# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 17-1905V**
**Filed: February 15, 2023**
PUBLISHED

JEANNE MICHELLE FORREST, as special administrator of the estate of JOANN FORREST,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Shoulder Injury Related to Vaccine Administration ("SIRVA"); Influenza ("Flu") Vaccine; Ruling on the Record; Significant Aggravation

*Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.*
*Jennifer A. Shah, U.S. Department of Justice, Washington, DC, for respondent.*

## Ruling on Entitlement[1]

On December 8, 2017, Joan Forrest filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that her receipt of an influenza ("flu") vaccination on December 16, 2014, caused a right shoulder injury, specifically a Table Injury of "SIRVA." (ECF No. 1.) On June 25, 2020, the current petitioner, Jeanne Michelle Forrest, was substituted as petitioner in her capacity as legal representative for the estate of Joann Forrest.[3] (ECF No. 58.) An amended petition was subsequently filed to additionally plead significant aggravation as an alternate theory. (ECF No. 63.) For the reasons set forth below, I conclude that petitioner is

[1] Because this document 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 document 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.

[3] Throughout this decision, Jeanne Michelle Forrest will be referred to exclusively as "petitioner" and Joan Forrest will be referred to as "Ms. Forrest."

entitled to an award of compensation for a significant aggravation of the Ms. Forrest's pre-existing shoulder injury.

## 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; 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 flu 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 provide more detailed explanation of what should be considered when determining whether a petitioner has proven the existence an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that the injury at issue meets the following four criteria:

> (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 ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (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 demonstrate: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between 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*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

A petitioner may also allege that the vaccine at issue caused a "significant aggravation" of a preexisting injury. The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a pre-existing injury, she must establish three additional factors. *See Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test.). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Id*.

## II. Procedural History

As noted above, this case was initially filed on December 8, 2017. Based on the allegations contained in the petition it was originally assigned to the Special Processing Unit or "SPU" for possible information resolution. (ECF No. 5.) Through her counsel, Ms. Forrest developed the record between March of 2018 and June of 2019. (ECF Nos. 9, 15, 25, 32, 35, 37, 39; Exs. 1-22.) Respondent then filed his Rule 4 Report on September 24, 2019. (ECF No. 44.) Respondent contended that Ms. Forrest could not establish a Table Injury of SIRVA and had not filed any expert medical opinion to support a cause-in-fact claim. (*Id*. at 9-12.) Respondent suggested that Ms. Forrest had a preexisting shoulder injury and that her symptoms were not limited to her shoulder. (*Id*.)

After respondent filed his report, the case was reassigned out of the SPU and to the undersigned and I ordered Ms. Forrest to file an expert report. (ECF No. 46-48.) She filed a report by Marco Bodor, M.D., and supporting material on March 12, 2020. (ECF No. 53; Exs. 24-29.) Respondent filed a responsive report by Julie Bishop, M.D., with supporting material on July 21, 2020. (ECF No. 59; Exs. A-B.) During this period, Ms. Forrest passed away due to conditions unrelated to her injury claim and Jean Michelle Forrest became petitioner as legal representative of the estate. (ECF Nos. 52, 56-58; Exs. 23, 30.) On August 31, 2020, petitioner filed a supplemental report by Dr. Bodor responding to Dr. Bishop's report. (ECF Nos. 60-61; Exs. 31-34.)

On September 2, 2020, I held a status conference during which I urged the parties to consider litigative risk settlement and also noted that I felt the case is appropriate for resolution on the written record. (ECF No. 62.) I discussed petitioner's claim as more likely to represent a claim for significant aggravation. (*Id*.) Specifically, I explained that my review of the medical records suggested three arcs of shoulder symptoms – the first predating the vaccination, the second immediately after vaccination, and a third subsequent to a later series of falls. (*Id*. at 2.) Respondent's expert, Dr. Bishop, opined this was the natural course of Ms. Forrest's degenerative conditions; however, both Ms. Forrest's primary care physician and Dr. Bodor opined the second arc of symptoms constituted a vaccine-related aggravation of Ms. Forrest's shoulder condition. (*Id*.) Subsequently, on September 14, 2020, petitioner amended her petition to include a claim for significant aggravation. (ECF No. 63.)

Thereafter, the parties exchanged several more expert reports. Respondent filed a supplemental report by Dr. Bishop on April 28, 2021. (ECF No. 71; Ex. C.) Petitioner filed a further report by Dr. Bodor on August 4, 2021. (ECF No. 74; Ex. 35.) Respondent then filed a report by Dr. Bishop on September 30, 2021, and petitioner responded with a report by Dr. Bodor on October 8, 2021. (ECF Nos. 76-77; Exs. D, 36-38.) Respondent filed a report by Dr. Bishop on January 5, 2022, and petitioner filed a report by Dr. Bodor on January 19, 2022. (ECF Nos. 79-80; Exs. E, 39-40.) Respondent filed a final report by Dr. Bishop on March 7, 2022. (ECF No. 83; Ex. F.)

On March 8, 2022, I ordered petitioner to file a motion for a ruling on the record and also permitted petitioner to simultaneously file a report by Dr. Bodor responding to respondent's final report by Dr. Bishop. Petitioner filed a final report by Dr. Bodor on March 10, 2022, and her motion for a ruling on the record on May 9, 2022. (ECF Nos. 84-85; Exs. 41-43.) Respondent filed his response on June 22, 2022, and petitioner filed a reply on July 6, 2022. (ECF Nos. 87-88.)

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

Ms. Forrest presented to her primary care physician on December 27, 2011, with a complaint of right shoulder pain. (Ex. 4, p. 1.) On physical exam she had crepitus[4] and impaired range of motion. (*Id*. at 2.) She followed up with an orthopedist (Dr. Johnson) on January 13, 2012.[5] (Ex. 2, p. 1.) She complained of "persistent," but "waxing and waning" shoulder pain for approximately eight years.[6] (*Id.*) The pain had worsened in the last few months. (*Id*.) She had previously tried physical therapy but felt it had made her symptoms worse. By the time she sought treatment from Dr. Johnson, the pain was interfering with her sleep. (*Id.*) On physical exam she had reduced range of motion and signs of impingement (Hawkins and Neer's testing were positive).[7] Ms. Forrest was diagnosed with right shoulder subacromial impingement and a suspected rotator cuff tear. (*Id*. at 3.)

Ms. Forrest returned to Dr. Johnson on February 9, 2012. A diagnostic ultrasound showed "a chronic right shoulder full-thickness tear of the anterior medial fibers of the supraspinatus with minimal tendon retraction" and acromioclavicular joint osteoarthritis. (Ex. 2, p. 5.) She declined a steroid injection and was referred for a surgical consultation that she apparently did not pursue.[8] (Ex. 15, p. 9.)

Ms. Forrest did not seek care again until about a year and a half later, when she sought care from her primary care provider on July 12, 2013, following a fall in her garden. (Ex. 4, p. 20.) She reported that about two weeks prior she fell down a slope in her garden and fell onto her knees and right shoulder. She complained of right shoulder

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[4] "The grating sensation caused by the rubbing together of the dry synovial surfaces of joints; called also articular c." *Joint crepitus,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=67378&searchterm=joint%20crepitus (last accessed Feb. 13, 2023).

[5] In addition to her shoulder complaint, petitioner also had bilateral hand pain and weakness that was separately diagnosed as arthritis. (Ex. 2, p. 3.)

[6] Petitioner would later report to Dr. Johnson that she recalled a prior fall occurring about eight to ten years prior. (Ex. 2, p. 4.)

