

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**

Reissued for Public Availability Date: October 16, 2025

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RICHARD DEAN HAUGAN,

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No. 21-2095V

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Petitioner,

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Special Master Christian J. Moran

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v.

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Filed: September 18, 2025

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SECRETARY OF HEALTH  
AND HUMAN SERVICES,

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Respondent.

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Richard Dean Haugan, *pro se*, Bainbridge Island, WA, for petitioner;  
Katherine Carr Esposito, United States Dep't of Justice, Washington, DC, for  
respondent.

**RULING FINDING ENTITLEMENT TO COMPENSATION, IN PART,**  
**AND DECISION DENYING ENTITLEMENT, IN PART**<sup>12</sup>

<sup>1</sup> Because this Ruling/Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling/Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

<sup>2</sup> Pursuant to Vaccine Rule 18(b), this Ruling/Decision was initially filed on September 18, 2025, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this Ruling/Decision is reissued in its original form for posting on the Court's website.

Richard Haugan alleges an influenza vaccine harmed him. The basic chronology is that Mr. Haugan was vaccinated and shortly thereafter experienced a rash and itching on his chest that persisted several days then slowly got better. Mr. Haugan also experienced right shoulder pain and weakness, trouble sleeping, sore joints, and unusual and significant pain.

While he was being treated, the doctors did not reach a consensus about the condition afflicting Mr. Haugan. Mr. Haugan's doctors, including his experts, concluded that he suffered from shoulder injury related to vaccine administration ("SIRVA") and serum sickness.

In this litigation, Mr. Haugan has retained three experts to support his claim. They are David Robinson, a board-certified allergist; David Belfie, a board-certified orthopedic surgeon with a specialty in sports medicine and shoulder and knee surgery; and Perry Mostov, his primary care physician. Together, they opined that Mr. Haugan suffered from SIRVA and serum sickness and that the influenza vaccination caused his conditions.

The Secretary opposes an award of compensation. He has retained two experts, Andrew MacGinnitie (board-certified in allergy/immunology and pediatrics) and Brian Feeley (board-certified in orthopedic surgery). Dr. MacGinnitie opined that the timeframes for Mr. Haugan's symptoms are not consistent with serum sickness, and Dr. Feeley opined that Mr. Haugan's right shoulder pain is more likely due to his partial rotator cuff tear or arthritis and unlikely that Mr. Haugan's left shoulder flu vaccination resulted in his right shoulder pain. After the experts disclosed their opinions, the parties advocated through briefs.

A review of this material leads to the conclusion that Mr. Haugan is entitled to compensation, in part. Mr. Haugan has met his burden of establishing that the influenza vaccine caused his shoulder injury; however, he has not met his burden of establishing that the influenza vaccine caused his serum sickness.

## **I. Facts**

### **A. Before Vaccination**

Mr. Haugan was born in October 1944. Exhibit 8 at 8. Before Mr. Haugan was vaccinated on October 31, 2018, he experienced several prior health conditions, including adhesive capsulitis of shoulder (onset in 2006); disorders of

bursae and tendons in shoulder region, unspecified (onset in 2006); and gout (noted in 2015). Exhibit 8 at 11-12. Although Mr. Haugan had other prior health problems, respondent has not suggested that any of them contribute to the question as to whether a vaccine harmed him.

In April 2006, Mr. Haugan was seen by Dr. Sundance Rogers following a motor vehicle accident when a

bus went through a stop sign and T boned him. Restrained driver, airbag went off. Noticing some headaches, ringing in both ears, very intense. Hasn't improved at all, worse on left and hit on that side with airbag. Dull headache in the back of his head, some in the face and temples. Focus is different. Thought processes are different, loses train of thought in the middle of a conversation. Speech and talking are more difficult. [ ]Left knee very sore, can walk on it but is tender. Lots of bruising on lower [abdomen]. Chest on left side hurts, likely from the seatbelt. Back is very tender and sore down low. Slightly more on the right than left. Right wrist more sore than left, starting to bruise. Stiff/sore neck.

Exhibit 13. Mr. Haugan's examination noted "bruising on ulnar aspect of both hands, left upper chest with modest hematoma, left knee and lower [abdomen] on the left" and he was assessed with "multiple contusions, some slowing of mentation but nothing alarming, severe tinnitus." Id.

Mr. Haugan previously worked as a marketer, a private airplane pilot, and a barge captain. Exhibit 8 at 36, 155, 358, 421, 495.

Additionally, Mr. Haugan had a series of medical appointments that occurred before his vaccination from July 2016 to October 2018.

#### 1. 2016 Medical Appointments

In July 2016, Mr. Haugan saw Dr. Mark Reeves, a podiatrist, for stiff and hurt feet. Exhibit 8 at 253, 256. Dr. Reeves assessed Mr. Haugan as having "[p]robable midfoot arthritis with possible ankle arthritis versus capsulitis versus [osteochondritis dissecans] lesion." Exhibit 8 at 241. Mr. Haugan messaged his primary care physician, Dr. Kim Leatham, regarding his arthritis and joint pains. Mr. Haugan explained that he also had "some other joints which are touchy – perhaps left over from a [motor vehicle accident] years ago." Exhibit 8 at 251.

On August 22, 2016, Mr. Haugan saw another podiatrist, Dr. Eric Heit, for right foot and left ankle pain. Dr. Heit noted that

[Mr. Haugan] has this odd history of some migratory joint pain affecting his right shoulder, left hip, right knee, right foot and left ankle and these have been off and on. He did have a cortisone shot, . . . in his right shoulder at some point and some deep tissue massage for the hip and that seems to have resolved and this has all been going on the last 5-6 years or so. No history of trauma. The knee bothered him about a year ago and this most recent onset of right foot and left ankle pain, happened after doing yoga a few days before. He went to Europe with his wife and it was stiff and sore through his trip to Europe.

Exhibit 8 at 512. Dr. Heit noted that Mr. Haugan had a history of gout. Exhibit 8 at 512. At this visit, Dr. Heit administered a cortisone shot to Mr. Haugan's left ankle. Exhibit 8 at 513.

On September 29, 2016, Dr. Heit administered another cortisone injection to Mr. Haugan's left ankle. Exhibit 8 at 485.

On November 3, 2016, Mr. Haugan presented to Dr. Heit for a follow-up appointment regarding his feet and ankle problems. Exhibit 8 at 483. Mr. Haugan reported that he had "new onset midfoot pain bilaterally which seemed to come out of nowhere, but also seems to be resolving as quickly as it came on." Exhibit 8 at 483. Dr. Heit also noted that Mr. Haugan seemed to be getting some "nerve symptoms into his toes." *Id.* Dr. Heit noted that Mr. Haugan "probably has an inflamed nerve in his foot and probably nothing to do about that acutely, but if his symptoms do become persistent and consistent, I think that would be something that we would treat and the treatment for that would be injection therapy just like we are doing for his ankle." Exhibit 8 at 484.

On December 15, 2016, Mr. Haugan saw Dr. Heit again for a follow-up appointment for his "[c]ontinued left ankle pain secondary to arthritis" and received another cortisone injection into his left ankle joint. Exhibit 8 at 482.

## 2. 2017 Medical Appointments

On January 31, 2017, Mr. Haugan saw Dr. Christopher Fellows, a cardiac electrophysiologist. Exhibit 8 at 510-11. Dr. Fellows saw Mr. Haugan to provide a second opinion, at the request of Dr. Kim Leatham, to evaluate the management of Mr. Haugan's coronary artery disease. Exhibit 8 at 510. Dr. Fellows noted that

Mr. Haugan had “some atypical jaw pain 2 years ago and had an evaluation by Dr. Wayne Hwang including a stress echo that was mildly abnormal and a coronary CT angiogram that showed moderate coronary artery disease but nothing critical.” Id. Dr. Fellows assessed Mr. Haugan as a

very anxious 72-year-old with coronary artery disease on the basis of a mildly abnormal stress echo and a coronary CT angiogram . . . . He definitely has coronary atherosclerosis that should be treated . . . . At this point, he is unwilling to take any medications, so we will just leave it at that, but again I strongly advised him to get this thing treated.

