In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-813V
Filed: February 7, 2022
PUBLISHED

JAMES CLARK, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration ("SIRVA"); Table Injury; Causation-in-Fact; Hepatitis B vaccine; Ruling on the Record

Caryn Fennell, Caryn S. Fennell P.C., Woodstock GA, for petitioner.
Nancy Tinch, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On June 8, 2018, petitioner, James Clark, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that his receipt of a Hepatitis B vaccination on February 17, 2017, caused a left shoulder injury. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is not entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

[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 (2012) (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] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, 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 Hepatitis B vaccine. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion 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 range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

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

42 CFR §100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must provide evidence of: (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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005)

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Such medical opinion must be "sound and reliable." *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019) (citing *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)). However, petitioner may rely upon "circumstantial evidence," which has been found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

II. Procedural History

This case was originally assigned to the Court's Special Processing Unit ("SPU")[3] on June 8, 2018, after petitioner filed his petition and several medical records. (ECF Nos. 1, 4.) After additional filings, petitioner filed a statement of completion on November 27, 2018. (ECF Nos. 10, 15, 16.) Respondent filed his Rule 4(c) report recommending against compensation on May 2, 2019. (ECF No. 20.)

[3] On May 7, 2019, this case was reassigned to Special Master Moran. (ECF No. 22.) This case was later reassigned to my docket on August 27, 2019. (ECF No. 29.)

On September 5, 2019, I ordered petitioner to file an expert report supporting his claim which he did on March 30, 2020, along with an affidavit from his wife. (ECF Nos. 30, 35, 36.) Respondent filed a responsive expert report on June 15, 2020. (ECF Nos. 39, 40.) Petitioner and respondent filed three more rounds of expert reports between August 14, 2020 and February 1, 2021. (ECF Nos. 41-43, 46, 49.)

On September 18, 2020, after prompting, the parties advised that neither objected to proceeding to a ruling on the written record. (ECF No. 44.) On December 15, 2020, the parties proposed a mutually agreeable briefing schedule. (ECF No. 48.) Ultimately, on March 2, 2021, petitioner filed a motion for a ruling on the record. (ECF No. 52.) Respondent filed a brief in response and a final expert report on June 2, 2021. (ECF Nos. 54, 55.) Petitioner elected not to file a reply.

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record."). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As reflected in the medical records

i. Pre vaccination

Prior to his vaccination, petitioner had a history of ankylosing spondylitis ("AS"), cervical spine pathology, and limb-girdle muscular dystrophy going as far back as 2006. (Ex. 19, p. 82.) Petitioner's available medical records begin with a February 14, 2006 appointment with rheumatologist Dr. Jonathan Waltuck who noted that petitioner had been diagnosed with AS in 1998, had a 2001 x-ray revealing fusion of his cervical vertebrae, exhibited persistently elevated muscle enzyme and liver function markers, with normal muscle biopsy and normal liver ultrasounds, and was HLA B27 positive. (*Id.*) Petitioner's primary complaint at this appointment was left shoulder pain with increased back pain in his cervical spine. (*Id.*) Petitioner's musculoskeletal exam was unremarkable and revealed full range of motion in both shoulders, but painful range of motion in the left. (*Id.* at 83.) Dr. Waltuck administered a steroid injection into petitioner's left shoulder and recommended he continue taking 200mg of Celebrex twice daily and 20mg of Enbrel twice weekly. (*Id.* at 83-84.)

Petitioner was again seen by Dr. Waltuck on August 14, 2006. (*Id.* at 85-86.) Petitioner reported significant loss of range of motion in his left shoulder, rated his pain as 3 out of 10, and received three x-rays which revealed "bony changes of osteoarthritis with glenohumeral osteophyte formation and subchondral cysts within the anatomic humeral neck," in addition to an "old cartilaginous calcification of the subcoracoid

space," believed to suggest "an intra-articular osteochondral body, posterior inferior subluxation, [and] moderate glenohumeral joint space narrowing." (Ex. 19, pp. 85-86, 134.)

Petitioner saw orthopedic surgeon Dr. Spero Karas on August 18, 2006. (Ex. 19, pp. 31-33.) Petitioner reported frequent sharp pain in his left shoulder at a 5/10, with weakness and stiffness lasting four weeks. (*Id.* at 32.) Petitioner's left shoulder exam revealed Hawkins and NEER positivity with AC joint tenderness. (*Id.* at 32-33.) He reviewed petitioner's previous x-rays and observed mild humeral spurring and mild glenoid space degenerative joint disease. (*Id.* at 33.) He diagnosed petitioner with shoulder degenerative disease, possible rotator cuff tear, and possible impingement syndrome to be evaluated by MRI. (*Id.*)

Petitioner received an MRI of his left shoulder on August 24, 2006. (*Id.* at 128-129.) The MRI revealed left shoulder osteoarthritis, supraspinatus and infraspinatus partial tears/tendinopathy, glenoid labrum irregularity with labral ligamentous degenerative change, and a subcoracoid osteochondral body that was about a centimeter in diameter. (Ex. 19, pp. 128-129.) Petitioner returned to Dr. Karas for another steroid injection on September 29, 2006 and was prescribed physical therapy. (*Id.* at 29-30.)

Petitioner reported to Dr. Waltuck on February 12, 2007, complaining of increased flare ups in his left shoulder, noting that it was stiffer and more painful both in the morning and at night. (*Id.* at 87.) Petitioner reported a pain level of 6/10, and his musculoskeletal exam revealed "some restriction to the lumbar spine movement and . . . to forward elevation of the left shoulder." (*Id.*) Dr. Waktuck prescribed the anti-inflammatory drug Humira. (*Id.* at 88.) On April 18, 2007, Dr. Waltuck noted that petitioner had been diagnosed with AS at age 40 "despite having problems since age 20." (*Id.* at 89.) He recorded "3+ limitation of his left shoulder in all planes, on passive ROM, and also on active ROM." (Ex. 19, p. 90.) Dr. Waltuck continued petitioner's Humira and Celebrex prescriptions and added Percocet for pain management. (*Id.* at 91.) Petitioner again reported stiffness and discomfort in his back and left shoulder to Dr. Waltuck on August 20, 2007. (*Id.* at 93.) His left shoulder exam revealed restriction to forward elevation and Dr. Waltuck adjusted petitioner Humira dosage while continuing all other prescriptions. (*Id.* at 94.)

The following year, petitioner was seen again by Dr. Waltuck on a February 6, 2008, for follow up with complaints of bilateral knee and shoulder pain, worse on the left side, and left ankle and foot pain. (*Id.* at 95-96.) Petitioner noted that his Humira regimen was not helping and that his pain and stiffness had increased. (*Id.* at 95.) Dr. Waltuck believed that petitioner's pain was the result of his AS, and adjusted petitioner's Humira dosage once again. (Ex. 19, p. 96.)

By April 8, 2008, petitioner reported to Dr. Karas that he was experiencing sharp, throbbing pain 90% of the time which he rated as an 8/10 with clicking, weakness, and

stiffness for the past four weeks. (*Id.* at 24-28.) Petitioner received an x-ray of his left shoulder which revealed definitive degenerative joint disease, moderate glenoid spurring that was severe in the glenoid space, and severe humeral spurring. (*Id.* at 26.) Petitioner's neck and back exams revealed painful decreased flexion, extension, lateral bending, and rotation. (*Id.*) Dr. Karas administered another cortisone injection into petitioner's left shoulder. (*Id.* at 27.)

Petitioner was seen by Dr. Karas on November 20, 2008 for another follow up. He reported his pain as sharp with some movements, but otherwise at a 6/10, aching, intermittent, and occurring at night. (*Id.* at 22.) Petitioner showed slightly decreased strength at 4/5, and pain with forward flexion, internal rotation, abduction, and external rotation. (Ex. 19, p. 22-23.) Petitioner received another cortisone injection. (*Id.)*

On May 18, 2009, petitioner reported worsening joint pain, back stiffness, wrist pain, neck pain, and finger tingling. (*Id.* at 97-98.) Petitioner's exam revealed decreased range of motion in the left shoulder and neck, and back stiffness on flexion. (*Id.* at 97.) Dr. Waltuck believed that petitioner's symptoms were consistent with worsening AS; he prescribed Remicade infusions, recommended that petitioner continue Celebrex and other anti-inflammatories as needed with oxycodone for pain management. (*Id.*)

Dr. Karas examined petitioner at a follow-up appointment on June 4, 2009. (*Id.*) He noted reduced range of motion, pain, and normal strength in petitioner's left shoulder. (Ex. 19, p. 20.) Petitioner was diagnosed with "definitive degenerative joint disease of the left shoulder – glenoid space severe." (*Id.* at 20.) Petitioner received another cortisone injection at this visit. (*Id.*)

Petitioner was seen by Dr. Waltuck for a follow up on August 17, 2009. (*Id.* at 100-01.) He reported worsening of symptoms while off Humira and Remicade and continued shoulder pain. (*Id.*) Dr. Waltuck increased petitioner's Remicade dose and scheduled a six-month follow up appointment. (*Id.*)

On September 8, 2009, petitioner was seen by Dr. Karas for a follow up on "inflammatory arthritis" in his left shoulder. (Ex. 17, pp. 17-19.) Petitioner's shoulder exam was consistent with prior exams, and he reported that his corticosteroid injections were providing less relief than before. (*Id.* at 17-18.)

Petitioner was seen again by Dr. Waltuck on October 27, 2009 and reported that his AS had improved upon increasing his Remicade dose. (Ex. 19, pp. 102-04.) However, he also reported continued pain in his left shoulder, with restriction with forward elevation. (*Id.* at 103.) Petitioner was directed to continue Remicade and Celebrex medications, and noted that he was to undergo shoulder surgery in early 2010. (*Id.*)

Petitioner underwent a total left shoulder replacement for "left inflammatory glenohumeral arthritis secondary to ankylosing spondylitis," on February 15, 2010. (Ex.

5, p. 51.) Petitioner's pre-operation imaging revealed "severe glenohumeral joint arthritis" and "glenoid spurs." (*Id.* at 52.) During the operation Dr. Karas observed adhesions and osteophytes which he removed. (*Id.* at 52, 70.) Petitioner's post-op report noted a successful operation with no complications, petitioner was referred to physical therapy and discharged the following day. (*Id.* at 52.)

Petitioner returned to Dr. Karas for a post-op follow up on February 25, 2010 where he reported "minimal, intermittent" pain of 2/10. (Ex. 19, pp. 15-16.) Petitioner's shoulder exam revealed passive flexion at 90 degrees without pain and passive external rotation at 15 degrees with no pain. (*Id.* at 15.) Petitioner was referred to continued physical therapy and scheduled a six-week follow up. (*Id.* at 16.)

Petitioner's next appointment with Dr. Karas was on April 13, 2010. His exams revealed improved range of motion and minimal pain. (*Id.* at 13-14.) Dr. Karas recommended continued physical therapy and an eight-week follow up. (*Id.* at 14.)

After completing his physical therapy, petitioner saw Dr. Karas for another follow up on June 11, 2010. (*Id.* at 11-12.) Petitioner again reported minimal pain and Dr. Karas noted that petitioner had "greatly improved" since his surgery. (*Id.* at 11.) Petitioner's shoulder exam revealed active flexion at 150 degrees, passive flexion at 155 degrees, active external rotation at 30 degrees, passive external rotation at 40 degrees, internal rotation at "L3," internal abduction at 20 degrees, and external abduction at 70 degrees. (Ex. 19, p. 12.)

Petitioner returned to Dr. Waltuck on August 29, 2011, where he reported that he was satisfied with his lack of pain and the range of motion that he experienced following his shoulder surgery. (*Id.* at 114-15.) However, Dr. Waltuck's exam revealed "slightly reduced range of motion" in his left shoulder. (*Id.* at 115.)

On February 28, 2012, petitioner returned to Dr. Waltuck who noted that petitioner was still taking Celebrex and Remicade. (*Id.* at 78-79.) Petitioner reported that he experienced an "episode of pain in the left shoulder . . . around Christmas, but it resolved after a week or so." (*Id.*) Dr. Waltuck observed some postsurgical changes in petitioner's left shoulder as well. (*Id.* at 79.)

Petitioner was seen again by Dr. Waltuck on August 28, 2012 where he reported he was doing well on Remicade and Celebrex. (Ex. 19, p. 70-71.) Petitioner did however, note experiencing more stiffness than usual in the week leading up to his Remicade infusion. (*Id.* at 70.) Petitioner complained of pain in the bases of his thumbs and his exam revealed some signs of osteoarthritis. (*Id.* at 71.)