[7] A Hawkins-Kennedy test is a test used in the evaluation of orthopedic shoulder injury. "A positive Hawkins-Kennedy test is indicative of an impingement of all structures that are located between the greater tubercle of the humerus and the coracohumeral ligament." *Hawkins-Kennedy test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Hawkins%E2%80%93Kennedy_test (last accessed Feb. 13, 2023). A Neer impingement test is a test designed to reproduce symptoms of rotator cuff impingement "through flexing the shoulder and pressure application." *Neer Impingement Test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Neer_Impingement_Test (last accessed Feb. 13, 2023). In a Neer's test, symptoms should be reproduced "if there is a problem with he supraspinatus or biceps brachii." *Id.*

[8] Petitioner was referred to Dr. Benjamin Widmer but there is no indication from the records that she saw Dr. Widmer at that time. (Ex. 15.) Petitioner's first visit to Dr. Widmer appears to be on July 6, 2015. (*Id.* at 11-16.)

and right knee pain as well as fatigue. (*Id*.) However, the fatigue was reportedly more concerning at this particular visit. Ms. Forrest reported that she was still experiencing shoulder pain, worse at night, that she felt was slowly improving and that her shoulder pain "is not overly concerning." (*Id*.) However, she did state that she could not cross her arm across her chest. (*Id*.) On examination, she had no crepitus and no tenderness to palpation, but reported some pain with resisted abduction and rotation. Apart from her cross-body movement, her range of motion was normal. Neer's test demonstrated "some tightness" but Hawkins test was negative. (*Id*. at 21.) No treatment was recommended.

However, Ms. Forrest returned to her primary care provider on August 5, 2013, reporting that her right shoulder pain had worsened due to attempting to pull a vine out of her garden. (Ex. 4, p. 24.) She now had mild tenderness to palpation in the inferior to the acromion, limited external rotation, and abduction limited to 90 degrees. For the first time she had pain with an empty can test.[9] (*Id.*) However, it was noted that her passive range of motion was good. Accordingly, the injury was considered "probably more consistent with rotator cuff tendinitis rather than tear" with an additional baseline of osteoarthritis. (*Id*. at 25.) Ms. Forrest was referred to physical therapy. (*Id*.) However, there is no evidence to suggest she acted on that referral.

On January 21, 2014, Ms. Forrest was hospitalized after a car accident. (Ex. 3, pp. 1, 66.) She suffered a fractured rib, a left scapula fracture, facial lacerations, and a pulmonary contusion. (*Id*.) There is no indication that the accident affected her right shoulder.

On November 4, 2014, Ms. Forrest returned to her primary care physician with a chief complaint of a rash on her face. (Ex. 4, p. 40.) Her history of osteoarthritis affecting her hands, knees, and shoulder was referenced; however, she was managing her pain with home exercises and herbal remedies. (*Id*.) Examination of Ms. Forrest's extremities provided only a cursory notation that she had no peripheral edema. (*Id*. at 41.) It was recommended that petitioner continue her home exercises, but no other treatment was indicated for her osteoarthritis. (*Id*.)

ii. Vaccination and subsequent treatment

Ms. Forrest received the flu vaccination at issue in this case in her right deltoid on December 16, 2014. (Ex. 16, p. 3; Ex. 1.) About a month later, on January 19, 2015, she sought treatment from her primary care provider "to evaluate right shoulder pain after receiving her flu shot." (Ex. 4, p. 46.) The following history was provided:

> She presents with right upper extremity pain that began after receiving her flu shot at Walgreens on 12/16/2014. She reports severe pain and difficulty

[9] The empty can test (Jobe's test) and full can tests are used to diagnose shoulder injuries. "Specifically, these physical examination maneuvers examine the integrity of the supraspinatus muscle and tendon." *Empty can/ Full can tests,* WIKIPEDIA, https://en.wikipedia.org/wiki/Empty_can/Full_can_tests (last accessed Feb. 13, 2023). In the empty can test, "the arm is rotated to full internal rotation (thumb down) and in the full can test, the arm is rotated to 45° external rotation, thumb up." *Id.* The test is considered positive "if weakness, pain or both are present during resistance. A positive test result suggests a tear to the supraspinatus tendon or muscle, or neuropathy of the suprascapular nerve." *Id.*

> lifting her right should[er] during the 2 days following her flu shot . . . The pain has caused multiple sleepless nights . . . Pain duration lasts from minutes to hours in some instances . . . She denies any recent trauma, but does report numbness, tingling, and weakness in the right arm.

(*Id*.) Ms. Forrest's prior rotator cuff tear was noted, but "she has not had many problems with the shoulder until after receiving the flu shot." (*Id.*) Physical exam showed impingement, with Neers and Hawkins tests producing pain. (*Id.* at 47.) Empty can test showed weakness and she had significant weakness with a push off test. Range of motion was full except for limited and "visibly painful" abduction. (*Id*.) The assessment was that this "may represent progression of the tear that was exacerbated by the inflammatory process [elicited] by the flu shot. Other thoughts include a bursitis directly from the shot itself vs. a nerve injury from the injection." (Ex. 4, p. 47.) Ms. Forrest was referred to her orthopedist for further evaluation. (*Id.*)

On May 15, 2015, Ms. Forrest returned to her primary care provider and reported that her shoulder pain "has slowly been improving." (Ex. 4, p. 50.) She was having difficulty securing an appointment with an orthopedist but reported that "the pain has almost resolved." (*Id*.) There is no indication of any relevant physical examination findings at this encounter. (*Id*. at 50-51.)

On July 6, 2015, Ms. Forrest saw an orthopedic surgeon (Dr. Widmer). (Ex. 2, p. 31.) Her "long history" of right shoulder dysfunction was noted, but Ms. Forrest reported that it "was not bothering her much but she had a flu shot in the fall and had pain and dysfunction with increasing stiffness and pain thereafter." (*Id*.) Petitioner reported a "waxing and waning" of her condition but indicated that "she is not remotely back to having as functional a shoulder as she would like." (*Id.*) The pain reportedly extended down to her hand at times. (*Id.*) She reported pain with internal and external rotation, but no issue with forward elevation. (*Id*.) Physical exam confirmed her reduced range of motion and an x-ray showed degenerative changes. She was diagnosed with adhesive capsulitis in addition to her ongoing rotator cuff disease. (*Id*. at 33.) An MRI was recommended. (*Id*.) Dr. Widmer did not specifically address whether Ms. Forrest's reported vaccination had any causal role in her condition.

Ms. Forrest opted not to undergo the MRI imaging recommended by Dr. Widmer. (Ex. 15, p. 17.) However, she agreed to a diagnostic ultrasound. (*Id*. at 18.)

iii. Subsequent treatment and falls

Before Ms. Forrest was able to present for her diagnostic ultrasound, she reported that she had experienced a fall while walking up steps. She "lost balance and grabbed the railing so she wouldn't fall, and she felt a pop in the middle of her forearm, and she is having pain there now." (Ex. 15, p. 20.) Ms. Forrest declined the recommendation to get an x-ray and indicated she would maintain her upcoming appointment for her diagnostic ultrasound. (*Id*.)

On August 7, 2015, Ms. Forrest underwent a right shoulder ultrasound which showed: (1) "right subscapularis partial tearing versus tendinosis. No evidence of a full

thickness tear"; (2) "atrophic appearing long head of the biceps tendon, likely indicating a chronic tear/rupture"; and (3) "right supraspinatus full thickness tendon tear with probable retraction of the anteromedial fibers. No evidence of an acute tear." (Ex. 2, p. 42.)

On August 20, 2015, Ms. Forrest saw a different orthopedic surgeon (Dr. Gardiner). (Ex. 20, pp. 17-19.) Ms. Forrest reported her history of chronic shoulder pain with additional persistent shoulder pain following her December 2014 flu vaccination. (*Id*. at 17.) Dr. Gardiner reviewed the ultrasound report and recommended a rotator cuff repair surgery given the severity of petitioner's reported symptoms. (*Id.* at 18-19.)

