Control and Prevention, *Seasonal Flu Vaccines*, https://www.cdc.gov/flu/prevent/flushot.htm (last visited July 16, 2023).

presented preponderant evidence that his exhibited pain and reduced ROM were limited to the shoulder in which the intramuscular vaccine was administered.

iv. Lack of Alternative Condition

The last QAI factor prohibits compensation for a Table SIRVA if any alternative condition is present that could explain Petitioner's symptoms. Petitioner is also unable satisfy this requirement. After a review of Petitioner's medical records and affidavit, expert reports, medical literature, and the parties' arguments, I find that there is preponderant evidence that Petitioner's post-vaccination symptoms would be explained by his RA. Petitioner was diagnosed with RA arthralgia on July 8, 2015, after complaints of "wrists[,] elbows[,] shoulder [, and] knee [sic] sore to palp[able with] slight swelling of hands" that began in March. Pet'r's Ex. 2 at 52. He initially refused to fill his steroid prescription, but an August 6, 2015 medical record noted improvement in joint pain with Prednisone. *Id.* at 49.

Petitioner also had been diagnosed with Graves' disease. During his November 5, 2015 medical visit, Petitioner's rheumatologist noted that it "is possible that [Petitioner's] joint pain is related to uncontrolled [Graves'] disease." Pet'r's Ex. 5 at 143. Petitioner has two pre-existing conditions that his treaters believed could be the cause of his shoulder pain. He consistently and specifically identified his shoulder as a source of severe pain. However, he often simultaneously described chest pain and armpit pain or pain in other joints, such as his knees. These symptoms are inconsistent with SIRVA and preclude a Table claim.

Petitioner has not presented preponderant evidence that he suffered from a Table SIRVA. Table claims carry a presumption because they are unhindered by previous similar injury, additional symptoms indicative or other conditions, and timing concerns. They are streamlined, and often resolve without medical expert reports or opinions to rule out other diagnoses. In cases where other issues are present, cases proceed more deliberately. It is Petitioner's burden to overcome those complications using the parameters set forth in *Althen*. While it is true that the QAI criteria set the parameters for a Table claim, failure to meet the standard for presumption does not disqualify Petitioner's assertion that he did in fact suffer a vaccine-caused shoulder injury, notwithstanding his RA diagnosis. In this case, Petitioner has presented some evidence that his shoulder injury was caused-in-fact by his vaccination, and he presented a theory of causation. Therefore, I will complete an *Althen* analysis.

B. Causation-in-fact

i. *Althen* Prong One: General Causation Theory

SIRVA is a well-known phenomenon in the Program, but petitioners must present a causation theory in all off-Table cases. Petitioner's expert clearly explained in his report how SIRVA occurs "due to an inflammatory effect from vaccine administration into the subdeltoid bursa or over-insertion into a tendon." Pet'r's Ex. 14.1 at 5–6. He conceded that the vaccine component responsible for the reaction is unknown but argued that the reaction may be exacerbated by the placement of the needle. *Id.* Respondent argues that outside the context of a Table injury that meets the QAI criteria, Petitioner's theory is only a "vague proposition." Resp't's Resp. at 16. Respondent has not, however, explained why such a reaction cannot occur in an individual that

does not meet the Table requirements because of a pre-existing condition. The biological mechanism can still be applicable if it can be identified in a case despite other potential causes. I do not find that the medically acceptable SIRVA mechanism, when explained, is unacceptable in an off-Table case. Petitioner has presented preponderant evidence that the flu vaccine can cause an off-Table shoulder injury related to vaccination, and he has therefore satisfied prong one of *Althen*.