Exhibit 8 at 511.

On February 10, 2017, Mr. Haugan saw Dr. Leatham for an annual well visit, and Dr. Leatham memorialized her assessment that Mr. Haugan has a personal history of renal cell carcinoma, Schatzki’s ring, hyperlipidemia, gout, benign neoplasm of colon, and acute rhinitis. Exhibit 8 at 442. Dr. Leatham noted that Mr. Haugan is “reluctant to take meds” for his gout and that she “strongly encourage[d] a statin for primary prevention.” Id.

On April 10, 2017, Mr. Haugan saw Dr. Kevin Connor, a naturopathic doctor, for adjunctive support for hyperlipidemia, atherosclerosis and one episode of atypical chest pain. Exhibit 8 at 480. Dr. Connor noted that Mr. Haugan has been recommended to start statin therapy by at least two providers and that Mr. Haugan was reluctant to start a statin therapy for fear of side effects, noting some adverse reactions to medications in the past. Exhibit 8 at 480. Dr. Connor also memorialized that Mr. Haugan had “recently started on some Chinese herbal medicine for ‘heart blockage.’” Exhibit 8 at 480. Dr. Connor also discussed statin therapy with Mr. Haugan and noted that Mr. Haugan was “adamant that he is not interested in taking a statin at the current time.” Exhibit 8 at 481. Mr. Haugan was advised to start a three-month trial of red yeast rice extract and if there were not any significant results in his cholesterol profile, that he should “strongly consider taking a statin.” Exhibit 8 at 481.

On June 6, 2017, Mr. Haugan saw Dr. Charles Helming, at the request of Dr. Heit, for “consideration of steroid injections in his knees.” Exhibit 8 at 508. Dr. Helming memorialized Mr. Haugan’s past surgical history. “Noteworthy for right rotator cuff repair, right nephrectomy for kidney cancer and lumbar laminectomy for disk disease.” Exhibit 8 at 508. Mr. Haugan was assessed as having mild to moderate arthritis in both knees, and Dr. Helming “suggested holding off on

injections.” Exhibit 8 at 509. Dr. Helming told Mr. Haugan that “the arthritis is going to be an ongoing issue to some extent.” Exhibit 8 at 509.

On July 5, 2017, Mr. Haugan requested a blood panel and stated that he has “been experimenting with ‘natural’ cholesterol supplements prescribed by Dr. Connor instead of statins.” Exhibit 8 at 144. Mr. Haugan reported he had a reaction to most of them. Exhibit 8 at 144. The test results showed that Mr. Haugan’s “cholesterol [was] elevated.” Exhibit 8 at 133.

On July 13, 2017, Mr. Haugan messaged Dr. Leatham regarding any recommendations for a sleeping pill for a plane trip. Exhibit 8 at 137. Later that day, Andrew Lingbloom, a physician assistant, responded and recommended melatonin, chamomile tea, and valerian root tea. Exhibit 8 at 136. Mr. Haugan responded, “I seem to be [allergic] to almost everything.” Exhibit 8 at 135.

On December 21, 2017, less than a year before vaccination, Mr. Haugan saw Dr. Perry Mostov to establish care. Exhibit 8 at 476. Dr. Mostov noted that Mr. Haugan had a history of hyperlipidemia and gout; neither of which were being treated medically. Exhibit 8 at 477. Mr. Haugan reported that melatonin was effective for his insomnia. Id.

### 3. 2018 Medical Appointments

On March 13, 2018, Dr. Heit administered another cortisone injection to Mr. Haugan’s left ankle. Exhibit 8 at 475. Three days later, Mr. Haugan messaged Dr. Heit and reported that the cortisone shot really helped and there was a noticeable difference the next day. Exhibit 8 at 123. Mr. Haugan also inquired how often can he receive cortisone injections. Dr. Heit responded that it is “generally accepted that 3-4 injections per year is safe but there really is no definitive number.” Exhibit 8 at 123.

On June 27, 2018, Mr. Haugan started physical therapy at Kitsap Physical Therapy (“KPT”) for “left [sacroiliac joint] and buttock pain, and . . . left [sacroiliac joint] rotation and piriformis pain.” Exhibit 2 at 38-39. Mr. Haugan continued with physical therapy at KPT four more times in July 2018. Exhibit 2 at 39-40. On July 5, 2018, Linne Stringer, a physical therapist, noted that Mr. Haugan’s left sacroiliac joint “was doing better,” but “made surgery site in back sore with his trying a yoga stretch over a block.” Exhibit 2 at 39. On July 23, 2018, Mr. Haugan’s symptoms were easing, but Mr. Haugan “had a trip and fall outside . . . which jarred the back.” Exhibit 2 at 40.

On October 29, 2018, two days before Mr. Haugan's vaccination, he contacted Dr. Mostov regarding administrative records and requests, including "for some PT." Exhibit 8 at 112. Dr. Mostov's staff responded to Mr. Haugan and clarified that she saw

a couple of physical therapy referral requests earlier this year, one for your shoulder and one for your back . . . . The shoulder therapy referral was addressed to Dr. Mostov, who asked his medical assistant to contact you and advise that an appointment would be needed. It looks like you did speak with one of our staff and declined an appointment.

Exhibit 8 at 111.

On October 31, 2018, Mr. Haugan received a Fluzone high-dose flu vaccination at Walgreens on Bainbridge Island in Washington. Exhibit 1 at 2; Exhibit 9 at 2. See Halverson v. Sec'y of Health & Hum. Servs., No. 15-227V, 2020 WL 992588, at \*1 (Fed. Cl. Spec. Mstr. Feb. 4, 2020) (describing Fluzone as a high-dose seasonal influenza vaccine). The quality of the vaccination record makes it difficult to read, but the box reading "Complete AFTER Vaccine Administration" appears to indicate that the site of vaccine administration was the left arm. Exhibit 9 at 2. However, Mr. Haugan disputes which arm the vaccine was administered. Pet'r's Br. at 2.

## **B. After Vaccination**

Mr. Haugan did not immediately see a medical provider regarding his shoulder pain until January 2019. However, although not documented in a medical record created shortly after the vaccination, other evidence attempts to fill in a gap. According to the pro se petition, on October 31, 2018, a few hours after receiving the allegedly causal vaccination, Mr. Haugan "experienced and documented a persistent rash and itching on [] his chest that persisted several days and then slowly got better." Pet., filed Oct. 28, 2021, at 1. Mr. Haugan's wife, Susan Haugan, averred that on the "evening of October 31, 2018 when preparing for bed Dick said 'check this out.' His chest was splotchy and red. It was very noticeable. He complained it was itchy. It slowly abated over a few days as I recall." Exhibit 10 (filed Jan. 5, 2020).

Mr. Haugan traveled to the Big Island in Hawaii from December 1, 2018 to December 9, 2018. Exhibit 15 at 3. According to Ms. Haugan, Mr. Haugan "complained about his right shoulder and could not lift a suitcase in the luggage

bin of an airplane as he usually could.” Exhibit 10. Although this problem with lifting luggage is not memorialized in a medical record created in December 2018, other records corroborate the account. See Exhibit 2 at 34 (Mar. 20, 2019); Exhibit 8 at 88-89 (Feb. 20, 2019), 552 (Mar. 20, 2019).

1. December 2018 – January 2019: Little Finger

On December 16, 2018, Mr. Haugan messaged Dr. Mostov. Exhibit 8 at 106-107. Mr. Haugan stated that

About four days ago my left little finger swelled up suddenly. Swollen to the point I could not bend it. Painful if I brushed against it. Took anti inflammatory Aleve. And indomethacin. Swelling went down a bit but is not going away. Can’t use that finger. Still very sensitive.

I whacked that knuckle a few years ago and it never been the same since. [Virginia Mason] looked at it once and then dismissed it. But the symptoms have never been this acute.