Subsequently, on September 10, 2015, Ms. Forrest returned to her primary care provider reporting that she had experienced another fall on August 31, 2015. She had landed on her chest and had ongoing chest pain. (Ex. 4, p. 63.) On September 29, 2015, Ms. Forrest reported that she had another fall that caused her to hit her head. (*Id*. at 66.) She had no residual symptoms of head trauma, apart from a resolving hematoma, but reported worsened right shoulder pain over time as her "bigger concern." (*Id.*) She reportedly had a shoulder exam "consistent with rotator cuff strain, not consistent with full-thickness tear." (*Id*. at 67.) There was no indication for imaging, but petitioner was referred to physical therapy. (*Id*.) Ms. Forrest presented for a physical therapy evaluation on October 22, 2018. (Ex. 20, p. 9.) She was given instructions for a home exercise program but did not otherwise return for further physical therapy sessions. (*Id*.) However, her primary care provider subsequently noted on November 4, 2015, that her shoulder was improving with physical therapy. (Ex. 4, p. 77.)

iv. Further records

Ms. Forrest did not seek any care for the next four months. Then, on March 9, 2016, she established care with a new primary care provider. (Ex. 7, p. 20.) At that time Ms. Forrest reported a history of her post-vaccination injury that suggested she had nerve damage caused by her vaccination in addition to her previously diagnosed rotator cuff tear. (*Id.*) The Review of Systems recorded right arm neuropathy and shoulder pain, but physical examination was only cursory with no indication of range of motion or any specific testing maneuvers. (*Id.* at 21.) She was referred for both orthopedic and neurologic evaluation. (*Id*. at 23.) Ms. Forrest's neurology follow up was unrevealing. Her neurologist felt it was "[d]ifficult to separate symptoms from rotator cuff problems." (Ex. 9, p. 15.) A subsequent electrodiagnostic study was normal. (*Id.* at 6-12.)

On August 16, 2016, Ms. Forrest saw a new orthopedist. (Ex. 10, p. 9.) The orthopedist felt Ms. Forrest was a "poor historian" and recorded no history of any of the prior inciting events reflected in her prior medical history. (*Id*.) She reported severe pain localized to the lateral aspect of the shoulder, worse with activities. (*Id*.) On physical exam, Ms. Forrest had reduced range of motion and positive Neer, Hawkins, and empty can tests. (*Id*. at 11.) She was diagnosed with mild to moderate glenohumeral osteoarthritis and a suspected rotator cuff tear. She was referred for an MRI study. (*Id*. at 12.) That MRI, conducted October 3, 2016, showed "[m]oderate degenerative changes [at the] humeral head [as well as] [d]egenerative changes in the

acromioclavicular joint with undersurface spurring impress[ing] upon the supraspinatus musculotendinous junction region." (Ex. 10, pp. 6-7.) It also showed "[f]ull thickness tearing of the supraspinatus and infraspinatus tendons with retraction beneath the acromioclavicular joint and abutment of the humeral head and acromion. The supraspinatus and infraspinatus muscles are retracted and appear small/atrophic." (*Id.* at 7.) There was also "[m]oderate joint effusion with suspected debri[s]." (*Id*.) Upon review of the MRI, the orthopedist advised Ms. Forrest she had a chronic irreparable rotator cuff tear and recommended a reverse total shoulder arthroplasty as a last resort. (*Id.* at 5.) Ms. Forrest declined a subacromial steroid injection and the orthopedist referred her to physical therapy. (*Id*.) Ms. Forrest attended physical therapy from February through July of 2017, seeing improvement in her pain but not a resolution of her limited function. (Ex. 5.)

Ms. Forrest subsequently sought a fourth orthopedic opinion on August 2, 2017. (Ex. 8, pp. 1-4.) Ms. Forrest reported history that included her post-vaccination pain as well as a fall in April of 2016 that she felt improved her symptoms. She reported that she had been told by her doctor that the fall broke up some of her scar tissue. She reported numbness and tingling down her arm in addition to her shoulder pain. (*Id*. at 1.) Ms. Forrest was diagnosed with an unspecified rotator cuff tear or other rupture of the right shoulder along with bursitis, impingement, and cervical radiculopathy. (*Id*. at 4.) Ms. Forrest deferred on a recommended cervical MRI study because her symptoms were improving. She was to continue physical therapy and undergo a shoulder MRI to further evaluate her rotator cuff. (*Id*.) The MRI showed complete tears of the supraspinatus and infraspinatus tendons with five centimeters of retraction and moderate to severe muscle atrophy as well as mild subscapular tendinosis, a complete stable tear of the biceps tendon, subluxation of the humeral head, mild to moderate glenohumeral and acromioclavicular osteoarthritis, and a small glenohumeral joint effusion. (*Id.* at 9.) A capsular reconstruction was recommended. (*Id.*) Initially, Ms. Forrest deferred because she felt she had "functional range of motion," but she returned about a month later and indicated she would proceed with surgery. (*Id*. at 9, 15.)

Ms. Forrest never pursued the recommended surgery. She passed away on November 8, 2019.

**b. As reflected in Ms. Forrest's affidavits**

Ms. Forrest filed two affidavits in this case. (ECF Nos. 1. 15.) I have reviewed these affidavits and they are consistent with the history reflected in the above-discussed medical records. The affidavits do not contain any additional details that would affect the resolution of entitlement in this case.

## IV. Summary of Expert Opinions

### a. Initial Report by Petitioner's Expert, Marco Bodor, M.D.[10]

Dr. Bodor opines that Ms. Forrest sustained a significant aggravation of preexisting shoulder dysfunction caused by her December 16, 2014 influenza vaccination. (Ex. 24, p. 3.) He explains that "[p]rior to this vaccination, she had intermittent pain but little disability, whereas afterwards she had considerable disability. This is a key distinction." (*Id*. at 3-4.)

Dr. Bodor explains that the likely mechanism of injury is injection of the vaccine into the subacromial bursa and adjacent rotator cuff. (Ex. 24, p. 4 (citing Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction,* 25 VACCINE 585 (2007) (Ex. 26); Brian P. McColgan & Frank A. Borschke, *Pseudoseptic arthritis after accidental intra-articular deposition of the pneumococcal polyvalent vaccine: a case report,* 25(7) AM. J. EMERG. MED. 1 (2007) (Ex. 27); S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049 (2010) (Ex. 28) (as filed as Ex. A, Tab 3)).) Further to this, he cites a case report to demonstrate that a preexisting full thickness rotator cuff tear may make it more likely that the substance of the vaccine would pass through the tear into the joint. (*Id*. (citing Andrew Neviaser & Jo A. Hannafin, *Adhesive Capsulitis: A review of current treatment,* 38(11) Am. J. Spots Med. 2346 (2010) (Ex. 29)).) Dr. Bodor opines that vaccine deposition into the infraspinatus and teres minor insertions is common in cases of SIRVA and that this would be consistent with Dr. Widner's finding of painful external rotation in Ms. Forrest's case. (*Id*.) He also opines that petitioner's subsequent development of adhesive capsulitis as diagnosed by Dr. Widner is also consistent with SIRVA. He explains that adhesive capsulitis is a "true inflammatory disorder" and that SIRVA patients are at increased risk of adhesive capsulitis compared to the general population. (*Id*.) Dr. Bodor acknowledges that Ms. Forrest also reported some symptoms consistent with nerve involvement but noted that after she was referred to a neurologist her EMG and neurologic exam were normal. (*Id*.)

[10] Dr. Bodor received his medical degree from the University of Cincinnati in 1987 and completed a surgery internship at the University of California, San Diego, in 1988. (Ex. 25, p. 1.) He completed his physical medicine and rehabilitation residency at the University of Michigan in 1993. (*Id.*) Along with three fellows, he sees approximately 28 patients per day, where he performs diagnostic and therapeutic procedures. (*Id.* at 2.) Dr. Bodor is affiliated with the UCSF Department of Neurological Surgery and the UC Davis Department of Physical Medicine and Rehabilitation, collaborating in the care of patients and teaching visiting faculty, fellows, residents, medical and pre-medical students. (*Id.*) He also serves as the medical director of the Napa Medical Research Foundation, spending approximately 10-20 hours per week supervising research assistants and PhD students. (*Id.*) Dr. Bodor was the first person to describe vaccination-related shoulder dysfunction in the journal Vaccine in 2007, which was subsequently renamed SIRVA by Atanasoff et al. in 2010. (Ex. 24, p. 1.) He has treated 15 patients with SIRVA in his practice since 2007 and has reviewed over 35 SIRVA petitions for the VICP. (*Id.*)

### b. Initial Report by Respondent's Expert, Julie Y Bishop, M.D.[11]

Although Dr. Bishop disagrees with Dr. Bodor's assessment of Ms. Forrest's own clinical history, she does not offer any specific challenge to his explanation of how a vaccine could, in general, significantly aggravate a preexisting shoulder condition. Dr. Bishop opines that Ms. Forrest's course both before and after the vaccination at issue is consistent with a "waxing and waning" course of mild osteoarthritis and rotator cuff tear. (Ex. A, p. 7.) She disagrees with Dr. Bodor's assessment that her condition was substantially worse post-vaccination and instead indicates that it was not until the summer of 2015, when Ms. Forrest began experiencing falls and noted feeling a popping in her arm, that the tempo of her care increased. (*Id*.) Dr. Bishop charges that Dr. Bodor does not account for the "known and expected course of someone with Ms. Forrest's pre-vaccine shoulder condition." (*Id*.)