Petitioner next saw Dr. Waltuck on February 21, 2013. He complained of continuing issues in his hands. (*Id.* at 68-69.) Dr. Waltuck noted "osteoarthritic changes" in both of petitioner's hands with Heberden's nodes and squaring of the first CMC joints. (*Id.* at 69.) He also noted slightly decreased range of motion in forward

elevation of petitioner's right shoulder. (*Id.*) Dr. Waltuck did not believe that petitioner's hand symptoms were related to an inflammatory disorder. (Ex. 19, p. 69.)

Petitioner returned to Dr. Waltuck on February 5, 2014, reporting that he was stable in terms of his joint issues but continued to experience some minor stiffness and discomfort in his neck and back. (*Id.* at 64-65.) Petitioner did, however, report a shooting pain down his right leg which began suddenly several months prior when he was getting into a boat. (*Id.* at 64.) Dr. Waltuck noted that this pain was unrelated to petitioner's AS and "probably nerve compression." (*Id.* at 65.)

On March 20, 2014, petitioner was seen by Dr. Ernest Howard for evaluation of his leg pain. (Ex. 12, pp. 2-4.) Petitioner complained of pain, arthralgias, weakness, shoulder pain, hand pain, hip pain, leg pain, knee pain, and foot pain. (*Id.* at 3.) Dr. Howard diagnosed petitioner with lower back pain, spinal enthesopathy, AS, lumbar/thoracic radiculopathy, and sacroiliitis. (*Id.* at 4.) He recommended that petitioner continue his medications and begin spinal stretching and exercise. (*Id.*)

Petitioner saw rheumatologist Dr. Roel Querubin on June 4, 2014 for evaluation of joint and back pain. (Ex. 18, pp. 175-78.) Petitioner reported 4/10 joint pain and 6/10 spine pain. (*Id.* at 175.) Dr. Querubin recorded that petitioner was experiencing numbness in both hands that worsened with sleep once or twice per month over the past several years. (*Id.* at 176.) Petitioner's neck exam revealed decreased range of motion to anterior flexion at approximately 30 degrees, decreased bilateral rotation to approximately 30 degrees, and decreased extension to approximately 15 degrees. (*Id.* at 177.) Petitioner's musculoskeletal exam revealed normal range of motion in upper and lower extremities except for a decreased range of motion in left shoulder abduction at 120 degrees and anterior flexion at 170 degrees. (*Id.*) Dr. Querubin's assessment was AS and polyarthralgia likely associated with AS. (*Id.* at 178.)

Petitioner saw Dr. Querubin for a follow up on September 9, 2014. (Ex. 18, pp. 162-66.) Petitioner complained of moderate finger, thumb, hand, and joint pain and exhibited decreased range of motion in his left shoulder consistent with his June 4, 2014 exam. (*Id.* at 164.) Importantly, however, petitioner exhibited painful active range of motion in his left shoulder. (*Id.*) Dr. Querubin also observed decreased range of motion in petitioner's neck consistent with his June 4 exam. (*Id.*)

On October 28, 2014, petitioner returned to Dr. Querubin for another follow up. (*Id.* at 152-56.) This time, petitioner's pain had decreased to a 3/10, but his shoulder and neck exams still revealed decreased range of motion and pain consistent with what was recorded in prior exams. (*Id.* at 153-55.)

Petitioner saw Dr. Querubin again on January 6, 2015 where he reported being stable since the previous visit but rated his hand and joint pain as a 4/10 and his back pain as a 7/10. (Ex. 18, pp. 144-48.) Petitioner's exam once again revealed pain with active range of motion in the left shoulder, decreased range of motion in the left shoulder and neck, and hand numbness. (*Id.* at 144-46.)

Petitioner underwent a muscle biopsy of his right quadricep muscle on February 19, 2015 which revealed mild myopathy and denervation atrophy. (Ex. 15, pp. 15-16.)

On May 5, 2015, petitioner returned to Dr. Querubin complaining of decreased grip strength, axial spine pain radiating to the right thigh and foot rated at a 5/10. (Ex. 18, pp. 126-131.) Based on petitioner's biopsy and elevated CPK levels, Dr. Querubin recommended a neurology consult. (*Id.* at 129-30.)

Petitioner saw neurologist, Dr. Reyzelman on July 2, 2015. (Ex. 15, pp. 6-7.) Based on petitioner's biopsy, Dr. Reyzelman recommended petitioner be evaluated for underlying genetic neuromuscular disease, noting differential diagnoses of "mild, autoimmune necrotizing myopathy, an indolent muscular dystrophy, a mitochondrial disorder with mildly abnormal eye movements or a metabolic myopathy or channelopathy." (*Id.* at 7-8.)

Petitioner followed up with Dr. Querubin on December 1, 2015. (Ex. 18, pp. 98-102.) Dr. Querubin once again observed decreased range of motion with mild pain on active range of motion in petitioner's left shoulder. (*Id.* at 101.) Petitioner's neck exam also revealed reduced range of motion consistent with his previous exams. (*Id.*) Upon reviewing a September 24, 2014 MRI of petitioner's cervical spine, Dr. Querubin noted "loss of normal lordotic curvature, reversal centered at C5-6, C5-6 mild spinal stenosis/effacement of the cord to the left to midline . . . narrowing of the left neutral foramen at C5-6, C6-7 . . . [and] narrowing of the right neural foramen at C4-5," which he believed was suggestive of impingement of the exiting nerve roots. (*Id.* at 102.) Petitioner's MRI also revealed "C2-3, left facet arthropathy with mild to moderate left neural foraminal narrowing, prominence to the posterior ligament, which abuts the cord [and a] facet arthropathy." (*Id.*)

On December 28, 2015, petitioner reviewed the results of his genetic testing with Amy Bradley, MMSc. (Ex. 18, pp. 94-95.) Petitioner's genetic testing revealed two pathogenic mutations in the ANO5 gene, suggesting an ANO5-related muscle disease. (*Id.* at 94.) The test also showed petitioner to carry "one likely-pathogenic mutation in the PLEC gene . . . associated with limb-girdle muscular dystrophy." (*Id.*) Ms. Bradley wrote that "ANO5-related muscle diseases have been estimated to be one of the most common causes of LGMD [and that the] spectrum of ANO5-related muscle diseases is a continuum . . . with the most common presentation being LGMD type 2L with late-onset proximal lower limb weakness." (*Id.*) She noted petitioner's symptoms of difficult ambulation, nonspecific exercise myalgia and/or burning sensation in his calves, and noted that petitioner's "disease progression is slow and ambulation is preserved until very late in the disease course." (*Id.*) She recommended a neurological evaluation to establish a baseline muscle force measurement in order to track the progression of petitioner's symptoms, a CT or MRI to identify the affected muscles, and cardiac evaluation to gauge petitioner's increased risk for cardiomyopathies and arrhythmias. (*Id.* at 95.)

Petitioner was next seen by Dr. Querubin on June 28, 2016 where he reported that his musculoskeletal issues had recently worsened. (Ex. 18, p. 65.) He specifically reported increased joint pain in his hands, increased cervical and thoracic spine pain at a 6/10, increased morning back stiffness now lasting 8-9 hours (previously lasting 4-6), and decreased range of motion in his spine, and pain radiating to his right thigh and foot. (*Id.*) Petitioner's left shoulder and neck exams revealed the same pain and reduced range of motion as his previous exams. (*Id.* at 66-67, 69.)

On November 2, 2016, petitioner reported to Dr. Querubin that his thumb and finger pain persisted at about a 4/10, but was reduced to 0/10 and 2/10 respectively with topical pain treatments. (Ex. 18, pp. 43-48.) He also reported that his spinal pain was a 5/10, his morning back stiffness now lasted all day, and his pain radiated from the right thigh to the foot. (*Id.* at 43.) Petitioner's shoulder and neck exams once again revealed decreased range of motion and pain, and his spinal exam revealed decreased range of motion and abnormal Schober's testing. (*Id.* at 47-48.) Dr. Querubin also noted hypertrophic changes in petitioner's hands. (*Id.*)

Petitioner was seen by Dr. Lenhard on January 18, 2017 where he was noted to have a history of fatty liver disease, and was administered Hepatitis A and B vaccines. (Ex. 3, pp. 23-24.)

Petitioner returned to Dr. Querubin on February 6, 2017 where he reported continued pain in his hands, spine, and right thigh radiating to his right foot. (Ex. 18, pp. 31-36.) Petitioner also reported mild difficulty with activities of daily living and his physical exams continued to reveal decreased range of motion and pain in his neck, back, and left shoulder. (*Id.* at 34.)

ii. Vaccination and subsequent treatment

Petitioner received a second Hepatitis B vaccination in his left deltoid on February 21, 2017. (Ex. 2, p. 1.) Five days later, on February 26, he e-mailed Dr. Lenhard stating that "[f]our days post immunization [he] developed significant pain in the shoulder that received the shot[.]" (Ex. 6, p. 7.) Petitioner further wrote that "today (day 5 post) the pain is still there and is limiting my left shoulder movements but I believe the pain is less than yesterday." (*Id.*)

On March 7, 2017, petitioner e-mailed again, stating that he was still experiencing pain with movement of his left shoulder and that he believed it may be associated with the February 21 vaccination which he received "4 days before the pain started." (Ex. 6, p. 6.) Dr. Lenhard advised petitioner to see an orthopedist. (*Id.*)

On March 8, 2017, petitioner e-mailed Dr. Karas to ask for guidance on his shoulder problems. (*Id.* at 3-4.) In his e-mail, petitioner described receiving his vaccination on February 21, 2017, with significant pain starting on February 26. (*Id.* at 4.) Dr. Karas recommended that petitioner obtain an x-ray of his shoulder and receive

future vaccinations in his gluteus. (*Id.*) Petitioner received a left shoulder x-ray on March 16, 2017 which revealed mild AC joint hypertrophy. (Ex. 3, pp. 35-36.)

Petitioner next saw orthopedist Dr. Peter Symbas on March 22, 2017. (Ex. 24, p. 8.) He reported posterior left shoulder pain for over two weeks, describing the pain as dull and ranging from 3 to 7/10. (*Id.*) During this visit, petitioner associated his shoulder pain with his hepatitis vaccination. (*Id.*) His exam revealed "good motion of the shoulder" in light of his total shoulder replacement, mild tenderness with range of motion, and significantly improved pain compared to his pre-op status. (*Id.* at 9-10.) Dr. Symbas reviewed petitioner's x-rays, noting a "well-seated well-maintained total shoulder arthroplasty." (*Id.* at 10.)

Petitioner e-mailed Dr. Lenhard again on April 26, 2017, stating that at the time, he was unable to lift a glass of water to his mouth without significant pain and asked about receiving an MRI of his shoulder. (Ex. 6, p. 1.) Dr. Lenhard advised petitioner to follow up with Dr. Symbas. (*Id.*)

On June 13, 2017, petitioner saw Dr. Querubin to follow up on his AS. (Ex. 18, pp. 16-20.) Petitioner's exam revealed a reduced range of motion and mild pain to active range of motion in his left shoulder. (*Id.* at 19.)

Petitioner was seen by spine specialist Dr. Virlyn Bishop on June 27, 2017 with a chief complaint of neck pain. (Ex. 8, pp. 10-12.) Petitioner's Hawkins and Neer tests showed no signs of impingement. (*Id.* at 11.) Petitioner received a cervical spine MRI on July 10, 2017 which showed severe degenerative disc disease at multiple levels, with the most significant being at the C5-6 level. (*Id.* at 1-3.)

On September 28, 2017, petitioner saw Dr. Karas, reporting post-vaccination shoulder pain since February 2017. (Ex. 19, pp. 8-10.) Petitioner noted that the pain was worse when sleeping on his side, and that it improved with Remicade infusions. (*Id.* at 8.) Petitioner's exam revealed no tenderness to palpation, 150-160 degree range of motion to flexion and abduction with pain, normal external and internal range of motion, positive Hawkins test, normal shoulder x-ray, and a small defect in the subscapularis tendon on ultrasound. (*Id.* at 9.) Dr. Karas believed that petitioner suffered from rotator cuff impingement related pain and administered another steroid injection into petitioner's left subacromial space. (*Id.* at 10.)