Reaction [p]ossibly related to a bug bite right on top of the knuckle in question a few week[s] ago.

Exhibit 8 at 106-107. Dr. Mostov responded that “Sounds like may be gout episode, but best to have a look at the finger. Can you come to the office in the next few days?” Exhibit 8 at 106.

Two months after his vaccination, Mr. Haugan saw Dr. Mostov for his left finger pain on January 3, 2019. Exhibit 8 at 472. Dr. Mostov memorialized that Mr. Haugan’s left pinky was injured four years ago in a boating accident and is incompletely resolved. Exhibit 8 at 472. Dr. Mostov also recorded that three weeks ago, in Hawaii, Mr. Haugan experienced sudden swelling and that he may have had a bug bite just before onset. Id. Mr. Haugan also had recurrent, left ankle swelling and hyperuricemia. Exhibit 8 at 472. Hyperuricemia is the “excess of uric acid or urates in the blood; it is the prerequisite for the development of gout and may lead to renal disease.” Dorland’s Illus. Med. Dict. 887 (33rd ed.). Mr. Haugan reported that his finger was hard to bend, and it was difficult for him to play his guitar. Exhibit 8 at 473. Mr. Haugan reported sometimes feeling a cranking/popping sensation in his finger. Id. Dr. Mostov noted that Mr. Haugan had a gout episode a few years ago and is still with “stiffness, clicking with movement, and tender.” Exhibit 8 at 472. An x-ray of Mr. Haugan’s hand showed “severe degenerative change of the PIP [proximal interphalangeal] joint with

severe joint space narrowing and osteophyte formation. There is soft tissue swelling about the PIP joint. No juxta-articular erosions or soft tissue tophi typical of gout noted.” Exhibit 8 at 876.

On January 10, 2019, Mr. Haugan messaged Dr. Mostov regarding his x-ray results from January 4, 2019, and asked if the flu shot could have caused inflammation or caused his flare-up. Exhibit 8 at 102-03. On January 11, 2019, Dr. Mostov responded to Mr. Haugan and stated that he did “not have a good explanation for his flare-up arthritis, but very unlikely that it was due to influenza vaccine.” Exhibit 8 at 102.

On January 13, 2019, Mr. Haugan messaged Dr. John D. Osland, an orthopedic surgeon. Exhibit 8 at 99. Mr. Haugan explained that he had “pretty much lost functionality in my left finger. Can’t play piano or guitar any more. Or lift. And it hurts. Never a problem like this before.” *Id.* On January 15, 2019, Mr. Haugan had an appointment with Dr. Osland. Exhibit 8 at 469. Dr. Osland recorded Dr. Haugan’s history of present illness as

74-year-old male who states that he had an injury to the left little finger for 5 years ago but did fine until November of this year. He had a flu shot in October. He noticed he had some twitching in the little finger in the beginning of [ ] November. Then by the end of November the finger swelled up and ever since then it has been stiff and sore [and] painful. The swelling [has] gone down some but when he tries to move it[, it] is very stiff and he is not able to bend at the PIP joint. He has seen Dr. [Mostov] and did have x-rays recently that showed severe osteoarthritis at the PIP joint of the left little finger . . . he is here today wondering if it is related to the flu shot or why it came on so suddenly. He is right-hand dominant. . . . He denies numbness or tingling.

Exhibit 8 at 469. Dr. Osland recommended that if Mr. Haugan is interested in pursuing anything more that he should see a hand surgeon. Exhibit 8 at 471. Dr. Osland discussed the possibilities of living with the pain, a fusion, and a joint replacement, but Dr. Osland did not see any easy cures for Dr. Haugan at this point. Exhibit 8 at 471.

## 2. January 2019: Shoulder Problems and Other Complaints

On the same day, Mr. Haugan messaged Dr. Mostov that he had been using the topical anti-inflammatory for almost a week and had “[n]o perceptible

improvement.” Exhibit 8 at 94-95 (Jan. 13, 2019). Mr. Haugan also noted that his shoulders were getting more painful and that the pain below his right shoulder was worse than his left. Mr. Haugan described these symptoms as “all new.” Exhibit 8 at 95. Mr. Haugan also described that he “[n]ow [has] an issue with the outside of my left ankle. Different than the swelling I had before.” Id.

On January 16, 2019, Dr. Mostov responded to Mr. Haugan that

Difficult to say what is causing the shoulder pain, but your ankle pain may be due to gout. Uric acid level is elevated, and higher than previous. This elevation increases your risk for recurrent gout episodes. May be worthwhile adding medication to lower the uric acid level in order to prevent gout attacks. . . . We’ll need to see you to evaluate the new shoulder pain.

Exhibit 8 at 94. Mr. Haugan’s lab results showed his uric acid level at 9.0 mg/dL (reference range 3.5 – 8.0). Exhibit 8 at 93.

On February 20, 2019, Mr. Haugan messaged Dr. Mostov and stated that he wanted to wait several weeks to see if there was improvement in his condition. Exhibit 8 at 88. Mr. Haugan stated

LEFT FINGER. I met with Dr[.] Osland and he said it was severe arthritis. End of discussion. I explained that it was caused by an injury five years ago and it became severely inflamed right after the flu shot which I had not had for some time. The swelling has gone down quite a bit but is significantly more sensitive and significantly less able to bend than before the flu shot. The gel anti-inflammatory you prescribed did not help.

SHOULDERS – mostly right. Continues to be irritated[.] Difficult, for example, to lift a suitcase into an overhead bin on an airplane. That too started after my flu shot 10/31/2018. It seems [to] be getting worse – especially if I do certain yoga exercises I have been doing for years. I did have a MVA 5-6 years ago and tore my right rotator cuff. It was painful but went away.

LEFT ANKLE. May be unrelated but Dr. Heit has given me a Cortisone shot in my left ankle from time to time. It helps. Another old injury from a broken leg as a teenager I think.[.] But, again, right after the flu shot, [t]he ankle flared up again. Typically it takes a couple of years before I get a shot.

You may recall that I also got a rash on my chest after the flu shot so something in me does not like whatever it does.

So... my question is[,] is it possible, probably not common but possible that the flu shot could cause inflammation or other reaction in prior injuries? Seems like too much of a coincidence to me. And... how long will there be any side effects of any nature from a flu shot?

Exhibit 8 at 88-89 (ellipses in original).

On March 8, 2019, Dr. Mostov responded to Mr. Haugan and stated that

Although reactions like yours to the influenza vaccine are not common, it certainly seems that was the case. Joint pain is not listed out as a separate reaction, but muscle pain is reported in up to 34% (!), and rash even more frequently, but usually at the injection site. I would have expected the reaction to have resolved by now, some 5 months later.

Exhibit 8 at 89; Exhibit 5 at 1.

On March 14, 2019, Mr. Haugan saw Melissa Rejon, a medical assistant, as a proxy for Dr. Mostov for his left finger and right shoulder pain. Exhibit 8 at 465. Mr. Haugan stated he had right shoulder pain since the influenza vaccine in October 2018. Mr. Haugan stated that he had been doing upside down yoga that aggravated his pain in his shoulder and fingers. Exhibit 8 at 465. An x-ray was performed on Mr. Haugan's right shoulder that showed "some mild arthritis changes, as expected, and signs of tendon inflammation." Exhibit 8 at 79.

One day later, Dr. Mostov messaged Mr. Haugan and stated that his theory "that your joint/muscle reaction may be related to the flu vaccine are based on my knowledge of and experience with human biology, not based on any cutting edge research. Sorry I do not have any specific references for you." Exhibit 8 at 69; Exhibit 4 at 1.