Dr. Bishop agrees that Ms. Forrest may have experienced two days of mild post-vaccination irritation of her shoulder as she reported, but also notes that this was noted to have improved and that Ms. Forrest's pain was otherwise documented as intermittent, which is more consistent with osteoarthritis and rotator cuff disease. (Ex. A, p. 8.) Dr. Bishop also acknowledges there was progression of Ms. Forrest's condition but opines that this progression cannot be explained by her vaccination. (*Id*.) Dr. Bishop contends that Ms. Forrest's objective imaging over time confirms the progression of her preexisting shoulder dysfunction as the explanation of her clinical course. (*Id*.) In particular, she stresses that the imaging shows the worsening of petitioner's rotator cuff tears over time. (*Id*.)

Further to this, Dr. Bishop explains that glenohumeral osteoarthritis is itself a progressive condition with no treatment that can reverse or slow its natural progression. Decreased function generally occurs over months to years. (Ex. A, p. 8.) Over time, osteoarthritis results in pain and stiffness resulting in functional imitations, especially with overhead activities and external rotation. (*Id*.) "The loss of motion is due to capsular thickening and contraction and is a hallmark of the disease." (*Id*.) Dr. Bishop opines that Ms. Forrest's condition, as documented by Dr. Widner, "clearly matches" the course of osteoarthritis. (*Id*. at 9.) Dr. Bishop agrees with Dr. Widner's diagnosis of adhesive capsulitis but disagrees with Dr. Bodor's attribution of that adhesive capsulitis

[11] Dr. Bishop serves as a professor in the department of Orthopaedic Surgery at the Ohio State University, Wexner Medical Center, as well as Chief of the Division of Shoulder surgery, and Vice Chair of Finance for the Orthopaedic Department. (Ex. A, p. 1.) As a shoulder specialist, all of Dr. Bishop's research interests, publications, book chapters, and presentations have been on the treatment of shoulder pathology. (*Id.*; Ex. B pp. 9-41.) Dr. Bishop has treated multiple patients with SIRVA in her practice over the years and has published in this area as well. (*Id.*) Dr. Bishop received her medical degree from Cornell University Medical College in 1997. (Ex. B, p. 1.) She completed fellow training in 2003 specifically in shoulder surgery (fellowship at Mount Sinai Hospital in New York City) and Orthopaedic sports medicine (visiting fellowship at the University of Pittsburg Medical Center). (Ex. A, p. 1.) She is board certified in orthopedic surgery. (Ex. B, p. 2.) Dr. Bishop is also a fellow of the American Academy of Orthopaedic Surgeons, an active member of the American Shoulder and Elbow Surgeons, a member of the American Orthopaedic Society for Sports Medicine as well as an elected member of the American Orthopaedic Association. (Ex. A, p. 1.)

to vaccination. (*Id*.) Whereas Dr. Bishop agrees that primary idiopathic adhesive capsulitis may be associated with SIRVA, she asserts that Ms. Forrest had secondary adhesive capsulitis related to her underlying osteoarthritis. (*Id*.)

According to Dr. Bishop, "[a]nother hallmark finding of [glenohumeral osteoarthritis] is that the pain is often intermittent and can be aggravated by various activities, thus there are times when it flares up and times when it calms down." (Ex. A, p. 9.) This, she concludes, "is in step with [Ms. Forrest's] statements that her symptoms were intermittent and when aggravated, the pain was present for a short period of time." (*Id*.) Dr. Bishop further indicates that Ms. Forrest's documented falls may also have contributed to the progression of her rotator cuff tear and also aggravated her underlying osteoarthritis. (*Id*. at 10.)

With regard to neurologic symptoms, Dr. Bishop disagrees that these symptoms could be referred from the shoulder. (Ex. A, p. 10.) Rather, Dr. Bishop stresses that Ms. Forrest had documented degenerative disc disease that likely explains her neurologic symptoms. (*Id*.) Nonetheless, Dr. Bishop characterizes the neurologic symptoms as "nonspecific" and explains that while the neurologic condition may explain Ms. Forrest's difficulty with fine skills, her pain and reduced range of motion in her shoulder are related to her rotator cuff and arthritic changes. (*Id*.)

#### c. Subsequent Reports by the Parties' Experts

After providing their initial opinions, both parties' experts filed multiple supplemental reports. (Exs. 31, 35, 41, C-F.) I have carefully reviewed all of these reports; however, it is not necessary to summarize each report. A substantial portion of the analysis contained in these reports relates to the question of whether neurologic symptoms of numbness and tingling can be seen among patients experiencing shoulder conditions. However, as explained above, even though the experts differ on their interpretation of the neurologic symptoms at issue in this case, they both nonetheless also opine that Ms. Forrest's clinical history is largely explained by her shoulder pathology. Whether Ms. Forrest's numbness and tingling into her hand is consistent with the shoulder pathology itself or separately explained by an additional condition is immaterial to resolving whether that agreed upon shoulder pathology was aggravated by her vaccination.

## V. Party Contentions

### a. Petitioner's Motion

In her motion for a ruling on the record, petitioner focuses exclusively on the significant aggravation claim included in her amended petition. (ECF No. 85.) Petitioner argues that while Ms. Forrest had a history of osteoarthritis and a rotator cuff tear, "[t]he difference in symptomology in the right shoulder from before to after the vaccine administration was dramatic" and constitutes a significant aggravation of Ms. Forrest's condition inclusive of adhesive capsulitis, severe pain, and loss of range of motion. (*Id*. at 1.)

Petitioner stresses that under a *Loving* analysis for significant aggravation, respondent is incorrect to suggest (through his expert) that Ms. Forrest's preexisting condition should be evaluated by looking to the expected course of the underlying conditions. (ECF No. 85, p. 15.) Rather, petitioner indicates that under the legal standard at issue only petitioner's pre- and post-vaccination conditions may be compared and petitioner is not obligated to prove that her post-vaccination condition is worse than her expected outcome. (*Id.* at 15-16) (quoting *Sharpe v. Sec'y of Health & Human Servs*., 964 F.3d 1072, 1082 (Fed. Cir. 2020).)

Petitioner argues that through Dr. Bodor she has set forth a mechanism of significant aggravation that is "essentially the same as any SIRVA injury." (ECF No. 85, p. 16.) That is, petitioner argues that the significant aggravation in this case was caused by injection of a vaccine into the subacromial bursa and adjacent rotator cuff. (*Id*.) She further argues that this is consistent both with Ms. Forrest's treating physician's assessment and the medical literature filed in this case. (*Id*. at 16-18.) Further to this, petitioner argues that the medical records are clear in attributing Ms. Forrest's worsened condition to her vaccination, both in terms of the history she provided and the treating physician's assessment, and that the timing is medically appropriate for vaccine-causation. (*Id.* at 18-20.) Thus, petitioner argues that she has proven *Loving* prongs four through six. (*Id*.)