Petitioner saw orthopedist Dr. Anthony Grasso on February 22, 2018 for an evaluation of cervical pain. (Ex. 20, pp. 1-3.) At this point, petitioner reported numbness and tingling in both arms and hands. (*Id.* at 1.) Petitioner described his pain as sharp and noted that it was worse when moving his neck. (*Id.*) Petitioner exhibited decreased range of motion in his spine, normal range of motion in his upper extremities, and no pain or weakness with resisted movements or range of motion. (*Id.* at 2.) Dr. Grasso assessed petitioner with cervicalgia, cervical disc displacement and degeneration, anesthesia of skin, muscle spasms, AS, and muscular dystrophy. (*Id.*) He also noted that petitioner's MRIs showed no evidence of radiculopathy or nerve root

compression. (*Id.* at 3.) Dr. Grasso recommended medial branch block injection at the C4-6 levels. (*Id.*) Petitioner received these injections on February 28, 2018 and again on March 9, 2018. (Ex. 20, pp. 5-10.) Petitioner reported a 60% improvement in his pain after receiving the medial branch block injections. (*Id.* at 11.)

Petitioner returned to Dr. Grasso on April 16, 2018 where he reported an 80% improvement in his pain which he rated as a 2/10. (*Id.* at 17-19.) However, petitioner complained of mid-back pain with muscle spasms which he described as "a constant dull aching sensation with intermittent sharp exacerbations." (*Id.* at 17.) Petitioner's exam revealed tenderness in the thoracic spine with limited range of motion and a normal upper extremity exam. (*Id.* at 18.) Petitioner received a thoracic spine MRI on April 23, 2018 which revealed mild degenerative changes and mild bulging annulus at T2-3, T5-6, T7-8, and T11-12. (Ex. 23, pp. 1-2.)

Petitioner again saw Dr. Grasso on April 30, 2018. (Ex. 20, pp. 20-22.) Petitioner noted that his pain was now affecting his middle back and left shoulder and had increased to about a 3/10 that worsened with overhead activity. (*Id.* at 20.) Petitioner's exam revealed decreased range of motion in his upper extremities, pain with internal and external rotation, and positive signs of shoulder impingement in the left upper extremity. (*Id.* at 21.) Dr. Grasso diagnosed petitioner with bicipital tendinitis and impingement syndrome of the left shoulder. (*Id.*) He recommended petitioner undergo an MRI and CT scan of his left shoulder to evaluate for internal derangement. (*Id.*) Petitioner received a CT scan on May 8, 2018. (Ex. 21, p. 2.) The scan revealed a subacute to chronic-appearing nondisplaced glenoid fracture involving the articular surface and glenoid neck, and mild cortical irregularity along the medial aspect of the humerus neck that was thought to be a previously healed fracture. (*Id.*)

On May 17, 2018, petitioner returned to Dr. Grasso, reporting that his left shoulder pain began in February of 2017 after his hepatitis vaccination. (Ex. 20, p. 23.) Petitioner's exam revealed a decreased range of motion in his upper extremities, pain with internal and external rotation, and positive signs of left shoulder impingement. (*Id.* at 24.)

Petitioner was seen by Dr. Symbas again on May 23, 2018. He complained of continued left shoulder pain. (Ex. 24, pp. 5-7.) Petitioner's exam again revealed "good" range of motion in his shoulder, "considering he had a total shoulder arthroplasty." (*Id.* at 7.) Dr. Symbas reviewed petitioner's CT scan and believed it showed "perhaps a nondisplaced glenoid fracture and maybe some loosening of his glenoid." (*Id.*) Dr. Symbas referred petitioner to orthopedic surgeon Dr. James Kercher. (*Id.*)

Petitioner saw Dr. Kercher on June 4, 2018. (Ex. 22, pp. 7-8.) Petitioner again noted onset of his pain in February of 2017 after receiving his hepatitis vaccination. (*Id.* at 7.) Petitioner's exam revealed 5/5 strength with pain in his supraspinatus, and abnormal belly press, tenderness to palpation, limited motion, abnormal strength, and tenderness to palpation in his subscapularis. (*Id.* at 8.) Dr. Kercher believed that

petitioner's CT scan suggested "osteolysis around the cement mantle though it is largely intact [and] what appears to be a high riding humeral head suggestive of rotator cuff rupture in addition to a weak belly press." (*Id.*) Dr. Kercher suggested revision surgery on petitioner's shoulder, with a possible workup to evaluate for an infection, but chose to monitor petitioner over the next six months because his prognosis was generally good. (*Id.*)

On June 21, 2018, petitioner returned to Dr. Karas for a follow up on his shoulder pain. (Ex. 21, pp. 1-4.) He reported pain of 4/10 and feeling weakest with internal and external rotation. (*Id.* at 1.) Petitioner's exam revealed no tenderness to palpation, range of motion of 150-160 with pain for flexion and abduction, external rotation to the SI joint on internal rotation, and 30 degrees on external rotation. (*Id.* at 2.) Petitioner's strength was 4/5 with mild pain at flexion, 4/5 with mild pain on abduction, 5/5 with mild pain on external rotation, and 4/5 with no pain on internal rotation. (*Id.* at 2-3.) Petitioner's empty can, Neer's, active compression, Speed's, and O'Brien's tests were all normal. (*Id.*) His Hawkins test, however, was positive. (*Id.* at 3.) Dr. Karas noted that petitioner's CT scan showed "some nondisplaced fractures that could be from the tunnels that were drilled during surgery." (Ex. 21, p. 3.) He also noted that petitioner's glenoid component may be loose, but that it was hard to tell from the CT scan. (*Id.*) After an anesthetic injection, petitioner noted that his pain remained the same but that he had an increased range of motion. (*Id.*) Dr. Karas advised petitioner to continue with his normal activities and to follow up as necessary. (*Id.* at 3-4.)

b. As reflected in testimony

i. Petitioner's affidavit

Petitioner filed an affidavit with his petition on June 8, 2018. (Ex. 4.) Petitioner states in this affidavit that he received his Hepatis B booster on February 21, 2017 at Dr. Lenhard's office. (*Id.* at 1.) He affirms that he had a successful left shoulder replacement in 2010, and although he saw his PCP on January 18, 2017, for hypertension and hyperlipidemia, he was not experiencing any pain or other shoulder symptoms. (*Id.* at 2.) Petitioner describes his vaccination as "more painful than other vaccinations" he received in the past, noting unusual pain when the needle was inserted and removed. (*Id.*) He states that "[t]he movement of the needle felt like it was being inserted and then removed through a rubber band and not a muscle. The onset of pain from the injection was immediate and pain has remained to this day . . . ." (*Id.*) Petitioner further affirms that he reported his pain to Dr. Lenhard on February 26, 2017 and was advised to treat with ibuprofen. (*Id.*) On March 7, 2017 petitioner e-mailed Dr. Lenhard again and was referred to Dr. Symbas, an orthopedic surgeon who performed an x-ray on petitioner's shoulder on March 22, 2017. (Ex. 4, p. 2.) Petitioner e-mailed Dr. Lenhard once more on April 27, 2017 and was again referred to Dr. Symbas. (*Id.*)

Petitioner states that he met with Dr. Karas, the surgeon who performed his pervious shoulder replacement on September 28, 2017. (*Id.*) Dr. Karas performed an

x-ray which revealed "a small defect in the subscapularis tendon and mild AC joint arthropathy." (*Id.*) Petitioner received a therapeutic corticosteroid injection into his left subacromial joint space. (*Id.*)

Petitioner concludes his affidavit stating that he continues to suffer shoulder pain on a daily basis, that he has never filed any action for his injury, and that he has never received any award or settlement for his injury. (*Id.* at 3.)

ii. Louise H. Andrews' affidavit

On March 30, 2020, petitioner's wife, Louise H. Andrews submitted an affidavit on his behalf. (Ex. 26.) Ms. Andrews affirms that when her husband returned home after receiving his booster shot, "he complained that his left shoulder, which was the site of the injection, was very painful," and that his shoulder pain has persisted to this day, negatively impacting his daily activities, recreation, exercise routine, and his ability to travel, play with his grandchildren, and maintain his home. (*Id.* at 1-3.)

IV. Summary of Expert Opinions and Qualifications

Petitioner filed reports from allergy, immunology, and rheumatology specialist David Axelrod, M.D., to support his claim.[4] (Exs. 27, 30, 36, 43.) Respondent filed expert reports from orthopedist Geoffery Abrams, M.D., to support his position.[5] (Exs. A, C, D.)

a. Dr. David Axelrod's Initial Report

First, Dr. Axelrod opines that petitioner suffered a SIRVA, consistent with the well-known Atanasoff study, which was cited as support for the creation of the SIRVA Table Injury. (*see* Sarah Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049 (2010) (EX. 31).) Dr. Axelrod explains that SIRVA occurs when "over-penetration of the needle through the upper deltoid muscle into the shoulder bursa, with injection of the antigens (vaccine) into the bursa of

[4] Dr. Axelrod received his medical degree and master's degree in Clinical Research Design and Biostatistics from the University of Michigan. He has worked as a basic and clinical scientist, and as a medical professor at medical schools and private teaching hospitals. Dr. Axelrod has worked as a private practitioner in the areas of adult rheumatology, allergy, and immunology, and has treated reactions to medications and vaccines in this practice. He is board certified in internal medicine, allergy & immunology, adult rheumatology, and medical laboratory immunology. (Ex. 27, p. 1.)

[5] Dr. Abrams received his bachelor's degree in human biology – neuroscience from Stanford University in 2000 and his medical degree from the University of California, San Diego in 2007. He completed his surgical internship at Stanford University Hospital and Clinics in 2008 before serving as a Resident in the hospital's department of orthopedic surgery until 2012. Following his residency at Stanford, Dr. Abrams completed a fellowship in orthopedic sports medicine at Rush University Medical Center in 2013. He is board certified by the American Board of Orthopedic Surgery and holds medical licenses in California and Illinois. He served as a clinical instructor at Rush University Medical Center from 2012 to 2013. He has been an attending physician at the Veterans Administration Hospital in Palo Alto, California and an assistant professor at Stanford University School of Medicine since 2013. Since 2016, Dr. Abrams has served as director of the Lacon Sports Medicine Clinic at Stanford. (Ex. B, pp. 1-8.)

individuals previously immunized or exposed to the same antigens (vaccine) results in the development of chronic pain," possibly related to "acute and chronic inflammation, as a result of a memory response to the vaccine within the shoulder bursa." (Ex. 27, p. 4) (citing Atanasoff et al., *supra,* at Ex. 31).) Dr. Axelrod writes that in petitioner's case, he had suffered shoulder pain that resulted in a left shoulder replacement in 2010, and that petitioner did not report any shoulder pain at a rheumatologist visit on February 6, 2017. (Ex. 27, pp. 4-5.) Dr. Axelrod suggests that petitioner did not experience subsequent shoulder pain until after his vaccination on February 21, 2017, was previously vaccinated for Hepatitis B on three occasions, experienced pain immediately following his vaccination which was confined to his left shoulder, and had limited range of motion consistent with rotator cuff impingement that might be seen "with a local immune-mediated inflammatory musculoskeletal shoulder injury." (*Id.* at 5.) Dr. Axelrod further notes that petitioner received a CT scan of his shoulder on May 8, 2018, which revealed irregularities that were "likely an old healed fracture." (*Id.*) Based on petitioner's presentation and course, Dr. Axelrod concludes that petitioner meets the characteristics for a SIRVA as described in the Atanasoff study. (*Id.*) (citing Atanasoff et al., *supra,* at Ex. 31.)

Dr. Axelrod also opines that petitioner's injury additionally meets the criteria for an environmentally associated autoimmune disease ("EAAD") put forth in a study by Miller et al. (*see* Frederick W. Miller et al., *Criteria for Environmentally Associated Autoimmune Diseases*, 39 J. AUTOIMMUN. 253 (2012) (Ex. 47).) This criteria is met when there is a temporal association between the injury and trigger, lack of an alternative cause, biologic plausibility, analogy, and/or specificity. (*Id.*) (citing Miller et al., *supra*, at Ex. 47.) Dr. Axelrod explains that studies have found that a secondary immune response peaks between two to three days post-exposure to an antigen. (*Id.* at 6.) Petitioner noted pain within four days of his vaccination, which Dr. Axelrod argues is consistent with a "secondary (memory) adaptive immune response to his Hepatitis B vaccination of February 21, 2017," thus satisfying the first criteria for an EAAD. (*Id.*) (citing Miller et al., *supra,* at Ex. 47.)

In fact, Dr. Axelrod suggests that the Atanasoff study shows SIRVA to be an EAAD itself, noting that "the rapid onset of pain following vaccination results from a robust and prolonged immune response within an already sensitized shoulder."[6] (Ex.