ii. *Althen* Prong Two: Specific Causation

Petitioner has presented preponderant evidence that the flu vaccination can cause an off-Table shoulder injury. Petitioner has failed, however, to present preponderant evidence that his shoulder pain manifested after vaccination. While Dr. Costouros distinguished Petitioner's post-vaccination local shoulder pain from his diffuse joint pain and pre-existing left shoulder pain by describing the former as acute, Petitioner's physical therapist noted that Petitioner's left shoulder pain had an "insidious onset[.]" Pet'r's Ex. 14.1 at 11; Pet'r's Ex 8 at 142. Dr. Costouros focused on Petitioner's limited mobility as support of the adhesive capsulitis diagnosis and related that back to Petitioner's vaccination. However, upon exam approximately one week post vaccination, Petitioner displayed normal ROM in his left shoulder. Pet'r's Ex. 2 at 47. Petitioner was ultimately diagnosed with adhesive capsulitis, more than two years post vaccination, but contemporaneous physical therapy records that contemplate Petitioner's AC do not associate his condition with vaccination. *See* Pet'r's Ex. 8 at 142. Petitioner has not presented preponderant evidence of when his alleged adhesive capsulitis manifested or preponderant evidence that it is separate from his pre-existing shoulder pain. Therefore, his causation theory is inapplicable to his condition. *See, e.g.*, *Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness."). Although Petitioner's shoulder pain manifested before his vaccination, he has not raised a significant aggravation claim.[22] *See* Pet.; Pet'r's Mot. Furthermore, Petitioner has not demonstrated how his causation theory, based on the injury that it contemplates, could be applicable to his symptoms that far exceed the scope of SIRVA. Petitioner's theory does not explain, or even contemplate, the additional symptoms that he experienced contemporaneously with his shoulder injury. Indeed, the medical evidence and statements from Petitioner to treaters

[22] Whether a petitioner's claim is analyzed as causation-in-fact or significant aggravation is generally determined by a petitioner's allegations. *See* 42 U.S.C. § 300aa-11(a)(1) ("A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by . . . the filing of a petition containing the matter prescribed by subsection (c) . . . ."); *see also* 42 U.S.C. § 300aa-11(c)–(c)(1)(C)(ii)(I) ("A petition for compensation under the Program for a vaccine-related injury or death shall contain[] . . . an affidavit, and supporting documentation, demonstrating that the person who suffered . . . injury . . . sustained, or had significantly aggravated, any illness, disability, or condition caused by [a covered vaccine.]"). Special masters are not expected to consider a possible significant aggravation claim when a petitioner fails to allege it and does not present a theory explaining how a vaccination could significantly aggravate a certain preexisting condition. *See Hirmiz v. Sec'y of Health & Hum. Servs.*, 119 Fed. Cl. 209, 220 (2014) (rejecting the petitioners' attempt to raise a significant aggravation claim after a special master issued an entitlement decision because the evidence "cited by petitioners that would support a significant-aggravation theory . . . was submitted in support of separate and distinct theories of causation[] . . . [that involved] neurological dysfunction beginning after the administration of the influenza vaccine[]") (emphasis in original).

support a diagnosis that contemplates Petitioner's chest and armpit pain and his other swollen and painful joints. Therefore, Petitioner has not satisfied his burden under *Althen* prong two.

i. *Althen* Prong Three: Temporal Relationship

During the Table claim analysis, I found that Petitioner has not presented preponderant evidence that his injury manifested within 48 hours of his vaccination. The record contains preponderant evidence that Petitioner complained of left shoulder pain and swelling five days prior to his vaccination. This is inconsistent with the temporal relationship seen in Table SIRVA cases, and off-Table shoulder injuries related to vaccination. Petitioner has not provided preponderant evidence to satisfy the third prong of *Althen*.

VII. Conclusion

After considering the entire record, Petitioner has not established by preponderant evidence either that his November 10, 2015 flu vaccination resulted in a Table SIRVA or, alternatively, was the cause-in-fact of a local shoulder injury consistent with a SIRVA. Accordingly, Petitioner is not entitled to compensation. Therefore, his case is **DISMISSED**.[23]

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[23] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.