**b. Respondent's Response**

Respondent agrees that a *Loving* analysis is the relevant legal framework. (ECF No. 87, p. 10.) However, respondent counters that nothing in the *Sharpe* decision cited by petitioner "prohibits respondent from introducing, or the special master from considering, evidence that petitioner's post-vaccination clinical course is consistent with the expected clinical course of the condition, and that the vaccine was therefore not a 'substantial factor' in aggravating that condition." (*Id*. at 11.) Respondent contends that petitioner has failed to demonstrate by preponderant evidence that Ms. Forrest's vaccination was a substantial factor in causing a significant aggravation of her preexisting condition as opposed to her condition having evolved "in a manner wholly consistent with the natural progression of her diagnoses, perhaps with accelerations caused by falls and other incidents." (*Id*. at 12.)

Regarding petitioner's theory of causation, respondent contends that Dr. Bodor's theory is not supported by any medical literature and further that petitioner is engaged in conflation when she equates a primary de novo shoulder injury and the worsening of a pre-existing shoulder injury. (ECF No. 87, p. 13.) Respondent stresses that none of the cited literature supports vaccines as the cause of a progression of a rotator cuff tear and asserts that the literature is inapposite. (*Id*.) In contrast to the evidence petitioner has cited regarding Ms. Forrest's own history, respondent stresses the evidence Dr. Bishop has brought forward regarding the fact that glenohumeral arthritis and rotator cuff tears naturally progress over time, arguing that Ms. Forrest's history is consistent with this type of progression. (*Id*. at 13-19.) Further to this, respondent disputes that Ms. Forrest had primary adhesive capsulitis caused by her vaccination. (*Id*. at 19-20.) Finally, because respondent distinguishes the two days of post-vaccination petitioner experienced as temporary irritation separate from her broader condition, respondent

contends that petitioner has not demonstrated a medically acceptable temporal relationship between Ms. Forrest's vaccination and her worsened condition. (*Id*. at 21-22.)

### c. Petitioner's Reply

In her reply, petitioner contends that respondent is seeking to "complicate" this case. Petitioner stresses several aspects of the medical records to illustrate why she believes the significant aggravation in this case is clear cut. She contends that "[t]here is significant, credible evidence that the flu vaccination Ms. Forrest received on December 16, 2014, either directly caused, or significantly aggravated, Ms. Forrest's increased shoulder symptomology." (ECF No. 88, p. 3.) Petitioner further stresses that because she has presented a prima facie case of vaccine-caused significant aggravation, she is not required to eliminate alternative causes of her injury. She contends that respondent has not, in turn, presented preponderant evidence that Ms. Forrest's injury was due to a factor unrelated to vaccination (namely the natural progression of her pre-existing shoulder conditions). (*Id.*) That is, respondent has not presented preponderant evidence satisfying his own burden of proof that eliminates Ms. Forrest's vaccination as a substantial factor in her subsequent symptomology. (*Id*. at 4.) In that regard, petitioner stresses that respondent has conceded that Ms. Forrest suffered a post-vaccination inflammatory response and that his expert has failed to address the fact that Ms. Forrest's own treating physician concluded that this inflammatory reaction caused a significant aggravation of her shoulder prior shoulder condition. (*Id.* at 3.)

## VI. Analysis

### a. Petitioner's Table Injury claim

Although the parties focus on significant aggravation in their briefing, I first note in the interest of completion that petitioner has not demonstrated a Table Injury of SIRVA as pleaded in the original petition. The first SIRVA QAI prong requires "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." 42 CFR §100.3(c)(10). The Table SIRVA criteria does not necessarily require a spotless prior health history of the affected shoulder. *Compare, O'Leary, M.D. v. Sec'y of Health & Human Servs.*, 18-584V, 2021 WL 3046617, at *8 (Fed. Cl. Spec. Mstr. June 24, 2021) (finding petitioner suffered a Table SIRVA despite an "old history of trauma to his shoulder" that had previously resolved); *and, Clark v. Sec'y of Health & Human Servs.,* 18-813V, 2022 WL 16635681 (Fed. Cl. Spec. Mstr. Feb. 7, 2022) (finding that "[a]lthough 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."). However, as discussed further below, I find that this case represents a significant aggravation of Ms. Forrest's preexisting shoulder condition. In short, Ms. Forrest's medical records confirmed she had preexisting shoulder dysfunction confirmed by objective imaging and medical records created shortly before vaccination indicated

her shoulder complaints were still symptomatic. Further, when she presented for care post-vaccination, her treating physicians understood her symptoms as an exacerbation of her preexisting shoulder dysfunction. And, indeed, this is also how petitioner's expert approaches his causal opinion. Therefore, petitioner cannot demonstrate that Ms. Forrest's history is compatible with the first SIRVA criterion. *Accord Kelly v. Sec'y of Health & Human Servs.,* No. 17-1918V, 2022 WL 1144997 (Fed. Cl. Spec. Mstr. Mar. 24, 2022).

**b. Petitioner's Significant Aggravation Claim**

i. Petitioner's condition prior to administration of the vaccine (*Loving* prong one)

In light of all of the above, and upon consideration of the record as a whole, I find that the following is supported by preponderant evidence: Prior to the vaccination at issue Ms. Forrest had right shoulder rotator cuff disease and glenohumeral joint osteoarthritis. (*See, e.g*. Ex. A, p. 7; Ex. 31, p. 1.) Ms. Forrest had a confirmed rotator cuff tear with only "minimal"/"no significant" tendon retraction. (Ex. 2, p. 5.) Prior to vaccination, symptoms associated with these conditions were occasionally exacerbated by isolated events (Ex. 4, pp. 20, 24); however, Ms. Forrest was not experiencing continuous disability. She had a baseline of ongoing pain and reduced range of motion that was "not overly concerning." (*E.g*. Ex. 4, p. 20.) The medical records confirm that shortly before the vaccination at issue, on November 4, 2014, Ms. Forrest was experiencing only mild pain that she was satisfied managing with home exercise and herbal remedies. (Ex. 4, pp. 20, 40.)

ii. Petitioner's current condition/condition after administration of the vaccine (*Loving* prong two)

In light of all of the above, and upon consideration of the record as a whole, I find that the following is supported by preponderant evidence: After vaccination, Ms. Forrest suffered an "exacerbation" of her prior shoulder pain along with reduced range of motion that both she and her primary care provider attributed to her vaccination. (Ex. 4, p. 47; Ex. 2, p. 31.) Her primary care physician initially focused on her reported severe pain for the two days following her vaccination followed by continued, but intermittent, pain, the pattern of which was generally consistent with symptoms of her prior shoulder dysfunction, but the severity of which was worse than she had been experiencing prior to vaccination. (*Id.* at 46; Ex. A, p. 8.) Eventually, her treating orthopedist diagnosed adhesive capsulitis in addition to her prior rotator cuff tear as explanation for her stiffness and reduced range of motion. (Ex. 2, pp. 31, 33.) By the time of her orthopedic presentation in early July of 2015, Ms. Forrest's post-vaccination pain and reduced range of motion had improved but not completely resolved. (Ex. 2, p. 31.) Subsequently, Ms. Forrest had imaging performed on multiple occasions that confirmed progression of her rotator cuff tear, though her osteoarthritis was still only mild to moderate (Ex. 2, p. 42; Ex. 10, pp. 6-7; Ex. 8, p. 9.); however, this imaging was captured after Ms. Forrest experienced a separate exacerbation of her condition in that she reported falls to which she had attributed a "pop" in her shoulder and increased

pain. (Ex. 15, p. 20; *see also* Ex. 4, pp. 63, 66.) Thus, Ms. Forrest's subsequent history after late July of 2015 is less informative of her condition during the months following her vaccination.

iii. Whether the post-vaccination condition is a "significant aggravation" of the prior condition (*Loving* prong three)

The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). Here, consistent with the statutory definition, a comparison of the findings of fact under *Loving* prongs one and two shows that Ms. Forrest's post-vaccination condition reflects a change for the worse in her pre-vaccination condition inclusive of pain and disability as well as a physical deterioration in health during the months following her vaccination. Indeed, respondent agrees that Ms. Forrest's condition deteriorated in the three years following her vaccination. (ECF No. 87, p. 12.) What respondent disputes is that this deterioration was vaccine-caused. (*Id*.) This is addressed relative to *Loving* prongs four through six below.

iv. Medical theory of causation (*Loving* prong four/*Althen* prong one)

Petitioner is required to present a persuasive medical theory of causation demonstrating that the influenza vaccine could have significantly aggravated Ms. Forrest's preexisting shoulder condition. *Althen,* 418 F.3d at 1278. It is well-established in the Vaccine Program that compensation may be awarded for shoulder injuries on a cause-in-fact basis. *See, e.g.*, *A.P. v. Sec'y of Health & Human Servs.,* No. 17-784V, 2022 WL 275785 (Fed. Cl. Spec. Mstr. Jan. 31, 2022); *L.J. v. Sec'y of Health & Human Servs.,* No. 17-0059V, 2021 WL 6845593 (Fed. Cl. Spec. Mstr. Dec. 2, 2021); *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *rev. den.*, 142 Fed. Cl. 329 (2019). However, petitioner's medical theory must be supported by "reputable" scientific evidence and must "pertain[] specifically to the petitioner's case." *Moberly,* 592 F.3d at 1322.