[6] A study by Dumonde and Glynn showed that "immunization with human fibrin resulted in synovial inflammation, including cells that result in antibody production." (Ex. 27, p. 8) (citing Dudley Cohen Dumonde & L.E. Glynn, *The production of arthritis in rabbits by an immunological reaction to fibrin*, 43 BRIT. J. EXPERIMENTAL PATHOLOGY 373 (1962) (Ex. 48).) Further, in a rabbit model conducted by Cooke and Jasin, intra-articular injections of antigen resulted in synovial inflammation, "including lymphocytes and plasma cells . . . . [showing] that antibodies produced within the synovium were specific for the immunizing antigen." (T. Derek Cooke & Hugo E. Jasin, *The pathogenesis of chronic inflammation in experimental antigen-induced arthritis. I. The role of antigen on the local immune response*, 15(4) ARTHRITIS & RHEUMATISM 327 (1972) (Ex. 49).) Finally, in a study by Cooke, Hurd, Ziff, and Jasin, intraarticular injections of antigens were observed to directly stimulate specific antibodies in the synovial tissue that participated "in the formation of complement-binding antigen-antibody complexes that

27, p. 8) (citing Atanasoff et al., *supra,* at Ex. 31.) With respect to the analogy/specificity criterion for EEAD, Dr. Axelrod cites two case reports of three subjects all of whom developed shoulder pain after immunizations into the deltoid muscles; however, none of these cases involved the hepatitis B vaccine. (citing Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction*, 25 VACCINE 565 (2007) (Ex. 45).)

Dr. Axelrod proposes that molecular mimicry is the mechanism responsible for petitioner's autoimmune reaction, citing a study by Cusick et al. which suggested that because infectious agents are the principal triggers for autoimmune disease, and because the "vast majority of individuals exposed to infectious agents do not develop autoimmune disease, it is likely that those who do . . . following exposure to an infectious agent, have a defective immune system that . . . [reacts] to self-antigens or similar antigens, to which they would otherwise be tolerant." (*Id.*) (citing Matthew F. Cusick et al., *Molecular Mimicry as a Mechanism of Autoimmune Disease*, 42(1) CLIN. REV. ALLERGY & IMMUNOL. 102 (2012) (Ex. 41).) Dr. Axelrod identifies seven different synovial and cartilage antigens that could be targets for an immune response causing synovitis, all of which he says, "have structures that are homologous or antigenically similar to amino acid sequences of the Hepatitis B Surface antigen . . . ."[7] (Ex. 27 at 9.)

Dr. Axelrod also purports to rule-out alternative causes of petitioner's shoulder pain suggested by his medical history. Dr. Axelrod explains that evidence of petitioner's glenoid fracture was seen on MRI as early as August 24, 2006, and that an x-ray

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contribute to the production and maintenance of synovial inflammation. (T. Derek Cooke et al., *The pathogenesis of chronic inflammation in experimental antigen-induced arthritis. II. Preferential localization of antigen-antibody complexes to collagenous tissues,* 135 J. EXPERIMENTAL MED. 323 (1972) (Ex. 50).) Dr. Axelrod concedes that the Hepatitis B surface antigen is present in small amounts in the vaccine, but argues that it is still enough to generate an immune response. (Ex. 27, p. 8.)

[7] These antigens include: CILP protein, collagen alpha-1, coagulation factor XIIIB, glucose-6-phosphate isomerase chains, PADI4 protein, Myeloperoxidase, and metalloproteinase. (*Id.*) (citing Jun-Ichiro Tsuruha et al., *Implication of cartilage intermediate layer protein in cartilage destruction in subsets of patients with osteoarthritis and rheumatoid arthritis*, 44 ARTHRITIS & RHEUMATOLOGY 838 (2001) (Ex. 54); Patrik Önnerfjord et al., *Quantitative proteomic analysis of eight cartilaginous tissues reveals characteristic differences as well as similarities between subgroups*, 287 J. BIOLOGICAL CHEMISTRY 18913 (2012) (EX. 55); J. Brice Weinberg et al., *Extravascular fibrin formation and dissolution in synovial tissue of patients with osteoarthritis and rheumatoid arthritis*, 34 ARTHRITIS & RHEUMATOLOGY 996 (1991) (Ex. 56); Keiichi Iwanami et al., *Arthritogenic T cell epitope in glucose-6-phosphate isomerase-induced arthritis*, 10 ARTHRITIS RES. & THERAPY R130 (2008) (Ex. 28); Xiaotian Chang et al., *The expression of PADI4 in synovium of rheumatoid arthritis*, 29 RHEUMATOL. INT'L 1411 (2009) (Ex. 57); Sanna Turunen et al., *Rheumatoid arthritis antigens homocitrulline and citrulline are generated by local myeloperoxidase and peptidyl arginine deiminases 2, 3 and 4 in rheumatoid nodule and synovial tissue*, 18 ARTHRITIS RES. & THERAPY 239 (2016) (Ex. 58); Shinichiro Nishimi et al., *A Disintegrin and Metalloprotease 15 is Expressed on Rheumatoid Arthritis Synovial Tissue Endothelial Cells and may Mediate Angiogenesis*, 8 CELLS 32 (2019) (Ex. 29).) Dr. Axelrod explains that in the case of an immune response to amino acid sequences of the shoulder synovium, the response and inflammation may perpetuate "long after the vaccine disappears" thus explaining petitioner's long-standing injury.

following onset of petitioner's pain did not show any evidence of a glenoid fracture nor a loose glenoid component, and therefore, neither condition would explain petitioner's shoulder pain. (*Id.*) Regarding petitioner's AS, Dr. Axelrod writes that petitioner was seen by his rheumatologist around the time his pain began. During this period, petitioner's rheumatologist did not document any active inflammatory disease, and continued to administer the usual dose of Remicade which suggests that petitioner's AS was inactive and thus, not the cause of his shoulder pain. (*Id.*) Finally, Dr. Axelrod notes that petitioner's pain was at the lateral aspects of his left shoulder, which, if caused by disc degeneration, would be at the C3 and C4 level of the spine. (Ex. 27, p. 7.) However, Dr. Axelrod explains that no abnormalities were observed at the C3 or C4 level on petitioner's July 10, 2017 MRI, and therefore, it is unlikely that his shoulder pain was caused by a degenerative of displaced disc. (*Id.*)

Based on the preceding analysis, Dr. Axelrod concludes that petitioner's injury was ultimately caused by his February 21, 2017 hepatitis B vaccination.

b. Dr. Abrams' Initial Report

Dr. Abrams indicates that petitioner's case fails to meet the criteria for a SIRVA. (Ex. A, p. 3.) Dr. Abrams opines that petitioner did not meet the first, second, or fourth requirement because petitioner has a history of shoulder dysfunction predating his vaccination, onset was outside the typical 48-hour timeframe, and petitioner's history of AS and/or severe cervical spine pathology would explain petitioner's symptoms. (*Id.*)

Dr. Abrams notes that petitioner's history of shoulder dysfunction was severe enough that he received a total shoulder arthroplasty in February of 2010. (*Id.*) Further, although petitioner's pain did improve following his shoulder replacement, Dr. Abrams notes that petitioner continued to report episodic shoulder pain up to the date of his vaccination. (*Id.*) Specifically, Dr. Abrams cites reports of shoulder pain in February of 2012, June of 2014, several reports between March of 2016 and February of 2017, and on February 6, 2017, just prior to petitioner's vaccination. (*Id.* at 4-5 (citing Ex. 8, pp. 377, 642).)[8] Thus, Dr. Abrams opines the first SIRVA criterion, requiring no history of shoulder dysfunction, is not met in this case.

[8] When petitioner initially filed this petition, over 800 pages of medical records from multiple medical providers were filed collectively as Exhibit 8. During the initial status conference, the parties discussed the need to have petitioner refile these medical records with each medical provider's records being separated and given an individual sequential exhibit designation. Petitioner was instructed to begin with Exhibit 8 on the assumption that the original Exhibit 8 would be struck. (ECF No. 9.) Petitioner then filed Exhibits 8-19 at ECF No. 10 in response to this instruction and included fourteen pages of record from Dr. Bishop as Exhibit 8 (ECF No. 10-1); however, the original Exhibit 8 at ECF No. 1-8 was never struck. In completing his recitation of the records, Dr. Abrams appears to have relied upon the medical records as they were originally filed collectively as Exhibit 8 rather than the later re-filed medical records separately marked as Exhibits 8-19. Accordingly, Dr. Abrams's citations to Exhibit 8 refer to the documents at ECF No. 1-8. However, apart from direct references to citations within Dr. Abrams's reports, all references to Exhibit 8 within this decision refer to Dr. Bishop's records as filed at ECF No. 10-1.

Regarding the second criterion, Dr. Abrams notes that petitioner's own e-mail on February 26, 2017 states that he developed significant shoulder pain "four days post immunization . . . ." (Ex. A, p. 5.) (*See* Ex. 6, p. 7.) Dr. Abrams opines that not only is such a presentation inconsistent with the SIRVA Table Injury requirements, but also inconsistent with much of the literature on SIRVA. (Ex. A, p. 5.) He cites nine different case reports/ studies which all reported onset of shoulder pain within, at most, 48 hours of vaccination. (*Id.* at 5-6.) (citing Gail B. Cross et al., *Don't aim too high: Avoiding shoulder injury related to vaccine administration*, 45(5) AM. FAM. PHYSICIAN 303 (2016) (Ex. A, Tab 2)).)

Regarding the fourth criterion, Dr. Abrams discusses several of petitioner's conditions which he views as relevant. He explains that AS is a systemic inflammatory disease which leads to arthritis, primarily in the spine, but may affect other joints including the shoulder. (Ex. A, p. 6) (citing R. J. H. Emery et al., *The Shoulder Girdle in Ankylosing Spondylitis*, 73 J. OF BONE & JOINT SURGERY AM. 1526 (1991) (Ex. A, Tab 10); Gabriel Horta-Baas & Francisco Javier Jimenez-Balderas, *Radiographic Findings of Shoulder Involvement in Ankylosing Spondylitis,* 12(5) REUMATOL. CLIN. 296 (2016) (Ex. A, Tab 11)).) Dr. Abrams notes that "over 60%" of AS patients demonstrated enthesitis at the rotator cuff and showed a significantly higher rotator cuff tendon pathology (42% in AS patients) compared to the control group (15%). (Ex. A, p. 6) (citing Sanae Ali Ou Alla et al., *Ultrasound features of shoulder involvement in patients with ankylosing spondylitis: a case-control study*, 14 BMC MUSCULOSKELETAL DISORDERS 272 (2013) (Ex. A, Tab 13).) Dr. Abrams explains that the presence of enthesitis in AS patients is relevant because although petitioner's shoulder replacement addressed pain associated with cartilage loss in his shoulder, entheses would remain even after the shoulder replacement and would likely explain petitioner's reports of episodic pain.