On March 18, 2019, Mr. Haugan saw Dr. Jeff Pentek, a podiatrist, for evaluation of his left ankle. Exhibit 8 at 506. Dr. Pentek memorialized that Mr. Haugan had longstanding osteoarthritis to his left ankle. *Id.* Mr. Haugan told Dr. Pentek that he "believe[d] that the arthritis stem[med] back to an old injury when he was a teenager, broke his fibula and the bone was not set correctly, causing it to heal in unaltered position." *Id.* Mr. Haugan reported that within the last three-to-four days, another flare-up developed, making his ankle stiff and painful around

the joint. Id. Mr. Haugan also informed Dr. Pentek that his “joint ha[d] been acting up a little more recently as well as several other joints throughout his body where old injuries had taken place, ever since a flu shot near the end of last October.” Id. Mr. Haugan received another cortisone shot in his left ankle. Exhibit 8 at 506-07.

### 3. March 2019 – April 2019 Physical Therapy Appointments for Shoulder and Ankles

Two days later, Mr. Haugan saw physical therapist, Linne Stringer, at KPT for evaluation of his shoulder pain and weakness. Exhibit 2 at 34. Mr. Haugan reported that symptoms began on October 31, 2018 and the “mechanism of injury was flu shot and lifting a suitcase plus a MVA history with partial tear about 5 years ago.” Id. Mr. Haugan described his symptoms as “intermittent, dull aching, throbbing, intermittently more intense/sharp, sharp/stabbing, and tingling [and] numbness and rated the pain as 5 on a scale of 0-10.” Id. Mr. Haugan stated that the pain wakes him at night and is aggravated by lying down, sleeping, reaching, repetitive activities and motions, recreation, sports, and household activities. Id. Ms. Stringer’s diagnosis was shoulder impingement syndrome. Id. Ms. Stringer assessed Mr. Haugan as having “a 5 month history of shoulder pain after a flu shot, he had multiple joints irritation from the injection and a steroid into his ankle, shoulder irritation of a prior [rotator cuff] partial tear and flared [symptoms] in his little finger at the site of an old crush injury and will see a hand specialist.” Exhibit 2 at 34-35. Mr. Haugan continued with PT at KPT on April 17, 2019; April 22, 2019; April 25, 2019; and April 29, 2019. Exhibit 2 at 32, 35, 36.

On April 22, 2019, Mr. Haugan requested a PT referral for his ankles from Dr. Mostov. Exhibit 8 at 67. On April 25, 2019, Mr. Haugan saw Ms. Stringer for his ankle pain and stiffness. Exhibit 2 at 32. Mr. Haugan described the cause of his ankle pain and stiffness as “flu shot [and] old ski injury.” Exhibit 2 at 17. Ms. Stringer memorialized that Mr. Haugan has a “history of an arthritic flare in bilateral ankles which occurred a week after a flu shot, he has some history of left ankle pathology and [degenerative joint disease].” Id. at 33. On April 29, 2019, Mr. Haugan described that his ankles “felt really good” and his shoulder felt more sore from sanding on his hands and knees for hours over the weekend. Id. at 36.

### 4. Remaining Medical Records from 2019

On May 3, 2019, Mr. Haugan had an appointment with Dr. David Belfie, an orthopedic surgeon, for his right shoulder pain. Exhibit 8 at 463. Dr. Belfie noted that Mr. Haugan’s “right shoulder pain [] began sometime around a flu shot

injection. Since that time, he has had left shoulder pain and a previous diagnosis of prior right shoulder rotator cuff tear sometime in the past.” Id. Dr. Belfie’s overall impression was the Mr. Haugan was most likely having pain at that time “secondary to his rotator cuff.” Id. Dr. Belfie ordered an MRI.

Four days later, Mr. Haugan returned to see Dr. Belfie to review his MRI results. Exhibit 8 at 462. The MRI showed “a very small partial-thickness rotator cuff tendon tear.” Id. Dr. Belfie noted that Mr. Haugan’s shoulder was asymptomatic prior to his flu shot injection and recommended a progressive resisted exercise program. Id. The MRI impression noted

1. Rotator cuff tendinosis with low to intermediate grade bursal surface tearing. No definite high-grade tear. Suspected calcification present along the distal infraspinatus tendon, suggestive of calcific tendinitis.
2. Moderate acromioclavicular degeneration.
3. Mild glenohumeral degeneration with degenerative labral tearing.

Exhibit 8 at 880.

On the same day, petitioner also saw Dr. James Schlenker, a plastic surgeon specializing in the hand, for left small finger pain and swelling. Exhibit 8 at 503-05, 523-24. Dr. Schlenker recorded Mr. Haugan’s history, noting that Mr. Haugan’s “pain began in 11/2018 when he was on a plane on the way to Hawaii and noted increased pain to the left finger.” Exhibit 8 at 503. Mr. Haugan also noted “new-onset pain of his right shoulder, [one] of his ankles, as well as his left finger, and thought that they may all be related to the flu shot.” Id. Mr. Haugan denied “any significant pain to the finger prior to the fall of 2018 except for a remote incident of injury about 5-8 years ago, at which time he whacked his hand on a fiberglass boat. He remembers it being painful and it settling down, but does not think that he broke the finger at the time.” Id. Dr. Schlenker noted that Mr. Haugan did not have his finger evaluated nor any x-rays taken. Id. Dr. Schlenker’s assessment was that Mr. Haugan could have been having a gout flare up. Exhibit 8 at 505. Dr. Schlenker noted that he would send Mr. Haugan for “inflammatory testing, including sedimentation rate, CRP, rheumatoid factor, and ANA screening to rule out any rheumatological inflammatory condition given that he does note always having flare-ups after flu shots.” Id. However, no subsequent inflammatory test results were filed.

On May 9, 2019, Mr. Haugan messaged Dr. Mostov that “[Dr.] Belfie could see a connection with the flu shot and the cuff. [Dr.] Schenkler did not have any explanation why the finger went from OK to not OK in the same time frame as the flu shot.” Exhibit 8 at 58. Dr. Mostov responded, “May never know for certain about the vaccine connection.” Id.

On July 5, 2019, Mr. Haugan saw Dr. Mostov for left wrist pain. Exhibit 8 at 459. Mr. Haugan reported that two weeks ago he developed “[f]airly severe” left wrist pain while driving his car, which resolved after one day. Id. Dr. Mostov assessed Mr. Haugan with a “likely mild sprain injury.” Id.

On July 25, 2019, Mr. Haugan messaged Dr. Mostov to report that his left wrist was not improving. Exhibit 8 at 53. Mr. Haugan described the discomfort as significant on some days. Id.

On August 7, 2019, Mr. Haugan saw Dr. Mostov for his left wrist pain. Exhibit 8 at 456. Dr. Mostov assessed that Mr. Haugan’s left wrist pain appeared to be due to osteoarthritis but also noted Mr. Haugan’s history of gout and that the left wrist was now complicated by some tendinitis. Id. The x-ray results findings reported “no fracture.” Exhibit 8 at 874. The x-ray impression of Mr. Haugan’s left wrist was negative. Id. On August 10, 2019, Mr. Haugan messaged Dr. Mostov regarding a recommended consultation with hand orthopedics for further evaluation and discussed possible treatments, including therapy, an MRI, an injection, and surgery after his test results. Id. at 45-46.

On September 4, 2019, Mr. Haugan messaged Dr. Mostov regarding a prescription for sleeping for an upcoming airplane trip. Exhibit 8 at 38. Mr. Haugan reported that “My wrist issue seems to be slowly resolving so am avoiding any other heroics for now. I sleep with the wrist brace and that seems to help.” Id.

In December 2019, Mr. Haugan underwent an endoscopy/colonoscopy. Exhibit 8 at 28, 428, 526-31. Mr. Haugan also was seen in early December 2019 for a cataract check. Id. at 450.

There were no additional medical records filed for the next two years.

## 5. 2022

On January 4, 2022, Mr. Haugan contacted Dr. David Robinson, an allergist-immunologist, via videoconference for an initial evaluation of adverse reaction to an influenza vaccine. Exhibit 14 at 1-2. Dr. Robinson memorialized that Mr. Haugan recalled

within a few hours [after receiving the influenza vaccine] that he developed a rash over the chest. This became a bit more extensive over the trunk. He developed arthritis symptoms at the areas of previous joint injury. No fever that he recalls. He did not seek medical attention for this but symptoms lasted for several days. He reported symptoms at the time. He received high-dose Fluzone according to historical report in our immunization tracker. He had a flu vaccine before [] for a number of years without difficulty. No problems with other vaccines and he is basically up to date. He notes that he had some persisting discomfort at area of previous rotator cuff injury that lasted for a couple of months, but rash and other manifestations all faded.