Petitioner may not merely rely on the fact that SIRVA was added to the Vaccine Injury Table to establish a medical theory for a cause-in-fact claim. *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[12] The government's

[12] In *Grant*, the Federal Circuit explained the distinction between Table and non-Table claims and quoted the legislative history of the Vaccine Act as follows:

> If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both these cases, however, the *petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine.* Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. (Such a finding of causation is

recognition of "SIRVA" as a vaccine-caused injury was limited by the accompanying QAI criteria. In this case, I have already concluded for the reasons discussed above that petitioner has not met those criteria. Thus, if petitioner's medical theory under *Althen* prong one/*Loving* prong four was limited to taking judicial notice of the government's recognition of SIRVAs as occurring in some contexts, petitioner's case would necessarily have to fail under *Althen* prong two/*Loving* prong five, because the facts of petitioner's case do not fall within the confines of that recognition. *Accord L.J.,* 2021 WL 6845593 (taking judicial notice of the Table Injury of SIRVA under *Althen* prong one and applying the Table SIRVA QAI as the basis for assessing *Althen* prong two); *Tenneson*, 2018 WL 3083140 (same). To hold otherwise would be to expand the causal presumption afforded by the Vaccine Injury Table.

Here, Dr. Bodor's theory is not explained in depth, but exists in the form of two assertions. First, he opines that "[t]he mechanism of injury most likely involved injection of vaccine into the subacromial bursa and adjacent rotator cuff." (Ex. 24, p. 4.) Among the accompanying citations, Dr. Bodor includes a publication of two case reports of which he is coauthor. In that report, he explains that "[w]e hypothesize that in both of our cases vaccine was injected into the subdeltoid bursa, causing a robust local immune and inflammatory response" ultimately leading to inflammation of the shoulder capsule due to the subdeltoid bursa being contiguous to the subacromial bursa. (Bodor & Montalvo, *supra,* at Ex. 26, p. 2.) Second, he opines that "the misplaced injection likely led to adhesive capsulitis." (Ex. 24, p. 4.) This was the ultimate resulting condition in one of Dr. Bodor's own two case reports. (Bodor & Montalvo, *supra,* at Ex. 26, pp. 2-3.) Further to this, Dr. Bodor cites the Atanasoff article, which is well known in SIRVA litigation. In pertinent part, the Atanasoff authors hypothesized that:

> In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions including impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis. In many cases these conditions may cause no symptoms until provoked by trauma or other events. Reilly et al. reviewed a series of shoulder ultrasound and MRI studies obtained in asymptomatic persons past middle age and found partial or complete rotator cuff tears in 39% of those individuals. Therefore, some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.

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deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table.)

*Grant,* 956 F.2d at 1147-48 (quoting H.R.Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986), reprinted in 1988 U.S.C.C.A.N. 6344, 6356) (emphasis in *Grant*); *see also Schick-Cowell v. Sec'y of Health & Human Servs.,* 18-656V, 2022 WL 619839 (Fed. Cl. Spec. Mstr. Feb. 8, 2022); *A.P.*, 2022 WL 275785; *but see L.J.,* 2021 WL 6845593 (taking judicial notice of the Table Injury of SIRVA under *Althen* prong one for case filed prior to inclusion of SIRVA on the Vaccine Injury Table, but decided after); *Tenneson*, 2018 WL 3083140 (same).

(Atanasoff et al., *supra* at Ex. 28, p. 3.)

For respondent, Dr. Bishop offers no critique that would challenge Dr. Bodor's first assertion. In fact, she agrees that "[a] vaccine could cause some irritation of the shoulder joint . . . ." (Ex. A, p. 8.) Instead, Dr. Bishop contends with regard to Dr. Bodor's second assertion that his theory conflates primary adhesive capsulitis and secondary adhesive capsulitis. (Ex. A, p. 9.) However, the distinction Dr. Bishop raises constitutes a *Loving* prong five rather than *Loving* prong four question. Dr. Bishop states in relevant part that "[p]rimary adhesive capsulitis, what Dr. Bodor is referring to in his report, is a condition that affects 3-5% of the population between ages of 30 and 60, and only this type of adhesive capsulitis has been associated with SIRVA cases."[13] (*Id*. (citing Atanasoff et al., *supra,* at Ex. A, Tab 3; Beth Hibbs et al., *Reports of atypical shoulder pain an dysfunction following inactivated influenza vaccines, Vaccine Adverse Event Reporting System (VAERS), 2010-2017,* 38 Vaccine 1137 (2020) (Ex. A, Tab 4)).) By Dr. Bishop's description, primary adhesive capsulitis is idiopathic and "associated with capsular inflammation in the absence of a known lesion." (Ex. A, p. 9.) In contrast, secondary adhesive capsulitis is a term used to describe "a constellation of conditions that result in stiff shoulder" secondary to "an underlying condition/pathology." (*Id*.) Thus, Dr. Bishop is not actually challenging whether an inflammatory vaccine response *can cause* adhesive capsulitis. She acknowledges that this association has been observed. Rather, she is observing that some cases of what appears to be adhesive capsulitis are otherwise explained by known shoulder dysfunction.[14]

In his motion response, respondent stresses Dr. Bishop's statement that "[t]here is no literature at all to support that an influenza vaccine can cause progression of a rotator cuff tear or influence the progress course of pre-existing arthritis." (ECF No. 87, pp. 12-13 (quoting Ex. A, p. 9.) Further to this, respondent argues in reference to both Dr. Bodor's above-discussed case report and the Atanasoff article that "[a]lthough the Atanasoff article theorizes that vaccination could cause symptoms to manifest in patients with pre-existing, asymptomatic RTC tears, neither of these articles mention the possibility that a vaccination could actually cause *progression* of a pre-existing RTC tear or pre-existing shoulder OA." (*Id*. at 13 (emphasis original).) Importantly, however, these assertions reflect respondent's interpretation of Ms. Forrest's clinical history rather than petitioner's. They do not directly refute the causal theory petitioner actually presented, which is based on a vaccine-caused inflammatory irritation of the joint capsule and ultimately adhesive capsulitis rather than progression of the underlying conditions themselves.[15]

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[13] In his response, Dr. Bodor took this statement as agreement that primary adhesive capsulitis is, in fact, associated with SIRVA without addressing the further contention that this would not extend to secondary adhesive capsulitis. (Ex. 31, p. 1.) Dr. Bishop noted this in her responding report. (Ex. C, p. 2.) This specific point was not addressed any further in any of the subsequent expert reports.

[14] In fact, as discussed further with respect to *Loving* prong five, below, Dr. Bishop cites to literature that actually contends that the term "secondary adhesive capsulitis" is effectively a misnomer when applied in the manner Dr. Bishop invokes.