Dr. Abrams also notes that even in the case of successful shoulder replacements, complications and continued pain are not uncommon, specifically at long-term follow up appointments. The most common reason for shoulder pain following replacements is glenoid loosening which was observed on petitioner's CT scan at a December 2018 visit to Dr. Kercher along with some osteolysis around the cement mantle of the glenoid, and a high riding humeral head suggesting a rotator cuff rupture. (Ex. A, pp. 6-7 (citing Ex. 22, pp. 8, 10).) Dr. Abrams concludes that these findings reasonably explain petitioner's subsequent shoulder pain.[9] Further, petitioner's CT

[9] He further clarifies that while petitioner's expert suggests that a September 2017 x-ray showed no signs of shoulder degeneration, this is unsurprising because CT scans reveal "a significantly more detailed view of [bone] structures," and that x-rays often do not "visualize subtle fractures or other pathologies of the glenoid following shoulder arthroplasty." (Ex. A, p. 7) (citing Thomas Gregory et al., *A CT scan protocol for the detection of radiographic loosening of the glenoid component after total shoulder arthroplasty*, 85(1) ACTA ORTHOPAEDICA 91 (2014) (Ex. A, Tab 20); Thomas Gregory et al., *Glenoid loosening after total shoulder arthroplasty: an in vitro CT-scan study*, 27 J. ORTHOPEDIC RES. 1589 (2009) (Ex. A, Tab 21); Edward H. Yian et al., *Radiographic and Computed Tomography Analysis of Cemented Pegged Polyethylene Glenoid Components in Total Shoulder Replacement*, 87 J. BONE AND JOINT SURG. 1928 (2005) (Ex. A, Tab 22).))

scan revealed signs of a glenoid fracture that is "almost certainly chronic and long standing and [present] at the time of vaccination," and because glenoid pathology "is the most common cause of pain following shoulder replacement," Dr. Abrams concludes that petitioner's history of AS and glenoid pathology is the likely cause of his shoulder pain. (*Id.*)

Dr. Abrams also addresses petitioner's cervical spine degeneration and how that may explain his shoulder pain. (*Id.*) He begins this discussion explaining that petitioner "has significant cervical spine disease," which can cause dysfunction and pain in the upper extremities. (*Id.*) He notes that weeks prior to petitioner's vaccination, he reported "3rd and 5th numbness" to his rheumatologist who suspected a cervical radiculopathy. (*Id.* (citing Ex. 8, p. 375).) As a result of this, petitioner underwent a cervical spine MRI which revealed "multilevel severe degenerative disc disease." (Ex. A, pp. 7-8 (citing Ex. 8, p. 1).) Dr. Abrams opines that petitioner's expert is incorrect to suggest that "there was no abnormal positioned disc material at C3-4," because the dermatomal diagram used to interpret the MRI results was referring to the exiting nerve root and not the spinal level. (Ex. A, p. 8.) In reality, petitioner's MRI showed "indenting of the anterior thecal sac . . . causing moderate narrowing of the bilateral neural foramina and lateral recess with possible abutment of the bilateral exiting C5 nerve roots." (*Id.* (citing Ex. 8, p. 2).) Dr. Abrams explains that the C5 nerve root "is directly at the lateral shoulder" and any aggravation of this nerve root would certainly cause pain consistent with petitioner's pain. (Ex. A, p. 8.) Further, Dr. Abrams notes that petitioner also reported neck pain that radiated to his bilateral upper extremities which is consistent with cervical radiculopathy. (*Id.*)

Dr. Abrams contends that based on Dr. Bishop's July 27, 2017 exam, petitioner also likely suffered from cervical spondylosis, otherwise known as cervical spine arthritis, based on the MRI findings of disc degeneration at the C5/C6 level. (*Id.*) (citing Ex. 8, p. 12.) Dr. Abrams supports this contention noting that cervical spondylosis is a "well documented cause of neck pain," that is often associated with neck, shoulder, deltoid, and lateral arm pain much like petitioner reported. (Ex. A, pp. 8-9 (citing Ginger Evans, *Identifying and treating the causes of neck pain,* 98 MED. CLIN. N. AM. 645 (2014) (Ex. A, Tab 25); Nikolai Bogduk, *The anatomy and pathophysiology of neck pain,* 22 PHYS. MED. REHAB. CLIN. N. AM. 367 (2011) (Ex. A, Tab 26); Grant Cooper et al., *Cervical Zygapophysical Joint Pain Maps,* 8 AM. ACAD. PAIN MED. 344 (2007) (Ex. A, Tab 27); Nalini Sehgal et al., *Systematic Review Of Diagnostic Utility Of Facet (Zygapophysial) Joint Injections In Chronic Spinal Pain: An Update*, 10 PAIN PHYS. J. 213 (2007) (Ex. A, Tab 28)).)

Finally, Dr. Abrams opines that petitioner had previously been diagnosed with limb-girdle muscular dystrophy which could also explain his shoulder pain. He notes that these diseases "are a group of disorders with wide genetic and clinical heterogeneity, characterized by muscle pain as well as weakness of the shoulder girdle musculature," and that this diagnosis would also be consistent with petitioner's pain.

(Ex. A, p. 9 (citing Ex. 8, p. 309; Veronique Bolduc et al., *Recessive Mutations in the Putative Calcium-Activated Chloride Channel Anoctamin 5 Cause Proximal LGMD2L and Distal MMD3 Muscular Dystrophies*, 86 AM. J. HUM. GENETICS 213 (2010) (Ex. A, Tab 29); Debbie Hicks et al., *A founder mutation in Anoctamin 5 is a major cause of limb girdle muscular dystrophy,* 134 BRAIN 171 (2011) (Ex. A, Tab 30)).)

Dr. Abrams concludes his initial report by reiterating that petitioner failed to meet the criteria for a SIRVA injury because he had complaints of shoulder pain preceding his vaccination, did not experience onset of pain within 48 hours, and suffered from several different conditions that would explain his symptoms.

c. Dr. Axelrod's First Supplemental Report

Regarding the suggestion that petitioner had a history of episodic shoulder pain after his February 2010 shoulder replacement, Dr Axelrod recounts 15 different medical records from 2011 to 2017 where petitioner did not report left shoulder pain, all included in an earlier section of this decision. (*see* Sec. II.) Dr. Axelrod also opines that the four-day post-vaccination onset petitioner experienced is medically appropriate. (Ex. 30, p. 3.) He notes that 8% of the subjects in the Atanasoff study reported pain within four days.[10] (*Id.* (citing Atanasoff et al., *supra,* at Ex. 31).) Dr. Axelrod also contends four days is consistent with a secondary adaptive immune response to the hepatitis B vaccine as described by Miao et al. (Ex. 30, p. 3 (citing Hongyu Miao et al., *Quantifying the Early Immune Response and Adaptive Immune Response Kinetics in Mice Infected with Influenza A Virus*, 84(13) J. OF VIROLOGY 6687 (2010) (Ex. 38)).)

Dr. Axelrod indicates that AS is an inflammatory arthropathy with gradual onset in the teens and twenties, (Ex. 30, p. 3 (citing Marc C. Hochberg et al., *Inflammatory back pain* and *The shoulder, in* RHEUMATOLOGY (7th ed. 2019) (Ex. 33)), and that the medical records in this case do not address the onset of petitioner's AS (Ex. 30, pp. 3-4). Dr. Axelrod cites two medical imaging records from 2006 that showed structural, but not inflammatory disease, in petitioner's left shoulder. (*Id.* at 4.) Dr. Axelrod notes that in September of 2009, petitioner was assessed with structural arthropathy in his left shoulder and that in 2010 he was assessed with osteoarthritis in his left shoulder, neither of which are inflammatory conditions. (*Id.*) Further, Dr. Axelrod writes, petitioner's cervical spine MRI on July 10, 2017, was consistent with structural and not inflammatory disease. (*Id.*) Although petitioner was diagnosed with AS, Dr. Axelrod concludes that the lack of inflammatory findings in his left shoulder suggests that petitioner's AS was well controlled thanks to his medications and not a credible cause of his shoulder pain. (*Id.*)

Dr. Axelrod explains that petitioner showed mild degenerative reduction at his C5 and C6 spinal cord, importantly, with possible impingement of the bilateral exiting C5

[10] He also suggests, however, that while petitioner reported pain to his physician within 4 days, he also described the pain as beginning on the day of his vaccination, consistent with 54% of the subjects in the Atanasoff study. (*Id.*)

and C6 nerve roots. (*Id.*) He concedes that the possible impingement of the bilateral exiting C6 nerve roots could contribute to petitioner's shoulder pain. (Ex. 30, p. 5.) However, due to the onset of petitioner's shoulder pain immediately following his injection and the lack of any trauma that would aggravate petitioner's degenerative disc disease, Dr. Axelrod concludes that the more likely cause for petitioner's shoulder pain was his vaccination. (*Id.* at 6.)

Finally, Dr. Axelrod notes that petitioner had elevated creatine kinase, an inconclusive muscle biopsy, and genetic testing that suggests a predisposition for limb-girdle muscular dystrophy, but stresses that petitioner did not suffer muscle weakness. According to Dr. Axelrod, these test results are not enough to support a clinical diagnosis of active limb-girdle muscular dystrophy, and therefore cannot account for petitioner's shoulder pain. Thus, Dr. Axelrod concludes that the most likely cause of petitioner's shoulder injury was his February 21, 2017 hepatitis B vaccination. (*Id.*)

d. Dr. Abrams's First Supplemental Report

Regarding petitioner's history of shoulder pain, Dr. Abrams stresses that petitioner had a rheumatology evaluation just two weeks prior to vaccination that demonstrated mild pain with active range of motion and that petitioner's pain could likely be explained by the decrement in function and increased pain that is often associated with wear and tear on shoulder replacements. (Ex. C, p. 1.) Dr. Abrams also writes that petitioner showed "decreased (range of motion) to left shoulder abduction to 170 degrees and [stable]," and that petitioner's "[a]ctive left shoulder range of motion mildly reproduces pain at region." (*Id.* (citing Ex. 8, p. 377).) Thus, Dr. Abrams concludes, by Dr. Axelrod's own admission, petitioner experienced shoulder pain prior to his vaccination. (Ex. C, p. 1.)

Dr. Abrams also notes that while "[o]ne may argue that the quality and intensity of shoulder pain was different before and after the injection, as the pre-existing shoulder pain reported by the petitioner was mild," it is "not uncommon for patients with conditions similar to the petitioner to experience acute exacerbations and increases in their pain levels, especially at the time frames present in this case." (*Id.* at 1-2.) Dr. Abrams stresses that this concept is "particularly relevant" considering petitioner's imaging results which revealed "osteolysis around the cement mantle (of the glenoid) as well as a high riding humeral head suggestive of rotator cuff rupture." (*Id.* at 2 (citing Ex. 22, p. 8 (internal quotations omitted)).) Further, Dr. Abrams notes that petitioner's records reveal a "subacute to chronic appearing glenoid fracture involving the articular surface and glenoid neck." (Ex. C, p. 2 (citing Ex. 22, p. 10).) Dr. Abrams opines that all of these conditions were present prior to petitioner's vaccination and "would be expected to cause shoulder pain," consistent with what was documented at petitioner's February 2017 rheumatologist exam. (Ex. C, p. 2.)

With regard to petitioner's theory of causation, Dr. Abrams concludes that petitioner's symptoms were caused by an innate immune response, and not the

adaptive response, and thus, the Miao study does not apply to petitioner's injury. (Ex. C, p. 3.) Dr. Abrams notes that antibodies take many days to weeks to be produced by the adaptive immune system, and that the innate immune system provides immediate protection and results in things such as redness, pain, and swelling after an injury. Dr. Abrams notes that the immune response that the Miao study describes as occurring after five days is an adaptive, and not innate response, while SIRVA is triggered by an innate response, explaining the relatively quick period of onset.

e. Dr. Axelrod's Second Supplemental Report

In response to Dr. Abrams' assertion that petitioner's onset is inconsistent with that of an adaptive immune response, Dr. Axelrod concedes that immediate onset of pain as described in SIRVA is too quick to be caused by an adaptive immune response. Worsening pain over a period of four days following the trigger, however, is consistent with an adaptive immune response, which is what petitioner experienced. (Ex. 36, p. 2.) Thus, Dr. Axelrod concludes on this point that even if Dr. Abrams is correct that onset of petitioner's pain occurred on the fourth day following his vaccination, this would still be consistent with an adaptive immune response as described in Miao study. (*Id.* (citing Miao et al., *supra,* at Ex. 38).)

f. Dr. Abrams' Second Supplemental Report

Dr. Abrams clarifies his earlier discussion regarding the Miao article and the fact that SIRVA is an innate, and not adaptive immune response. (Ex. D, p. 2.) He writes that an adaptive immune response would not be confined to a single shoulder, but instead spread throughout the body. Further, he writes, if SIRVA was caused by an adaptive immune response, there would be evidence of the mechanism and timing in the literature because patients would be primed for an adaptive immune response each time they were vaccinated. (*Id.*) Instead, the literature details an immediate immune response caused by antigenic material being injected into the subacromial space. (*Id.*)

In contrast, Dr. Abrams opines that petitioner's "abrupt" onset of shoulder pain after his vaccination "matches the clinical presentation of many patients with pain and decreased function many years after shoulder replacement." (Ex. D, p. 1.) Dr. Abrams explains that he has treated many patients with clinical situations that are similar to petitioner's and that "[i]n a great majority . . . they state that they were doing well for many years and then suddenly had a worsening in pain levels and/or shoulder function." (*Id.*) Dr. Abrams opines that there were numerous reasons for petitioner's shoulder pain noting that the radiographic findings described in his earlier reports, the pre-existing pain reported by petitioner to his rheumatologist prior to his vaccination, and likely loosening or tearing of the glenoid component or rotator cuff would explain the abrupt pain that petitioner experienced. (*Id.*)

g. Dr. Axelrod's Final Supplemental Report

With regard to the suggestion that an abrupt onset of pain is more consistent with sequelae from petitioner's shoulder replacement, Dr. Axelrod opines that the lack of evidence documenting any sort of issues with petitioner's shoulder replacement, and the fact that petitioner never reported any pain during this period, Dr. Axelrod argues that petitioner's pain is much more likely caused by a SIRVA.[11] (Ex. 43, p. 3.) Dr. Axelrod explains that a secondary adaptive immune response may occur within four days, citing a study by Miller et. al., which found that the maximum antibody response to repeat tetanus toxoid injections occurred by 4 to 6 days following booster vaccination. (Ex. 43, p. 4 (citing John J. Miller, et al., *The Speed of the Secondary Immune Response to Tetanus Toxoid with a Review of War Reports and Observations on Simultaneous Injection of Toxoid and Antitoxin,* 3 PEDIATRICS 64 (1949) (Ex. 63)).) Thus, Dr. Axelrod concludes, even if petitioner did not experience immediate pain, the pain which progressed over the four-day period following his vaccination is nonetheless consistent with a secondary adaptive immune response. (Ex. 43, p. 4.)