Id. at 1. Dr. Robinson's impressions and plan indicated that Mr. Haugan's condition

[s]ounds like a likely serum sickness reaction to high-dose flu vaccine reported to be Fluzone in 2018. Unfortunately, there is no easy way to test for this and likelihood of recurrence is fairly high. Mechanism of this is reviewed with him. Might tolerate standard dose flu vaccine, but on the other hand obviously at increased risk for recurrent serum sickness reaction. This may be a risk worth taking, if we are looking at a bad flu season, although it is always difficult to know ahead of time. . . . Probably should avoid flu vaccine in the future unless we are looking at a bad influenza pandemic.

Id. at 2. Serum sickness is a type III hypersensitivity reaction, which is a

Local or general inflammatory response due to formation of circulating antigen-antibody complexes and their deposition in tissues; the complexes activate complement and other inflammatory mediators, initiating processes including increased vascular permeability, stimulation of mast cell degranulation and neutrophil chemotaxis and accumulation, and aggregation of platelets, and resulting in tissue damage. Ensuing diseases, called also immune complex diseases, can be roughly classified as being due to persistent infection, to autoimmunity, or to inhalation of antigenic material; examples include serum sickness, Arthus reaction, subacute bacterial endocarditis, systemic lupus erythematosus, and farmer's lung. Called also immune complex-mediated hypersensitivity reaction.

Dorland's at 1575.

In February 2022, Mr. Haugan and Dr. Robinson exchanged messages, following up on Mr. Haugan's January 4, 2022 appointment. Exhibit 11 at 1-3. Mr. Haugan's message to Dr. Robinson reported that

'Serum sickness' is the term you described that causes a condition such as the reaction I had. My reactions were a pronounced chest rash, feeling abnormal and itching along the joint pain, inflammation and swelling. I have allergic reactions to many things but this time, perhaps accentuated with the adult dose (three times normal) as you noted, the joint pain and swelling flared up quickly migrated to old injury sites. And you said this is plausible and a known albeit uncommon reaction.

Especially painful was my right shoulder where I had a rotator cuff injury from a MVA in 2006. It took in excess of six months this time for the related shoulder pain to abate I think you said that was indeed possible. I think your language was the adverse reaction to serum sickness has a way to 'find' old injuries.

Exhibit 11 at 3. Dr. Robinson responded, "Excellent summary! All points are correct as stated." Id. at 2. Mr. Haugan asked Dr. Robinson if he had any academic proof that serum sickness could be caused by the flu vaccine. Id. Dr. Robinson replied that there were lots of papers but that serum sickness "is a really old immunologic concept and most of the studies are from the 30s-60s." Id. at 1. Dr. Robinson suggested that Mr. Haugan review Wikipedia for a good review of the mechanisms involved. Dr. Robinson also recommended a subscription-based service used by medical professionals, UpToDate. Id. Mr. Haugan then explained that he was "in contact with Health and Human Services" regarding his allegedly causal influenza vaccination and asked, "Would you say based on your professional experience that it is 'more likely than not' tha[t] my reactions (serum sickness) we discussed to the flu shot (triple dose for me) administered to me in October 2018 are an adverse reaction which may include 'finding its way back' to old injuries[?]" To which, Dr. Robinson replied, "Yes, more likely than not." Id.

On May 14, 2024, Dr. Mostov wrote a letter addressing an error in Mr. Haugan's surgical history. Exhibit 36. Dr. Mostov stated that the medical record incorrectly showed a right shoulder surgery in 2012. There were no additional treatment records submitted.

## **II. Procedural History**

### **A. Development before Expert Reports**

Representing himself, Mr. Haugan alleged the influenza vaccine caused him to suffer SIRVA and serum sickness. Pet., filed Oct. 28, 2021. Mr. Haugan supported his claim by filing medical records and affidavits.

The Secretary reviewed this material and recommended against compensation. Am. Resp't's Rep., filed Dec. 16, 2022. The Secretary challenged Mr. Haugan's claim and argued that Mr. Haugan failed to establish a Vaccine Injury Table claim for SIRVA for many reasons, such as a laterality problem in regards to which arm the vaccine was administered; prior history of pain, inflammation, and dysfunction of the shoulder; failing to establish that onset of pain was within 48 hours of intramuscular administration with contemporaneous medical records; additional complaints that were not limited to his shoulders; and the existence of other conditions that could explain Mr. Haugan's alleged SIRVA.

Alternatively, the Secretary argued that Mr. Haugan did not demonstrate that the flu vaccine caused-in-fact his alleged injuries nor that his vaccine significantly aggravated his alleged injuries. *Id.* at 19-25. The Secretary noted that Mr. Haugan did not offer any expert opinions.

### **B. Expert Reports**

Consistent with the scheduling orders, issued April 18, 2023 and June 2, 2023, Mr. Haugan filed his expert reports from Dr. Robinson, a board-certified allergist, on June 15, 2023 and from Dr. Belfie, a board-certified orthopedic surgeon, on July 18, 2023.

The Secretary submitted expert reports from Dr. Andrew MacGinnitie, a board-certified allergist/immunologist, and Dr. Brian Feeley, a board-certified orthopedic surgeon, on November 2, 2023. Exhibits A and C. Both experts also submitted medical literature to support their expert reports. Exhibit A, Tabs 1-6; Exhibit C, Tabs 1-14.

Mr. Haugan submitted supplemental responses from Dr. Robinson and Dr. Mostov on December 22, 2023. Exhibits 28 and 29.

1. Dr. Robinson's First Expert Report

Dr. Robinson is a board-certified practicing allergist at Virginia Mason Medical Center in Seattle for 35 years. Dr. Robinson is the section head and clinical principal investigator for the Allergy Research Program at Benaroya Research Institute. Exhibit 24 at 1. Dr. Robinson has authored or co-authored 45 peer-reviewed publications in the fields of allergy, immunology, and autoimmunity. Id.

Dr. Robinson's expert report was two pages. Exhibit 24. Dr. Robinson opined that Mr. Haugan's diagnosis was a "rather unusual reaction of a serum sickness type reaction." Exhibit 24 at 2. Dr. Robinson noted that Mr. Haugan "unfortunately, did not seek medical attention during this time so we only have his detailed report of what occurred during the episode." Exhibit 24 at 1-2. Dr. Robinson explained that a serum sickness type reaction occurs when a person receives a substance by injection, has pre-existing antibodies and they form what are known as antigen/antibody complexes. Id. at 2. "This normally occurs in a lot of immune recognition events, but with serum sickness, the patient makes a lot of these and they get stuck in joints, kidneys and other tissues and can cause local inflammation." Id. Dr. Robinson stated that there have been several reports of "this type of symptom complex occurring following influenza vaccine" and references two articles, an article about severe serum sickness after H1N1 vaccinations and an article about serum sickness like reaction after influenza vaccinations. Id. at 2; see Exhibits 17 (Chiong)<sup>3</sup> and 18 (Bonds).<sup>4</sup> Dr. Robinson opined that "Mr. Haugan did experience a serum sickness type reaction following influenza vaccination on 10/31/2018, on a more likely than not basis." Exhibit 24 at 2.

2. Dr. Belfie's Expert Report

Dr. Belfie is a board-certified orthopedic surgeon with specialties in sports medicine and shoulder and knee injuries. Dr. Belfie has 20 years of experience and has been an employee of Virginia Mason Medical Center since 2004. Exhibit 25 at 1.

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<sup>3</sup> Fabian Joon Kiong Chiong et al., Serum sickness-like reaction after influenza vaccination, PUBMED CENTRAL, PMID 26677148 (2015); filed as exhibit 17.