[15] In *Kelly v. Secretary of Health & Human Services*, I explained that a limitation of the Atanasoff article in the context of significant aggravation is that it constitutes a descriptive analysis without comparison to

v. Logical sequence of cause and effect connecting the vaccination and significant aggravation (*Loving* prong five/*Althen* prong two)

The second *Althen* prong/fifth *Loving* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu ex re. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375–77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant,* 956 F.2d at 1148. However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. §300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

As discussed above, there is preponderant evidence that Ms. Forrest experienced increased pain and reduced range of motion post-vaccination relative to her prior baseline. Her primary care physician considered this an "exacerbation" of her prior shoulder complaints likely caused by her vaccination[16] and her orthopedist subsequently diagnosed a post-vaccination onset of adhesive capsulitis with capsular

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background rates or controls and excludes subjects with preexisting shoulder conditions. 2022 WL 1144997 at *22. The Atanasoff authors further explain that there are no diagnostic tests available to assess whether the shoulder dysfunction they observed was vaccine-caused, leaving only their ability to clinically isolate the onset of symptoms to identify post-vaccination shoulder injuries as a distinct entity. (Atanasoff et al., *supra,* at Ex. 28, p. 4.) Thus, while the Atanasoff hypothesis is not wholly irrelevant to the significant aggravation context, the article itself is not helpful in distinguishing under what circumstances it would be reasonable to conclude that a vaccine can cause a worsening of the clinical presentation of a preexisting condition that is already symptomatic. In *Kelly*, the petitioner overcame this limitation by providing epidemiology that showed a statistically significant risk of post-vaccination bursitis where the *Kelly* petitioner himself had evidence of bursitis. *Kelly,* 2022 WL 1144997 at *22-23. Here, the specific expert presentations regarding adhesive capsulitis as discussed relative to both *Loving* prongs four and five, and the diagnosis of adhesive capsulitis arising post-vaccination, play a similar role. Had the contours of the expert opinions in this case been different, and had Dr. Bishop more directly challenged Dr. Bodor's theory as a matter of general rather than specific causation, it is not clear that the literature Dr. Bodor relied upon would be persuasive without more.

[16] To be clear, in identifying an "exacerbation" of Ms. Forrest's condition, Dr. Allred does include a reference to a possible "progression" of Ms. Forrest's rotator cuff tear (Ex. 4, p. 47), which I explained relative to *Loving* prong four is not petitioner's medical theory of the case. However, considering his impression as a whole, it is clear that this is not the sum total of Dr. Allred's opinion. He also cites a post-vaccination inflammatory process, bursitis, and nerve injury as possible mechanisms. On the whole it is clear that his impression balances his knowledge of Ms. Forrest's chronic conditions against her more acute presentation to opine that the chronic conditions alone do not explain her presentation. Although this ruling repeatedly references his use of the term "exacerbation" as a shorthand, the medical record as a whole reflects a medical opinion consistent with significant aggravation regardless of the specific use of that term.

irritability as an additional overlay to her preexisting rotator cuff disease. (Ex. 4, p .47; Ex. 2, pp. 32-33.) Based on his analysis of Ms. Forrest's complete medical history and his theory of causation, petitioner's expert opines that this constitutes a significant aggravation of her condition in the form of worsened symptoms and a vaccine-caused adhesive capsulitis. (Ex. 31.) Respondent's contrary view raises two overarching questions: (1) whether Ms. Forrest's adhesive capsulitis diagnosed post-vaccination must be understood as secondary to her preexisting shoulder dysfunction; and (2) whether Ms. Forrest's post-vaccination presentation is explained by the natural progression of her preexisting condition. Respondent asserts the answer to both questions is yes, thereby defeating petitioner's claim that Ms. Forrest's vaccine did substantially contribute to a worsening of her condition. However, this is not persuasive.

There are significant limitations regarding Dr. Bishop's opinion that Ms. Forrest's adhesive capsulitis must necessarily be understood as secondary to her preexisting condition(s) to the exclusion of a vaccine-caused inflammatory process. First, the literature Dr. Bishop cites explains that the question is one of clinical judgment. While underlying shoulder pathology can be a cause of the symptoms of adhesive capsulitis, these materials do not support any contention that preexisting shoulder pathology *per se* explains adhesive capsulitis. Neviaser and Hannafin explain that "[d]iagnosis can be challenging as factors both intrinsic and extrinsic to the shoulder can cause stiffness and pain." (Neviaser & Hannafin, *supra,* at Ex. 29, p. 1 (also filed as Ex. A, Tab 2).) "Distinguishing between primary or idiopathic disease and pain due to other causes can be difficult and there is frequent overlap." (*Id*. at 2.) "Subtle clues in the history and physical examination allow discrimination of primary adhesive capsulitis from these other conditions." (*Id*.)

Here, although the medical records are not robust, the expressed views of the treating physicians are closer to petitioner's view than respondent's. Given his ongoing treatment relationship with Ms. Forrest spanning both her pre- and post- vaccination history, Dr. Allred was well positioned to exercise clinical judgment in determining whether Ms. Forrest's own preexisting shoulder pain was exacerbated by extrinsic factors.[17] The Federal Circuit has recognized that "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano,* 440 F.3d at 1326 (quoting *Althen,* 418 F.3d at 1280); *Nuttall v. Sec'y of Health & Human Servs.,* 122 Fed. Cl. 821, 832 (2015) (noting the importance of the prior treatment relationship in giving special weight to treating physician opinions), *aff'd*, 640 F. App'x 996 (Fed. Cir. 2016).

Second, the literature Dr. Bishop cites further explains that the term "secondary adhesive capsulitis" is used in two distinct contexts. In some cases, it is used to refer to

[17] Ms. Forrest's primary care records show that a number of different physicians were involved in her care in the years prior to her vaccination. (Ex. 4, *passim*.) However, Dr. Allred was the physician that saw Ms. Forrest during her last encounter prior to vaccination. (*Id*. at 40-43.) He was also involved in her care in an attending capacity during prior encounters where she had reported prior inciting events that had aggravated her shoulder pain. (*Id*. at 20-27.) Thus, he was familiar with both her overall history and her baseline just prior to vaccination.

"extra-articular cause(s) of shoulder stiffness without involvement of the joint capsule." (Neviaser & Hannafin, *supra,* at Ex. 29, p. 2 (Ex. A, Tab 2).) This is the context in which secondary adhesive capsulitis may be explained by conditions such as glenohumeral arthritis and rotator cuff injury. (*Id*.) However, that use is effectively a misnomer. In contrast, "secondary adhesive capsulitis" may also be used to refer to isolated areas of capsular contracture that occur concurrently with other known injuries or diseases. (*Id*.) In that context, secondary adhesive capsulitis may be "indistinguishable from idiopathic adhesive capsulitis." (*Id*.) "The differentiation between the stiff and painful shoulder without any joint capsule involvement and with capsule involvement (true adhesive capsulitis) must be established before a rational treatment can be prescribed." (RJ Neviaser & TJ Neviaser, *The frozen shoulder: diagnosis and management,* 2223 CLIN. ORTHOP. RELAT. RES. 59 (1987) (Ex. A, Tab 5).)[18] "Although frozen shoulder and adhesive capsulitis are frequently used interchangeably, recognition that many conditions can cause a stiff and painful shoulder while adhesive capsulitis is a distinct pathological entity is essential for evaluating both patients and the literature." (Neviaser & Hannafin, *supra,* at Ex. A, Tab 2, p. 1.) The cause of true adhesive capsulitis is not known, but it has been linked to many preceding factors, including trauma and autoimmune disease. (*Id*.) And importantly, as Dr. Bishop recognizes, it has also been linked to vaccination. (Ex. A, p. 9.)

In this case, Dr. Widner's treating orthopedic assessment does not use the specific terminology of "primary" or "secondary" to describe Ms. Forrest's adhesive capsulitis; however, on physical examination he recorded "capsular irritability," which strongly suggests his opinion was that Ms. Forrest had capsule involvement, *i.e*. true adhesive capsulitis. (Ex. 2, pp. 32-33.) Thus, Dr. Bishop is not persuasive with respect to her suggestion that Ms. Forrest's own adhesive capsulitis is readily distinguishable from the type of primary or idiopathic adhesive capsulitis that is associated with vaccination. Dr. Bishop's opinion on this point is also less persuasive because she acknowledges that Ms. Forrest did experience at least temporary irritation of the shoulder joint caused by her vaccination and therefore relies on the notion that Ms. Forrest's subsequently diagnosed adhesive capsulitis is merely coincidental to this irritation despite the fact that her other shoulder dysfunction had existed for years prior and despite seeming to accept that vaccinations can lead to adhesive capsulitis. (Ex. A, p. 8.)