Dr. Axelrod disagrees that a systemic immune reaction would affect petitioner's entire body and not just his shoulder. (*Id.* at 5.) He notes that a review article by Sparks found that rheumatoid arthritis, a systemic autoimmune disorder, may present with single joint involvement. (*Id.* (citing Jeffrey A. Sparks, *Rheumatoid Arthritis*, 170 ANNALS OF INTERNAL MED. ITC1 (2019) (Ex. 65)).) Further, Dr. Axelrod points out, Atanasoff et al. suggest that SIRVA "begins by the interaction of an immune response already primed within the shoulder girdle," and that injection of a hepatitis B vaccine into the shoulder girdle would provoke an immune response within the joint. (Ex. 43, p. 5 (citing Atanasoff et al., *supra,* at Ex. 31).) Thus, he opines, a systemic immune response "does not preclude the presence of localized symptoms."[12] (Ex. 43, p. 5.)

[11] He notes that after petitioner's shoulder replacement, petitioner showed no signs of shoulder pain until after receiving his vaccination. (*Id.*) In fact, Dr. Axelrod points out, petitioner received both an x-ray and ultrasound of his left shoulder on September 28, 2017 that both showed an intact shoulder replacement, no fractures, good bone quality, and no signs of osteolysis, high riding humeral head, glenoid fracture, increased motion or loosening of the glenoid component, increased tearing or inflammation of the rotator cuff tendons, or increased propagation or stress at the glenoid fracture site. (*Id.* at 2.)

[12] Regarding the contention that it is unlikely that petitioner's hepatitis B vaccination caused an adaptive immune response because there are very few cases of the injury and a large number of hepatitis B vaccinations, Dr. Axelrod opines that there are likely a very few number of individuals who receive a hepatitis B vaccine administered into their shoulder girdle. (*Id.*) A study by Rojas et al. found that autoimmunity "represents an environmental related disorder, mediated by molecular mimicry," and that exposure to an antigen may cause an autoimmune disorder only in the genetically predisposed, which would explain the small number of hepatitis B induced SIRVA cases. (*Id.*) (citing Manuel Rojas et al., *Molecular mimicry and autoimmunity*, 95 J. OF AUTOIMMUN. 100 (2018) (Ex. 66)).)

h. Dr. Abrams' Final Supplemental Report

Dr. Abrams explains that Dr. Axelrod's reliance on studies that measure adaptive immune responses to tetanus toxoid injections focused on a systemic reaction as opposed to a local reaction like petitioner experienced and is therefore inapplicable to this case. (Ex. E, p. 2.) Further, he notes that Dr. Axelrod's reliance on the Firestein article discussing rheumatoid arthritis presenting in a single joint is misguided because it "has nothing to do with a local insult such as a vaccination." (*Id.*) Because "the majority of the literature regarding the mechanism of SIRVA focuses on a local inflammatory response incited by antigenic material," from the vaccine injected into the subacromial space, SIRVA will necessarily occur within 48 hours or less because it will trigger an innate immune response as opposed to an adaptive one. (*Id.*)

Dr. Abrams stresses that the important factor to consider in petitioner's case is that short term medical imaging results of a shoulder replacement are expected to be normal at first and deteriorate over time. (Ex. E, p. 1.) Further, the main long-term issue involved with shoulder replacement deterioration is loosening of the glenoid, which was exhibited on petitioner's imaging. (*Id.*) Dr. Abrams stresses that the ultrasound and x-ray results provide little utility, if any, in evaluating petitioner's shoulder deterioration because they are not sensitive enough to reveal the pathologies involved in these cases. (*Id.*) Further, petitioner's September 2017 x-ray does not rule out mild to moderate osteolysis nor loosening of the glenoid. (*Id.*) In addition to loosening of the glenoid, petitioner's May 2018 CT scan revealed osteolysis around the cement mantle, both of these conditions take years to develop, and were therefore almost certainly present prior to petitioner's vaccination, and the more likely explanation for his pain. (*Id.* at 2.)

V. Party Contentions

a. Petitioner's Argument

Neither the petition nor petitioner's motion for a ruling on the record is explicit in indicating whether petitioner is seeking to prove a Table Injury or a cause-in-fact claim. (ECF Nos. 1, 52.) However, petitioner does assert in his motion, consistent with the assertion of a Table Injury, that onset of his shoulder pain occurred "within the normal 48 hours." (ECF No. 52, p. 2.) Petitioner's motion focuses primarily on two issues, timing of onset and whether his medical history can otherwise explain his post-vaccination shoulder pain.

Petitioner stresses that his April 26, 2017 e-mail to Dr. Lenhard shows that onset of his shoulder pain occurred as soon as he received his hepatitis B booster shot. Petitioner distinguishes his earlier e-mail from February 26, 2017, from the April 26 e-mail by noting that on February 26, he wrote that his pain was significant by the fourth day post-vaccination, while the April 26 e-mail specifically noted onset immediately following vaccination. (ECF No. 52, p. 2.) According to petitioner, the earlier e-mail

described the progression of his pain, while the later one described the onset. (*Id.*) Petitioner argues that this report of onset is consistent with 54% of the subjects in the Atanasoff study, and that even if I find that onset occurred four days after vaccination, it would still be consistent with 8% of the Atanasoff subjects. (*Id.*) Petitioner also argues that a four-day onset of shoulder pain would be consistent with a secondary adaptive immune response as described in the Miao study. (*Id.* (citing Miao et al., *supra*, at Ex. 38).)

Petitioner further argues that the "[e]vidence shows no prior injury, or alternate causation of the shoulder pain . . . ." (ECF No. 52, p. 4.) Petitioner stresses that while he suffered chronic shoulder pain long before his vaccination, that specific instance of pain resolved following his shoulder replacement in 2010. (*Id.*) He relies primarily on several records from September 9, 2014, through February 20, 2017, a day before his vaccination, where petitioner was examined, but did not report any left shoulder pain. (*Id.* at 5-6) (*see* Ex. 17, p. 125; Ex. 18, pp. 31-36, 43, 47, 65, 69, 98, 101, 112, 114, 126, 129, 135, 138, 144, 146,152, 154, 162, 164.) Petitioner argues that in the years following his shoulder replacement and leading up to his vaccination, petitioner never reported significant left shoulder pain and only did so following his February 21, 2017 hepatitis B vaccination. (ECF No. 52, p. 7.)

Petitioner also argues that his AS was under control prior to and after his vaccination. First, he notes that AS is an inflammatory, and not a structural condition. (ECF No. 52, p. 7.) Next, petitioner highlights several pre-vaccination records which involve medical imaging that showed no inflammatory process at work, or diagnoses of structural shoulder degeneration from orthopedists. (*Id.* at 7-8) (*see* Ex. 5, p. 51; Ex. 19, pp. 17-18, 128-29, 134.) Petitioner also points out that on July 10, 2017, he received a cervical spine MRI almost five months after his vaccination. (ECF No. 52, p. 8.) The MRI revealed some disc degeneration in addition to ligamentum flavum thickening which petitioner argues is consistent with structural disease such as osteoarthritis, but not inflammatory disease like AS. (*Id.*) Petitioner argues that this finding in particular suggests that his AS was either nonexistent or controlled. (*Id.*)

Petitioner contends that his July 10, 2017 cervical spine MRI results prove that his disc degeneration and spinal arthritis were not the cause of his shoulder pain. (*Id.*) Petitioner highlights the fact that the results only showed possible abutment and impingement of the relevant nerve roots, and that the possibility was greater on the right side than on the left side. (*Id.*) Thus, petitioner argues, because he did not experience any nerve pain on his right side, where he was more likely to experience it, it is unlikely that his spinal condition was causing pain on his left side, where he was less likely to experience it. (*Id.* at 9.) However, petitioner does note that there was possible impingement at the C6 nerve root exit which could possibly contribute to left shoulder pain. (ECF No. 52, p. 9.)

Petitioner also argues that although his genetic testing showed a susceptibility to limb-girdle muscular dystrophy, he never showed any signs of weakness that would be

consistent with such a diagnosis, and as such, it is unlikely that limb-girdle muscular dystrophy was the cause of his shoulder pain. (*Id.* at 11.) Additionally, he contends the glenoid loosening/fracture found on his May 8, 2018 CT scan could not be the cause of his shoulder pain because on September 28, 2017, seven months after his vaccination, an X-ray revealed no evidence of glenoid fracture or loosening. Thus, petitioner was already experiencing left shoulder pain before his glenoid fracture/loosening. (*Id.* at 11-12.)

b. Respondent's Argument

Respondent argues that petitioner is not entitled to compensation because he has neither met the elements for a Table SIRVA nor presented preponderant evidence showing that his injury was caused-in-fact by his hepatitis B vaccination. (ECF No. 54, pp. 25, 35.) Respondent argues that petitioner's left shoulder pain goes as far back as 2006 and was caused by his AS. (*Id.* at 26.) He cites petitioner's various visits to rheumatologists who diagnosed petitioner with AS, and ultimately recommended a full shoulder replacement. (*Id.* at 26-27.) Respondent stresses that the most important records, however, arise after petitioner's shoulder replacement where he reported shoulder pain one year and two and a half years after his operation and as recently as two weeks prior to his vaccination. (*Id.* at 27.)

Respondent also points to petitioner's AS diagnosis, glenoid fracture and loosening, cervical spine pathology, and limb-girdle muscular dystrophy as alternative causes of his shoulder pain and as evidence his condition was not limited to his left shoulder. Respondent explains that petitioner's limb-girdle muscular dystrophy is a genetic disorder characterized by muscle pain and weakness in the shoulder girdle, which would also explain his pain. (ECF No. 54, p. 32.) He also argues that AS is a systemic inflammatory disease that leads to arthritis of the spine and other joints, with the shoulder being a "well-documented non-axial source of pain in this condition." (*Id.* at 29.) Respondent notes that when petitioner underwent his shoulder replacement, his entheses, or rotator cuff tendon/insertion and deltoid insertion, remained in place because they are critical for proper shoulder function. (*Id.*) However, respondent continues, a main finding in AS cases is enthesitis, or inflammation of the entheses at the rotator cuff or deltoid attachment on the acromion. (*Id.*) Thus, respondent concludes, it is likely that petitioner's AS led to enthesitis at his rotator cuff, and caused his shoulder pain. (ECF No. 54, p. 29.)

Respondent also argues that petitioner showed signs of glenoid loosening, the most common reason for pain following shoulder replacements which would also explain his shoulder dysfunction. (*Id.*) Petitioner's medical imaging following his shoulder replacement revealed osteolysis of the glenoid, a high riding humeral head suggestive of rotator cuff rupture, and subacute to chronic appearing glenoid fracture. (*Id.* at 30.) According to respondent's expert, glenoid loosening occurs at a rate of 67% in shoulder replacements with an average follow-up date of 74-months post-op. (*Id.*) Further, respondent argues, glenoid loosening and fracture take years to develop and

therefore would be more evident in later imaging results. (*Id.*) Respondent concludes then that petitioner did experience glenoid loosening and fracture which is a likely explanation for his pain. (ECF No. 54, p. 31.)

Additionally, respondent contends that petitioner's cervical spine pathology could also explain his left shoulder pain. Respondent notes that as of September 24, 2014, petitioner was observed to have "narrowing of the left neutral foramen at C5-6, C6-7 and narrowing of the right neural foramen at C4-5 such that impingement on the existing nerve root[s] [are] suggested." (*Id.*) (internal quotations omitted). Respondent also points to petitioner's July 7, 2017 MRI which showed "multilevel severe degenerative disc disease, worse at the C5-6 level." (*Id.*) Respondent notes that the C5 nerve root "is directly at the lateral shoulder, one of the areas of petitioner's reported pain," and that petitioner's own expert concedes that C5 and C6 nerve root impingement could explain petitioner's pain. (*Id.* at 32.) Respondent also explains that petitioner showed signs of cervical spine arthritis which is known to cause neck, upper extremity, and shoulder pain. (*Id.*) Thus, respondent concludes, petitioner's cervical spine disease is also a likely explanation of his shoulder injury. (*Id.*)

With regard to the timing of onset, respondent contends that even if I were to disregard petitioner's pre-existing shoulder pain, pain reported in other areas, and alternative causes, petitioner nonetheless failed to show that his pain began within 48-hours of his vaccination as required by the Vaccine Injury Table. (*Id.* at 33.) Respondent urges reliance on contemporaneous records wherein petitioner stated that his pain began four days after vaccination. (*Id.*) Further, respondent notes that petitioner reported this four-day onset again in an e-mail dated March 7 and March 8, 2017. (*Id.* at 33-34.)