<sup>4</sup> Rana Bonds & Brent Kelly, Serum sickness after H1N1 influenza vaccination, PUBMED CENTRAL, PMID 23221512 (2013); filed as exhibit 18.

Dr. Belfie’s expert report was two pages. Exhibit 25. Dr. Belfie based his opinion on a clinical encounter with Mr. Haugan on June 2, 2023. Id. at 1. Dr. Belfie stated that Mr. Haugan was well known to him from prior right shoulder pain that was reported to him on May 3, 2019. Id.; see Exhibit 8 at 463. Dr. Belfie stated that Mr. Haugan “spent a considerable amount of time with right shoulder disability and participated in physical therapy for greater than 6 months for return of normal function to his right shoulder . . . . Prior to his influenza vaccination, he had no shoulder problems.” Exhibit 25 at 1. Dr. Belfie has seen such injuries “2-3 times per year during flu shot season” over the course of his career. Id. Dr. Belfie stated that “there has been no objective data that demonstrates flu vaccine injections cause conditions such as rotator cuff tears or adhesive capsulitis.” Id. Dr. Belfie was concerned about Mr. Haugan’s shoulder and ordered an MRI. Id.

Dr. Belfie opined that the MRI “demonstrated rotator cuff tear pathology. It is highly unlikely that this flu vaccination injection resulted in the aforementioned rotator tear cuff.” Id. Dr. Belfie opined that this previous injury was not caused by the vaccine, but that the more recent shoulder pain was the result of the flu vaccine. Dr. Belfie concluded that the influenza vaccination caused Mr. Haugan’s shoulder pain and disability for a finite period of time and has since resolved without further disability. Id. at 2. Dr. Belfie did not cite any articles in support of his report.

### 3. Dr. MacGinnitie’s Expert Report

Dr. MacGinnitie is board-certified in allergy/immunology and pediatrics. Exhibit A at 2. Dr. MacGinnitie has been practicing as an allergist/immunologist for 21 years and is the attending physician and clinical chief for the Division of Immunology at Boston’s Children’s Hospital and an associate professor of pediatrics at Harvard Medical School. Id. at 1.

Dr. MacGinnitie’s expert report addressed Mr. Haugan’s claim of serum sickness. Dr. MacGinnitie explained that both true serum sickness reactions and serum sickness-like reactions “resolve over time as the immune complexes are scavenged by different immune cells, with resolution of symptoms seen within several weeks.” Exhibit A at 7. Dr. MacGinnitie opined that “It is possible that Mr. Haugan had a limited reaction to his vaccination . . . within a few hours after vaccination. However, this response is too rapid to be attributed to a serum sickness which . . . typically develops six to ten days after exposure.” Id.

Dr. MacGinnitie stated that Mr. Haugan’s symptoms appeared to be migratory, with his reported complaints in his finger, left ankle, and right shoulder, and that this “is highly unusual for serum sickness.” Exhibit A at 7-8. Dr.

MacGinnitie explained that patients with serum sickness “typically have symptoms in all affected joints that worsen and then improve concurrently.” Id. at 8.

The onset of serum sickness typically begins between one and two weeks after exposure. This is a much longer interval than that between vaccination and the alleged onset of Mr. Haugan’s rash the same evening, but also much shorter than the six weeks between vaccination and alleged onset of Mr. Haugan’s first joint symptom in his left little finger.

Id. Dr. MacGinnitie noted that the onset of symptoms in his cited articles was between 24 hours and seven days of vaccination. Id.<sup>5</sup> Dr. MacGinnitie also cited the lack of evidence in the medical record of inflammation, including no reported fever, which is a typical symptom of serum sickness. Id. Dr. MacGinnitie continued that “persistence of symptoms more than two to three months would typically lead one to question the diagnoses of serum sickness.” Id. at 9. Dr. MacGinnitie concluded that Mr. Haugan’s flu vaccination “did not trigger serum sickness in Mr. Haugan. Even if it did, any symptoms would have resolved within two to three months of vaccination.” Id. at 10.

#### 4. Dr. Feeley’s Expert Report

Dr. Feeley is a board-certified orthopedic surgeon. Exhibit C at 1. Dr. Feeley has been practicing orthopedic surgery since 2008 and is a professor in residence at University of California, San Francisco. Id. Dr. Feeley has published over 274 peer-reviewed manuscripts, review papers, and book chapters, as well as authoring a book on rotator cuff tears. Id.

Dr. Feeley’s expert report addressed Mr. Haugan’s claim of a shoulder injury following vaccination. Dr. Feeley noted that shoulder injuries following vaccinations tend to involve shoulder bursitis and reports of pain occur “almost immediately after the injection,” generally within the first 48 hours. Exhibit C at 7.

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<sup>5</sup> Anucha Apisarnthanarak et al., Serum Sickness-Like Reaction Associated with Inactivated Influenza Vaccination among Thai Health Care Personnel: Risk Factors and Outcomes, 49 CLINICAL INFECTIOUS DISEASES e18 (2009); filed as exhibit A, Tab 4.

Rana Bonds & Brent Kelly, Serum sickness after H1N1 influenza vaccination, PUBMED CENTRAL, PMID 23221512 (2013); filed as exhibit A, Tab 5.

Fabian Joon Kiong Chiong et al., Serum sickness-like reaction after influenza vaccination, PUBMED CENTRAL, PMID 26677148 (2015); filed as exhibit A, Tab 6.

Dr. Feeley stated that the American Academy of Orthopaedic Surgeons' ("AAOS") position on the risk of a vaccination causing a SIRVA reaction was that

Immunizations are also very common as many individuals are administered annual influenza vaccinations. The likelihood of first noticing a shoulder problem around the time of an immunization is highly likely. Most of these associations between immunization and shoulder pathology will be coincidental, even if they are perceived as causal.

Id. Dr. Feeley noted that AAOS estimated that as many as a million people a year might "inaccurately and inappropriately believe they were injured by vaccination each year" because so many older adults are vaccinated for the flu each year and the prevalence of existing, detectable rotator cuff tendinopathy. Id. Dr. Feeley explained that the Vaccine Injury Compensation Program defines SIRVA as occurring within 48 hours of vaccination, without a history of pain, inflammation, or dysfunction of the affected shoulder, and pain and reduced range of motion to the shoulder, and no other condition or abnormality that would explain the symptoms. Id. at 8. Dr. Feeley noted that Mr. Haugan did not report to a physician until a considerable time after vaccination and that Mr. Haugan did not have considerable loss of motion in his shoulder. Id. Dr. Feeley also commented that Mr. Haugan had a history of concerns with his right shoulder, including a history of a partial rotator cuff tear, recurrent pain noted in 2014, and a request for PT for his right shoulder just prior to his vaccination. Id. Dr. Feeley also emphasized that Mr. Haugan's right shoulder MRI demonstrated mild arthritis, which is not related to SIRVA, and there was no mention of bursitis. Id. Dr. Feeley concluded that

the influenza vaccine that was administered into Mr. Haugan's left shoulder on October 31<sup>st</sup>, 2018 is not the source of his right shoulder pain. While he has some symptoms that are consistent with right shoulder pain, he also has a history of prior shoulder pain that included seeing a shoulder and upper extremity specialist in the past, requesting PT for his shoulder prior to his vaccination, MRI finding that are non-specific in nature with the exception of mild glenohumeral cartilage degeneration (which is not a SIRVA based injury), and a record indicating that the injection was placed in the opposite arm.

Id. at 10.

5. Dr. Robinson's Second Expert Report

On December 11, 2023, Mr. Haugan saw Dr. Robinson, and Dr. Robinson responded to respondent's expert report from Dr. Andrew MacGinnitie in a "final report." Exhibit 29. Dr. Robinson responded to Dr. MacGinnitie's opinion regarding onset of symptoms.

Dr. MacGinnitie got most of the details of his episode correct, although felt there was a requirement of 1-2 weeks before serum sickness could occur. This certainly is the case for de novo sensitization, but . . . there are plenty of cases of nearly immediate serum sickness reactions, certainly within a much shorter time frame in patients that have preformed antibody and are supplied with appropriate antigen.