With regard to the second question raised by respondent's defense, while it is undoubtedly true that rotator cuff tears and osteoarthritis can both progress over time generally, both Dr. Bishop and respondent acknowledge that this is not Ms. Forrest's own history. Dr. Bishop stated that "[i]n addition to just the element of time, Ms. Forrest had many documented falls over the years and [it] is certainly possible that any of her falls, especially the ones that precipitated a call to see her doctor, could have led to progression of her rotator cuff tear and would have certainly aggravated her significant

[18] Respondent's Exhibit A, Tab 5, appears to be only the abstract of the article by Neviaser & Neviaser. This quote from the abstract simply underscores the differentiation of adhesive capsulitis with capsular involvement specifically as "true" adhesive capsulitis, which is also consistent with the substance of the Neviaser & Hannafin article. (*See* Neviaser & Hannafin, *supra,* at Ex. 29 (also filed as Ex. A, Tab 2).)

underlying osteoarthritis. (Ex. A, p. 10.) Thus, even by respondent's own characterization it is not the case that the progression of Ms. Forrest's condition is explained merely by the passage of time or the general nature of her degenerative conditions as progressive. Indeed, while Dr. Bishop explains that it is a "hallmark" of osteoarthritis that "there are times when it flares up and times when it clams down," she specifically couches these flares as constituting "aggravat[ions]" of the osteoarthritis. (Ex. A, p. 9.) In that context, respondent offers little reason for his disbelief that Ms. Forrest's vaccination would constitute a further aggravating event occurring in the course of a condition he acknowledges to have otherwise been aggravated multiple times. As noted above, this is especially difficult to accept given that Dr. Bishop agrees that Ms. Forrest likely did suffer at least a limited inflammatory reaction within her shoulder joint. (Ex. A, p. 8.)

To the extent Dr. Bishop relies on Ms. Forrest's objective imaging to confirm the progression of Ms. Forrest's preexisting conditions, the later imagining available for comparison post-dates the falls that Dr. Bishop agrees were likely to have been contributory. (Ex. A, p. 9 (citing Ex. 2, p. 42; Ex. 7, p. 36).) Thus, the imaging is not evidence of a "natural" progression of the underlying conditions and is not suggestive of the condition of Ms. Forrest's shoulder between the time of her vaccination and the subsequent falls. Further to this, it was the opinion of Ms. Forrest's primary care physician, who followed her shoulder condition both before and after the vaccination, that the post-vaccination presentation constituted an "exacerbation" of her condition rather than being explained as part of a waxing and waning course of the condition. In any event, petitioner is not obligated to prove that Ms. Forrest's ultimate outcome was worse than the expected course of her condition. *Sharpe*, 964 F.3d at 1082. Rather, petitioner is obligated to demonstrate that Ms. Forrest's vaccination was a substantial factor that *affected* her condition. *Id*. (citing *Locane v. Sec'y of Health & Human Servs*., 685 F.3d 1375 (Fed. Cir. 2012). Thus, even if Ms. Forrest's later falls obscured whether her post-vaccination adhesive capsulitis meaningfully contributed to her later history, this would not defeat a claim based on the arc of symptoms she experienced in the months following her vaccination.

vi. Proximate temporal relationship between vaccination and significant aggravation (*Loving* prong six/*Althen* prong three)

The third *Althen* prong/sixth *Loving* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Here, petitioner argues that the medical records reflect an onset of Ms. Forrest's post-vaccination symptoms that was "almost immediate," stressing Ms. Forrest's initial report to her primary care provider that she had severe pain during the two days following her vaccination. (ECF No. 85, p. 19.) Petitioner argues this is appropriate

timing when compared against the 48-hour onset reflected on the Vaccine Injury Table for SIRVA. (*Id*.) Although this is not a Table SIRVA claim, petitioner argues that she has set forth a mechanism of significant aggravation that is "essentially the same as any SIRVA injury." (*Id*. at 16.) Thus, for example, the above-discussed Atanasoff article likewise indicates that a clear majority of subjects experienced onset of shoulder pain within 24 hours of vaccination. (Atanasoff et al., *supra,* at Ex. 28, p. 2 (Table 1).) Respondent does not dispute any of these points but contends that the two days of post-vaccination pain that Ms. Forrest reported are separate from her ongoing symptoms that are better attributed to her osteoarthritis and her rotator cuff tear. (ECF No. 87, p. 12.) In particular, respondent argues that "petitioner improperly conflates the brief period of pain decedent reported in the days immediately following vaccination with the ongoing progression of her RTC tear and OA" and further that "considering the record as a whole, Dr. Bishop opines that any symptoms after May 15, 2015, were unrelated and instead represented the natural course of her pre-existing shoulder pathology." (*Id*. at 21.) There are two issues with this line of reasoning.

First, to the extent respondent appears to contend Ms. Forrest suffered only a couple days of distinct pain, this misinterprets Ms. Forrest's initial encounter with her primary care physician on January 19, 2015. (Ex. 4, p. 46.) Respondent is correct that the history of present illness specifically reports that petitioner had "severe pain and difficulty lifting her right should[er] during the 2 days following her flu shot." (*Id*.) However, it also states that "[t]he pain has caused multiple sleepless nights since that time and persists until today." (*Id*.) Thus, the medical records do not support any contention that the reference to two days of severe post-vaccination pain represented an isolated and unrelated phenomenon. Even accounting for Dr. Bishop's opinion that the intermittency of symptoms reported as part of this history is consistent with how osteoarthritis and rotator cuff tears present, this has far less significance in the context of significant aggravation. Dr. Allred, who had previously treated Ms. Forrest, was aware of Ms. Forrest's preexisting shoulder dysfunction and concluded that the history she reported was consistent with an exacerbation of the symptoms of her own condition. (Ex. 4, pp. 20, 24, 40, 47.) Inherent to that opinion would be an understanding that the complained of symptoms are consistent with known symptomology of the preceding condition only worse than they had been before.

Second, respondent's reliance on the May 15, 2015, follow up encounter is also misplaced. Respondent contends that the fact that Ms. Forrest's condition was "almost resolved" is evidence that it was more likely "associated with a mild irritation caused by her vaccination." (ECF No. 87, p. 21 (quoting Ex. A, p. 8).) While respondent is correct that this record provides a history that Ms. Forrest's pain "has slowly been improving" and, in fact, reportedly was "almost resolved," her medical records do not reflect this as the termination of either the course of her condition or her relevant treatment of that condition. (Ex. 4, p. 50.) Specifically, although Dr. Allred recorded "interval improvement" in Ms. Forrest's shoulder pain, he referred her to physical therapy at that time. (*Id*. at 51.) Moreover, Ms. Forrest subsequently sought further follow up treatment from an orthopedist where in July of 2015 she received her adhesive

capsulitis diagnosis based in part on a history of more severe symptoms over the prior six months. (Ex. 2, p. 33.)

### c. Factor Unrelated

Once petitioner has satisfied her own burden pursuant to the *Loving* test, the burden shifts to respondent to demonstrate that the injury was caused by factors unrelated to vaccination. § 300aa-13(a)(1)(B); *Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). In order to meet his burden, respondent must demonstrate by preponderant evidence "that a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor)." *de Bazan*, 539 F.3d at 1354. In this case, respondent has argued that Ms. Forrest's vaccination was *not* a substantial factor in bringing about her alleged injury. Respondent's arguments have been considered in the context of the above *Loving* analysis. Because his arguments were unpersuasive in that context, they likewise fail to suggest he has met his own burden of proof.

## VII. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this Program, I find by preponderant evidence that petitioner has demonstrated that Ms. Forrest suffered a significant aggravation of her pre-existing shoulder injury caused-in-fact by her December 16, 2014, flu vaccination. A separate damages order will be issued.

**IT IS SO ORDERED.**

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