Based on the foregoing respondent concludes that petitioner fails to satisfy the elements required for a table SIRVA because he had a history of left shoulder pain predating his vaccination, reported an onset outside the 48-hour window required by the vaccine injury table, had pain in areas other than his left shoulder, and suffered from various conditions that would explain his shoulder dysfunction. (*Id.*)

VI. Discussion

a. Petitioner has not satisfied the requirements to establish entitlement for a Table Injury of SIRVA

As stated above, the Vaccine Act's qualifications and aids to interpretation (QAIs) explain that a petitioner meets the requirement for a Table SIRVA if they show by preponderant evidence that: i) there was no history of pain, inflammation or dysfunction of the affected shoulder that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccination; ii) that the pain occurred within the specified time-frame (48 hours); iii) that the pain and reduced range of motion was limited to the shoulder in which the vaccine was administered; and iv) that there is

no other condition or abnormality that would explain the vaccinee's symptoms. *See* 42 CFR §100.3(c)(10). Here, petitioner has failed to meet any of the QAI's SIRVA criteria and, therefore, cannot show that he has suffered a Table SIRVA.

i. Petitioner has a long history of pain and dysfunction in his left shoulder that explains the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccination

Petitioner's medical records document significant shoulder pain and dysfunction prior to his vaccination. Although a total shoulder replacement relieved much of petitioner's earlier severe shoulder pain, it appears, contrary to petitioner's contention, that it never fully resolved. Petitioner initially noted that his pain had improved, but subsequent physical examination regularly revealed pain and reduced range of motion up until the weeks preceding his vaccination. (*See* Ex. 18, pp. 31-36, 46, 65-67, 101, 144-145, 153-55, 164, 177-78; Ex. 19, pp. 11-12, 13-14, 15-16, 70, 78-79, 114-115.) Although Dr. Axelrod stresses that during the period leading up to vaccination pain was reported only when evoked by physical exam, petitioner's pre- and post-vaccination physical exams evoked similar reports of pain and reduced range of motion, suggesting the prior history of pain and dysfunction does relate to or explain the post-vaccination signs and exam findings, even if petitioner subjectively reported increased pain. (*Compare* Ex. 18, p. 34 (rheumatologist on physical exam noting pre-vaccination decreased left shoulder range of motion to 170 degrees and "[a]ctive left shoulder range of motion mildly reproduces pain at region.") *and* Ex. 24, p. 9 (first post-vaccination orthopedic encounter noting "good motion of the shoulder" and "mild tenderness with range of motion.").)

Additionally, petitioner's CT scan at a December 2018 visit to Dr. Kercher showed osteolysis around the cement mantle of the glenoid, and a high riding humeral head suggesting a rotator cuff rupture. (Ex. A, pp. 6-7) (citing Ex. 22, pp. 8, 10.) Further, petitioner's CT scan revealed signs of a glenoid fracture that is "almost certainly chronic and long standing and [present] at the time of vaccination," and because glenoid pathology "is the most common cause of pain following shoulder replacement," Dr. Abrams concludes that petitioner's history of AS and glenoid pathology is the likely cause of his shoulder pain. (*Id.*) Dr. Abrams concludes that these objective findings reasonably explain petitioner's subsequent shoulder pain. Dr. Abrams is also persuasive in suggesting that petitioner's earlier ultrasound and x-ray imaging, would not have been sensitive enough to detect these conditions. (Ex. A, p. 7.)

Dr. Abrams explains that even in the case of successful shoulder replacements, complications and continued pain are not uncommon, specifically at long-term follow up appointments. (Ex. A, pp. 6-7.) Dr. Abrams opines that an "abrupt" onset of worsened shoulder pain during the period following petitioner's vaccination also "matches the clinical presentation of many patients with pain and decreased function many years after shoulder replacement." (Ex. D, p. 1.) Given his qualifications in orthopedics and

orthopedic surgery, Dr. Abrams is better suited than Dr. Axelrod to speak to the specifics of petitioner's prior shoulder surgery, long term post-surgical prognosis, and the significance of the specific imaging at issue. On the whole, Dr. Abrams is persuasive in connecting petitioner's prior history of shoulder pain and dysfunction to the signs, symptoms, examination findings, and diagnostic studies, occurring after vaccination.

ii. Petitioner's shoulder pain arose outside the 48-hour window for a Table SIRVA

Although petitioner experienced shoulder pain prior to his vaccination, it is clear that he also reported pain that he attributed to his vaccination. Respondent argues that petitioner's post-vaccination pain did not begin until four days post-vaccination, while petitioner argues that his pain began immediately after receiving the vaccination. Contrary to petitioner's contention, the evidence preponderates in favor of finding that petitioner's reported post-vaccination shoulder pain began roughly four days after his vaccination.

The key pieces of evidence on this point are three e-mails that petitioner sent to his physicians shortly after receiving his vaccination. The first e-mail was sent on February 26, 2017. Petitioner states: "Four days post immunization I developed significant pain in the shoulder that received the shot and today (day 5 post) the pain is still there and is limiting my left shoulder movements but I believe the pain is less than yesterday." (Ex. 6, p. 7.) In the second e-mail, sent nine days later on March 7, 2017, petitioner states in relevant part, "I am still experiencing pain upon movement of the left shoulder (replaced 2011) that I believe may have been associated with the Hepatitis B booster shot I received 4 days before the pain started." (Ex. 6, p. 6.) In the third e-mail, sent the following day on March 8, 2017, petitioner wrote: "26, February 2017 (5 days post IM vaccination) started to have significant pain in left shoulder . . . ." (*Id*. at 4.)

There are several reasons for giving these notations substantial weight. First, these are the most contemporaneous accounts of the onset of petitioner's post-vaccination shoulder pain. Second, this description is clearly presented in the context of seeking treatment, meaning petitioner had an incentive to be accurate. Third, as e-mail communications by petitioner, the description contained in the e-mails represents petitioner's own direct account. They are not subject to note-taking error or imprecision in paraphrasing. Fourth, and relatedly, the three e-mails describe onset fairly consistently and the description of onset is both precise and unambiguous. Petitioner's reinterpretation of the e-mails as indicating progression rather than onset of pain is not consistent with the explicit statement in the March 7 e-mail that the vaccination occurred four days "before the pain *started.*" (Ex. 6, p. 6 (emphasis added).) It was not until April 26, 2017, that petitioner later suggested in a follow up e-mail to Dr. Lenhard that his shoulder pain began the day of the vaccination. (Ex. 6, p. 1.)

Even setting aside the e-mail messages, petitioner's medical records do not preponderately establish onset within 48-hours of vaccination. Petitioner reported onset as occurring outside of the 48-hour window during his first orthopedic assessment. He told Dr. Symbas on March 22, 2017, that his left shoulder pain had lasted for over two weeks. This would place onset sometime in early March, at least 10 days post vaccination. (Ex. 24, p. 8.) Petitioner's later medical records largely fail to detail a specific date of onset, noting that his pain began sometime in late February, but failing to specify when it began exactly.[13] He reported to Dr. Karas on September 28, 2017, that his pain began in late February following his Hepatitis vaccination, but did not specify a date. (Ex. 19, pp. 8-10.) He did the same on a May 17, 2018 visit to Dr. Grasso, and again on a June 4, 2018 visit to Dr. Kercher. (Ex. 20, p. 23; Ex. 22, p. 7.) Petitioner's later medical records generally place onset of his shoulder pain in late February of 2017, while his more contemporaneous medical records place onset specifically outside the 48-hour window at four days post-vaccination. Ultimately, the record as a whole supports a finding that petitioner's shoulder pain began four days post-vaccination.

Petitioner states in his affidavit that his vaccination was "more painful" than others he received in the past, and that "[t]he movement of the needle felt like it was being inserted and then removed through a rubber band and not a muscle. The onset of pain . . . was immediate . . . ." (Ex. 4, p. 2.) Petitioner's wife also submitted an affidavit indicating that when petitioner returned home from his medical appointment, he was complaining of shoulder pain. (Ex. 26, p. 1.) Although witness testimony may be offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed.Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). I have considered the affidavit testimony available in this case; however, neither affidavit provides any explanation, let alone a "consistent, clear, cogent, and compelling" explanation, as to why these later written affidavits recount a history of onset that contradicts petitioner's contemporaneous medical records, including e-mails petitioner himself wrote to his physicians at the time he was seeking treatment. (*See* Exs. 4, 25, 26.)

iii. Petitioner's pain was not limited to his left shoulder

Petitioner's reports of pain ultimately included his back, neck, and bilateral upper extremities. On June 27, 2017, petitioner reported to Dr. Bishop with a chief complaint of neck pain. (Ex. 8, pp. 10-12.) He also reported tingling and numbness in his bilateral upper extremities on February 22, 2018. (Ex. 20, pp. 1-3.) Additionally, respondent's expert opines that petitioner's shoulder pain is related to his pre-existing AS. (Ex. A, pp.

[13] Medical records indicating that petitioner attributed his pain to vaccination without specifying onset do not suffice in this case to imply onset occurring within 48 hours because petitioner's initial e-mails to his doctors confirm that he was willing to draw a causal connection between his vaccination and pain beginning four days post-vaccination. (Ex. 6, pp. 6-7.)

4, 6-8; Ex. C, p. 4; Ex. E, p. 3.) To the extent the below analysis relative to the fourth SIRVA criterion suggests that cervical degeneration/radiculopathy and AS also contributed to petitioner's condition, there is consequently not preponderant evidence that the injury at issue was limited to petitioner's shoulder pursuant to the third SIRVA criterion.

iv. Petitioner suffered from several other conditions that could explain his symptoms

Petitioner suffered from several different conditions affecting his shoulder. Based on petitioner's medical history, Dr. Abrams is persuasive in contending that these other conditions are more likely explanations for petitioner's shoulder pain for all the reasons detailed above.

First, petitioner suffered from AS even before he underwent his shoulder operation. (Ex. 19, p. 82.) Dr. Abrams explains that because the entheses can remain after a shoulder replacement, patients such as petitioner are still at risk for AS related ethesitis, and because AS is a systemic, chronic disease, it would be a reasonable explanation for petitioner's shoulder pain.[14] (Ex. A, p. 6.) Dr. Axelrod disagrees based on the fact that petitioner's pre-vaccination records did not evidence an inflammatory condition while petitioner was on Remicade. (Ex. 36, p. 2.) Importantly, however, respondent observes that petitioner's post-vaccination shoulder pain responded to treatment with Remicade (the treatment protocol for his AS) rather than to steroid injections, commonly used to treat bursal inflammation. (ECF No. 54 (citing Ex. 17, p. 17; Ex. 18, p. 1; Ex. 19, p. 8).) Moreover, as discussed relative to the first SIRVA criterion, it is also not the case that petitioner was completely asymptomatic prior to vaccination.

Second, there is preponderant evidence that petitioner was experiencing complications from his prior shoulder replacement, including glenoid loosening. According to Dr. Abrams, glenoid loosening is the most common reason for pain and corrective shoulder surgery following a shoulder replacement.[15] (Ex A, p. 6.)

[14] As explained above, AS is an inflammatory disease that leads to arthritis in the spine and other joints of the body, including the shoulder. (Ex. A, p. 6) (citing Emery et al., *supra,* at Ex. A, Tab 10; Horta-Baas & Jimenez-Balderas, *supra* at Ex. A, Tab 11.) A primary finding of AS is enthesitis, or inflammation of the enthesis, the tissue where tendons or ligaments attach to bone; over 60% of AS patients show enthesitis of the rotator cuff tendon. (*Id.*) (citing Rajesh K. Kataria & Lawrence H. Brent, *Spondyloarthropathies*, 69 AM. FAM. PHYSICIAN 2853 (2004) (Ex. A, Tab 12); Ali Ou Alla et al., *supra,* at Ex. A, Tab 13.) Further, enthesitis of the deltoid attachment on the acromion is sometimes referred to as the "hallmark" of AS. (*Id.*) (citing Robert G. W. Lambert et al., *High Prevalence of Symptomatic Enthesopathy of the Shoulder in Ankylosing Spondylitis: Deltoid Origin Involvement Constitutes a Hallmark of Disease*, 51 ARTHRITIS & RHEUMATISM 681 (2004) (Ex. A, Tab 14).)