Exhibit 29 at 1. Dr. Robinson acknowledged that Dr. MacGinnitie's report noted that Mr. Haugan did not have a documented fever, "but [Mr. Haugan] notes that it was a long time ago, and I wonder if he could have had low-grade fever that went unnoticed. Unfortunately, [Mr. Haugan] did not seek any medical attention during this time period and did not have any inflammatory markers or other blood work checked." Exhibit 29 at 1. Dr. Robinson continued,

He was significantly impacted, however, with the episode and felt fairly incapacitated at least for the short term. Ultimately, he understands there is really little in the way of direct proof, but clinical situation certainly was consistent with some inflammatory reaction within the first 24 hours following influenza vaccination.

Id.

Dr. Robinson referenced a chapter dedicated to serum sickness by Dr. Mark Wener available in UpToDate. See Exhibit 35-A (Wener).<sup>6</sup> "Dr. Wener specifically notes that rapid onset of reactions can indeed occur. No reference, however, for this, but I suspect that references are really quite old." Exhibit 29 at 1.

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<sup>6</sup> Mark Wener, Serum sickness and serum sickness-like reactions, UPTODATE (2022); filed as Exhibit 35-A.

## 6. Dr. Mostov's Response

Dr. Mostov, Mr. Haugan's primary care physician, submitted a one-page letter to "provide medical documentation regarding [Mr. Haugan's] right shoulder pain reported as a side effect following the high dose influenza vaccination" and to "clarify the unlikely relationship of injuries sustained in April 2006 and subsequent right shoulder complaints to the right shoulder pain experienced after the influenza vaccine in 2018." Exhibit 28 at 1. Dr. Mostov opined that the "medical evidence strongly indicates that the symptoms experienced after the influenza vaccine were not related to this previous injury, but, rather, were acute and directly associated with the vaccination process." Id.

### **C. Briefing Stage**

After the parties finished disclosing the opinions from their experts, the next step was for the parties to submit their legal arguments. Order, issued Jan. 4, 2024.

Mr. Haugan argued his case through an 11-page brief, filed February 5, 2024. Mr. Haugan first disputed Dr. Feeley's claims that the vaccine was administered to Mr. Haugan's left shoulder. Mr. Haugan argued that the vaccine was administered to his right shoulder. Pet'r's Br. at 2. Mr. Haugan next disputed whether his right shoulder pain from a 2006 motor vehicle accident was related to the SIRVA complaint. Id. at 3. Mr. Haugan also acknowledged he is pursuing an off-Table claim related to his right shoulder. Id. at 4.

Mr. Haugan also advanced his serum sickness claim. Id. at 4-7. Mr. Haugan claimed that the flu vaccine significantly aggravated both his SIRVA and serum sickness claims. Id. at 4. Additionally, Mr. Haugan argued his position regarding onset of his injuries. Id. at 8-9.

The Secretary argued against a finding of entitlement in a 33-page brief, filed Mar. 5, 2024. The Secretary challenged (a) whether Mr. Haugan satisfied the severity requirement, (b) whether Mr. Haugan established a Table claim for a SIRVA injury, (c) whether Mr. Haugan demonstrated that the flu vaccine caused-in-fact his alleged serum sickness, or any other injury, and (d) whether Mr. Haugan demonstrated that his vaccine significantly aggravated his alleged injuries.

Mr. Haugan had the final word by filing a five-page reply on April 8, 2024. With Mr. Haugan's reply, this case is ready for adjudication.

#### **D. Adjudication without a Hearing**

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec’y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018). Here, a hearing is not necessary to resolve Mr. Haugan’s case. Mr. Haugan has submitted three reports from experts and argued his case through briefs. He has had a full and fair opportunity to establish that he is entitled to compensation. Similarly, the Secretary has submitted reports from two different experts and argued his case through briefs. The Secretary has also had a full and fair opportunity to argue against Mr. Haugan’s entitlement to compensation.

#### **III. Standards for Adjudication**

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

#### **IV. Analysis**

Here, Mr. Haugan alleges two injuries stemming from his vaccination, including serum sickness and an off-Table shoulder injury. These are taken up separately.

## A. Serum Sickness

Mr. Haugan's serum sickness claim is an injury not found in the Vaccine Table. With respect to Mr. Haugan's claim that the flu vaccine caused him to suffer serum sickness, the parties dispute several points. For example, through Dr. Robinson and Dr. MacGinnitie, the parties disagree as to whether any symptom associated with a serum sickness reaction developed in the appropriate time. This dispute is academic because there is another flaw within this claim – any serum sickness reaction did not fulfill the Vaccine Act's severity requirement.

### 1. Severity Requirement

To be eligible for compensation, the Vaccine Act requires a petitioner to have “suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” 42 U.S.C. § 300aa-11(c)(1)(D)(i) (“severity requirement”). In the alternative, petitioner can meet this statutory requirement by demonstrating that his alleged injuries resulted in inpatient hospitalization and surgical intervention. *Id.* However, petitioner does not allege, and the evidence does not show, that he was hospitalized for his alleged injuries or underwent surgical intervention. Like other elements of petitioner's proof, the severity requirement must be established by a preponderance of the evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(A); *see also* Song v. Sec'y of Health & Hum. Servs., 31 Fed. Cl. 61, 65-66 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence); Colon v. Sec'y of Health & Hum. Servs., 156 Fed. Cl. 534, 541 (2021).

### 2. The Parties' Evidence and Arguments

With respect to Mr. Haugan's serum sickness claim, the Secretary argued that Mr. Haugan did not establish preponderant evidence that he experienced serum sickness symptoms beyond May 1, 2019. The Secretary maintains that the record references that Mr. Haugan's complaints were fleeting and that Mr. Haugan averred that his rash was “[c]oincident with the flu shot” and “it did not last long.” Exhibit 15 (Mr. Haugan's affidavit) at ¶ 26. The Secretary also points to Mr. Haugan's wife's affidavit, which also supports that Mr. Haugan's rash did not last long. Exhibit 10 (Mrs. Haugan's affidavit) (“[The rash] slowly abated over a few days”). The Secretary's expert likewise stated that serum sickness does not last more than a few months. Exhibit A at 9. The Secretary argued that there is no evidence of Mr. Haugan's serum sickness lasting beyond six months from the date of his vaccination.

Mr. Haugan responded to the Secretary's arguments and claimed that his serum sickness reactions caused or worsened his arthritis and that his "arthritis may still not be totally resolved and have the potential to flare up again in the future." Pet'r's Reply at 2.

### 3. Assessment

Petitioner's position is not persuasive for two reasons. First, much of what Mr. Haugan is arguing comes from him. But, he is not a medical doctor. Special masters may not award compensation based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion. 42 U.S.C. § 300aa-13(a). See Gerami v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 299, 305-306 (2014) (finding that petitioner failed to establish that the residual effects of her alleged vaccine-related injuries lasted for more than six months based on her contemporaneous medical records); Byrd v. Sec'y of Health & Hum. Servs., 142 Fed. Cl. 79, 85 (2019), aff'd, 778 F.App'x 924 (Fed. Cir. 2019) ("[Petitioner's] showing that his injuries persisted beyond six months rests on his assertions alone, which the law requires the special master to disregard if unsubstantiated by medical records or medical opinion.") (internal quotations omitted); Armbruster v. Sec'y of Health & Hum. Servs., No. 17-1856V, 2020 WL 3833396, at \*8 (Fed. Cl. Spec. Mstr. Feb. 5, 2020) ("A petitioner cannot establish the length or ongoing nature of an injury merely through his or her own statements, but rather is required to submit supporting documentation which reasonably demonstrates that the alleged injury or its sequelae lasted more than six months.") (internal quotations omitted; see also Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1381 (Fed. Cir. 2021) (showing how other evidence can corroborate a petitioner's testimonial assertions).