[15] Dr. Abrams cites: Nicolas Bonnevialle et al., *Aseptic glenoid loosening or failure in total shoulder arthroplasty: revision with glenoid reimplantation*, 22 J. SHOULDER ELBOW SURG. 745 (2013) (Ex. A, Tab 15); Tyler J. Fox et al., *Survival of the glenoid component in shoulder arthroplasty*, 18 J. SHOULDER ELBOW SURG. 859 (2009) (Ex. A, Tab 16); Barbara Melis et al., *Glenoid loosening and failure in anatomical total*

Specifically, Petitioner's medical records document "some osteolysis around the cement mantle (of the glenoid)" and "a high riding humeral head suggestive of rotator cuff rupture," with the physician, Dr. Kercher, concluding that there was "some loosening of the glenoid component that may require additional surgery." (Ex. A, pp. 6-7; *see also* Ex. 22, p. 8.) Dr. Abrams explains that glenoid fracture and loosening takes years to develop, and therefore, it cannot be concluded that these conditions were not present at the time of petitioner's vaccination. He cites one study which found that glenoid loosening occurred within two years in 20% of cases that required revision surgery after a shoulder replacement, and another study which found that 67% of shoulder replacements showed glenoid loosening with a mean timeframe of six years, two months, compared to petitioner's first radiograph which occurred seven years and seven months after his shoulder replacement. (Ex. A, p. 7.)

Petitioner argues that his glenoid fracture wasn't evidenced until his 2018 CT scan and that he underwent an x-ray in September of 2017 which showed no evidence of glenoid or rotator cuff damage and therefore it is more likely that he did not suffer from these conditions until his 2018 CT scan. However, Dr. Abrams explains that x-rays "often [do] not visualize subtle fractures or other pathologies of the glenoid following shoulder arthroplasty," and that the CT scan which did show evidence of glenoid pathology "provides a significantly more detailed view of osseous (bone) structures." (Ex. A, p. 7.) Consequently, he concludes that while petitioner's September 2017 x-ray failed to reveal glenoid or rotator cuff damage, his 2018 CT scan suggests that he may have been experiencing effects of his glenoid fracture in 2017.

Third, Dr. Abrams is also persuasive in identifying petitioner's significant cervical spine degeneration as a likely cause of his shoulder pain. Petitioner's rheumatologist reports that several weeks before his vaccination, petitioner complained of "3rd and 5th numbness and suspected cervical radiculopathy." (*Id.* (citing Ex. 8, p. 375).) Cervical radiculopathy is a well-known cause of shoulder pain. (Ex. A, p. 7.) Subsequent MRIs revealed petitioner suffered from "severe degenerative disc disease." (*Id.* at 8.) (citing Ex. 8, p. 1.) Petitioner's expert, Dr. Axelrod, initially contended that lateral shoulder pain cannot be attributed to the disc degeneration found on petitioner's MRI because there were no issues at the C3-4 level. However, Dr. Abrams points out that Dr. Axelrod misinterpreted the results as referring to the spinal levels, when in reality it referred to exiting nerve roots. Thus, because petitioner's MRI revealed possible aggravation of the C5 exiting nerve root which is "the most common cause of cervical mediated shoulder pain," it can be concluded that petitioner's disc degeneration was a factor

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shoulder arthroplasty: is revision with a reverse shoulder arthroplasty a reliable option?, 21 J. SHOULDER ELBOW SURG. 342 (2012) (Ex. A, Tab 17); Lionel Neyton et al., *Mid- to long-term follow-up of shoulder arthroplasty for primary glenohumeral osteoarthritis in patients aged 60 or under*, 28 J. SHOULDER ELBOW SURG. 1666 (2019) (Ex. A, Tab 18); Patrick Vavken et al., *Rates of radiolucency and loosening after total shoulder arthroplasty with pegged or keeled glenoid components*, 95 J. BONE AND JOINT SURG. 215 (2013) (Ex. A, Tab 19)).

contributing to his shoulder pain, especially in light of the report of numbness extending to his fingers. (Ex. A, p. 8; Ex. 20, p. 1.)

b. Petitioner has not shown that his injury was caused-in-fact by his hepatitis B vaccination

Although petitioner did not explicitly plead a cause-in-fact claim, his expert did opine that if petitioner did not experience a SIRVA, he nonetheless suffered from a more general "environmentally associated autoimmune disease," ("EAAD") via molecular mimicry affecting the shoulder joint and resulting in a SIRVA-like presentation. Absent the presence of a Table Injury, petitioner is afforded no causal presumption. Under the *Althen* standard, petitioner may prove actual causation by providing a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect showing that the petitioner's specific vaccination was the cause of his injury, and a proximate temporal relationship between the vaccination and the injury. *See Althen*, 418 F.3d at 1278.

Dr. Axelrod's medical theory is unpersuasive. He purports to marry evidence in the medical literature examining post-vaccination shoulder injuries with evidence in the medical literature investigating the role of the immune system in joint deterioration. However, Dr. Axelrod stands alone in seeking to connect these two areas of inquiry. None of the literature filed in this case supports the idea that those investigating acute post-vaccination shoulder injuries suspected an autoimmune etiology to explain their findings of acute shoulder pain[16] whereas the literature Dr. Axelrod cites purporting to show potential molecular mimics within joint tissue involves the separate context of chronic conditions such as rheumatoid arthritis and osteoarthritis.[17] Additionally, though he stresses the cause of pain in SIRVA is unknown, Dr. Axelrod himself describes the

[16] *See*, Atanasoff et al., *supra*, at Ex. 31; Bodor & Montalvo, *supra*, at Ex. 45; Ian F. Cook, *Subdeltoid/subacromial bursitis associated with influenza vaccination*, 10 HUM. VACCINES & IMMUNOTHERAPEUTICS 605 (2014) (Ex. 46).

[17] *See,* Keiichi Iwanami et al., *Arthritogenic T cell epitope in glucose-6-phosphate isomerase-induced arthritis*, 10(6) ARTHRITIS RES. & THERAPY R130 (2008) (Ex. 28); Shinichiro Nishimi et al., *A Disintegrin and Metalloprotease 15 is Expressed on Rheumatoid Arthritis Synovial Tissue Endothelial Cells and may Mediate Angiogenesis*, 8 CELLS 32 (2019) (Ex. 29); Jun-Ichiro Tsuruha et al., *Implication of Cartilage Intermediate Layer Protein in Cartilage Destruction in Subsets of Patients With Osteoarthritis and Rheumatoid Arthritis*, 44 ARTHRITIS & RHEUMATISM 838 (2001) (Ex. 54); Patrik Önnerfjord et al., *Quantitative Proteomic Analysis of Eight Cartilaginous Tissues Reveals Characteristic Differences as well as Similarities between Subgroups,* 287 J. BIOLOGICAL CHEMISTRY 18913 (2012) (Ex. 55); J. Brice Weinberg et al., *Extravascular Fibrin Formation and Dissolution in Synovial Tissue of Patients with Osteoarthritis and Rheumatoid Arthritis*, 34 ARTHRITIS & RHEUMATISM 996 (1991) (Ex. 56); Xiaotiann Chang et al., *The expression of PADI4 in synovium of rheumatoid arthritis*, 29 RHEUMATOL. INT'L. 1411 (2009) (Ex. 57); Sanna Turunen et al., *Rheumatoid arthritis antigens homocitrulline and citrulline are generated by local myeloperoxidase and peptidyl arginine deiminases 2, 3 and 4 in rheumatoid nodule and synovial tissue*, 18 ARTHRITIS RES. & THERAPY 239 (2016) (Ex. 58).) Additionally, Dr. Axelrod himself acknowledges that the abrupt post-vaccination onset of shoulder pain examined by Atanasoff and others is more consistent with an inflammatory innate immune reaction rather than the type of adaptive immune response implicated by autoimmunity and molecular mimicry. (Ex. 36, p. 2 ("Innate responses occur from minutes to hours following an insult.") (citing Abul K. Abbas et al., *Properties and Overview of Immune Responses* and *Innate Immunity, in* CELLULAR AND MOLECULAR IMMUNOLOGY 1-11 (9th ed. 2018) (Ex. 42)).

immediacy of post-vaccination onset of shoulder pain examined by Atanasoff and others as more consistent with an inflammatory innate immune reaction rather than the type of adaptive immune response implicated by autoimmunity and molecular mimicry. (Ex. 36, p. 2 (explaining that "[i]nnate responses occur from minutes to hours following an insult" and citing Abul K. Abbas et al., *Properties and Overview of Immune Responses* and *Innate Immunity, in* CELLULAR AND MOLECULAR IMMUNOLOGY 1-11 (9th ed. 2018) (Ex. 42)). Accordingly, Dr. Axelrod's medical theory is not sound and reliable and is therefore insufficient to meet petitioner's burden under *Althen* prong one.

Additionally, even if petitioner did provide preponderant evidence of a causal theory to explain SIRVA-like presentations on a cause-in-fact basis, it is still unlikely that petitioner would be able to establish a logical sequence of cause and effect in this specific case under *Althen* prong two. Although the specific QAI criteria for a SIRVA Table Injury are not controlling with respect to a cause-in-fact claim, the above analysis with regard to petitioner's pre-existing condition and alternative explanations for his own shoulder symptoms remains illuminating in the cause-in-fact context and need not be repeated.

Even with respect to causation-in-fact, petitioner relies in significant part on the Atanasoff article to demonstrate how the proposed vaccine-caused shoulder injury can manifest. Although some Atanasoff subjects did have MRI evidence of shoulder dysfunction, that study purported to link vaccination and injury on the very basis that the lack of prior shoulder symptoms along with the rapid onset of post-vaccination pain allowed for the suspicion of an immune-mediated inflammatory state that provoked the symptoms. (Atanasoff et al., *supra,* at Ex. 31, p. 3.) The Atanasoff authors stressed that there is no diagnostic test available to assess whether shoulder dysfunction is vaccine-caused, leaving only this type of clinical qualification to aid in identifying post-vaccination shoulder injuries as a distinct entity. (*Id*. at 4.)

However, for all the reasons discussed above, petitioner's own clinical history both offers evidence of pre-existing, symptomatic shoulder dysfunction and affirmatively points to other likely etiologies for petitioner's shoulder pain and overall condition. Thus, his presentation is incompatible with the type of circumstantial causal inference (effectively a diagnosis of exclusion) advanced in the relevant literature by Atanasoff et al., and Bodor and Montalvo. Alternatively, nothing in petitioner's own medical history is indicative of the type of autoimmune attack Dr. Axelrod hypothesizes. Nor did petitioner's own treating physicians suspect vaccine-causation in this case under either scenario. Those of petitioner's physicians that did remark on petitioner's history of vaccination disclaimed sufficient knowledge to render any causal conclusion. (Ex. 6, pp. 1, 3-4.)

With regard to timing under *Althen* prong three, petitioner is correct that a four-day onset period is potentially consistent with the time necessary for an adaptive immune response to result in an autoimmune injury; however, because petitioner has not demonstrated that his injury manifested as a consequence of an autoimmune

response, this is of no moment. With respect to an inflammatory innate immune response, Atanasoff observed that 93% of cases reported onset of shoulder pain occurring within 24 hours of vaccination. (Atanasoff et al., *supra,* at Ex. 31, p. 2.) Bodor and Montalvo reported two cases with onset occurring within 48 hours. (Bodor & Montalvo et al., *supra*, at Ex. 45.) While Dr. Axelrod stresses that 8% of the Atanasoff subjects experienced onset of shoulder pain within four days of vaccination rather than within one day, 8% of the Atanasoff study group represents only one individual. (Atanasoff et al., *supra*, at Ex. 31, p. 1 (noting that the study included 13 potential cases).) The literature filed in this case does not necessarily *preclude* a four-day onset period; however, without more and especially in light of the weaknesses of petitioner's medical theory under *Althen* prong one, petitioner has not preponderately established on this record that it is a medically appropriate temporal interval for the type of injury alleged.

VII. Conclusion

Petitioner has my sympathy for the pain he has endured and I understand why he came to the personal conclusion that he suffered a vaccine-related injury. However, for all the reasons discussed above, I cannot conclude that his injury was vaccine-caused or aggravated based on the standards applicable in this Program. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.[18]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

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