Second, Mr. Haugan fails to account for the presence of arthritis before the vaccination. See Exhibit 8 at 13, 102, 241, 251, 469, 482, 509; Exhibit 2 at 11. Prior to his vaccination, on June 6, 2017, one of Mr. Haugan's treating doctors, Dr. Helming, told him that "the arthritis is going to be an ongoing issue to some extent." Exhibit 8 at 509. Mr. Haugan's claim that his arthritis may not be totally resolved and may flare up in the future is speculative. See Parsley v. Sec'y of Health & Hum. Servs., No. 08-781V, 2011 WL 2463539, at \*21 (Fed. Cl. Spec. Mstr. May 27, 2011) (holding an increased risk of future complications does not constitute a residual effect of the initial disease).

None of Mr. Haugan's experts or treating doctors opined that Mr. Haugan's serum sickness lasted in excess of six months. Even Mr. Haugan's expert, Dr. Robinson, opined that Mr. Haugan's serum sickness did not last long, stating that

Mr. Haugan was “significantly impacted, however, with the episode and felt fairly incapacitated at least for the short term.” Exhibit 29 at 1. The lack of support from treating doctors that serum sickness lasted many months is in accord with some prior adjudications about serum sickness. See Orgel-Olsen v. Sec’y of Health & Hum. Servs., No. 15-285V, 2022 WL 1598143, at \*28-29 (Fed. Cl. Spec. Mstr. Mar. 11, 2022); Keja v. Sec’y of Health & Hum. Servs., No. 17-1511V, 2021 WL 1736816, at \*20 (Fed. Cl. Spec. Mstr. Apr. 2, 2021) (concluding from the record “that if serum sickness occurred, it likely resolved well short of the six-month period required to establish severity in Program cases. *See* Section 11(c)(1)(D)” citing Watts v. Sec’y of Health & Hum. Servs., No. 17-1494V, 2019 WL 4741748, at \*3 (Fed. Cl. Spec. Mstr. Aug. 13, 2019)); see also Ferguson v. Sec’y of Health & Hum. Servs., No. 17-1299V, 2024 WL 4678064, at \*26 (Fed. Cl. Spec. Mstr. Oct. 16, 2024) (finding expert opinion and medical literature persuasive that serum sickness is a transient condition with a maximum duration of 14 days without further sequelae).

In short, for the serum sickness claim, Mr. Haugan has not met the severity requirement required under the Vaccine Act. Mr. Haugan relies on speculative possibilities of what may occur again in the future. This assertion is not adequate. There is no persuasive evidence that the serum sickness evolved into or was manifest as a shoulder problem which is discussed below. Therefore, no further analysis is required regarding Mr. Haugan’s serum sickness because Mr. Haugan’s claim cannot succeed. 42 U.S.C. § 300aa-11(c)(1)(D).

## **B. Shoulder Claim**

On March 21, 2017, the Vaccine Injury Table was amended to add SIRVA as a presumptive injury from the flu vaccine if the first symptom or manifestation of onset of the injury occurs within forty-eight hours of an intramuscular vaccine administration. See 42 C.F.R. § 100.3(a)(XII)(A). For claims regarding shoulder injuries that do not follow the prescribed requirements, petitioners must proceed with an off-Table claim for causation-in-face or significant aggravation, meeting the Althen / Loving prongs described below.

While Mr. Haugan’s petition seemingly alleged an on-Table SIRVA claim, Mr. Haugan later argued that he was not pursuing a Table claim related to his shoulder injury. “Petitioner *agrees* with [respondent] (and the Court) that this is not a table claim.” Pet’r’s Reply at 3 (emphasis in original). Mr. Haugan necessarily proceeds pursuing an off-Table causation-in-fact and/or significant aggravation claim. Id.

Regardless of the approach, Mr. Haugan bears the burden of proving his case by a preponderance of the evidence. 42 U.S.C. § 300aa13(a)(1)(A). A preliminary issue that the Secretary has raised is whether Mr. Haugan has satisfied the severity requirement of his injuries to be entitled to compensation under the Vaccine Act.

1. Shoulder of Vaccine Administration

As a preliminary matter, Mr. Haugan and the Secretary dispute into which shoulder the flu vaccine was administered. If it is determined that Mr. Haugan's flu vaccination was administered to his left shoulder, his claim must fail because he claims the vaccination caused his right shoulder injury. If it is determined that the vaccine was administered to Mr. Haugan's right shoulder, then he may prevail, as explained below. For the reasons explained below, Mr. Haugan has preponderantly established that the vaccine was administered to his right shoulder.

The Federal Circuit has recognized that medical records are presumptively accurate in recounting contemporaneous events relating to medical treatment. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Mr. Haugan does not cite to any cases in which special masters have found an error in vaccination records with respect to where vaccines have been administered. Even though Mr. Haugan does not cite to any cases regarding wrong side/wrong site vaccine administration records, special masters have credited testimony from petitioners about the site of administration. Special masters have sometimes made this type of finding when the petitioners have told their treating doctors that they were having shoulder pain in the shoulder they remember getting vaccinated in following a vaccine administration. See Magana v. Sec'y of Health & Hum. Servs., No. 21-1234V, 2024 WL 5088692, at \*1 (Fed. Cl. Spec. Mstr. Oct. 16, 2024); Haynes v. Sec'y of Health & Hum. Servs., 18-1925V, 2021 WL 5458676, at \*3 (Fed. Cl. Spec. Mstr. Oct. 13, 2021); see also Steinbach v. Sec'y of Health & Hum. Servs., 15-1546V, 2016 WL 4751772, at \*2 (Fed. Cl. Spec. Mstr. Aug. 4, 2016).

Mr. Haugan cites to many times in the record where he complains about his right shoulder pain after receiving his vaccination. See Exhibit 10 (Mrs. Haugan's affidavit) ("He also complained about his right shoulder and could not lift a suitcase"); Exhibit 8 (Virginia Mason Medical Center) at 95 ("Pain is below the shoulder right worse than left."), 463 (discussing "right shoulder pain that began sometime around a flu shot injection"), 465 (complaint of "[right] shoulder pain since influenza vaccine"), 503 ("He had just previously had a flu injection and had noted new-onset pain of his right shoulder"); Exhibit 11 (Dr. Robinson) at 3

(“Especially painful was my right shoulder where I had a rotator cuff injury from a MVA in 2006.”); Exhibit 25 (Dr. Belfie) at 1 (“referred to me . . . for ongoing right shoulder pain that began following an influenza vaccination”); and Exhibit 28 (Dr. Mostov) at 1 (“I can confirm that the patient reported discomfort in the right shoulder area and at other joints after receiving the influenza vaccine”). Even though the vaccine administration record appears blurry and unclear, the Secretary argued that the record shows that the vaccine was administered to Mr. Haugan’s left shoulder. However, Mr. Haugan consistently reported the pain in his right shoulder and associated this pain with his vaccination, where he maintains was the vaccine administration site. Exhibit 9 at 2. At no point in his medical record history does Mr. Haugan state he was administered a vaccine into his left shoulder.

Respondent’s argument is based on the contemporaneously created vaccine administration record. Exhibit 9 at 2. Here, the vaccine administration record is difficult to read, and it is unclear which shoulder the vaccine was administered based on that record alone. Perhaps a deposition from the pharmacist who administered the vaccine would have yielded clarity. However, no party sought to depose the pharmacist. But, Mr. Haugan submitted a declaration and stated that

I DECLARE that: On December 12, 2023 at approximately 3PM local time, I took Exhibit 9 to the same Walgreens Drug Store on Bainbridge Island where I live and where I received a flu shot October 31, 2018 and asked the Mr. Nyguyen, the pharmacist, to read the Exhibit 9 document and tell me if it was the right or left arm where the injection was given.

He could not make a determination. I further asked if the document was legible would it be positively accurate. The pharmacist shrugged and said “we do our best[.]”

I took the same document to our current Bainbridge Community Pharmacy and asked two pharmacists behind the counter if they could read the document. They could not.

Exhibit 30. Without a more legible vaccination record or deposing the pharmacist, it is uncertain whether Mr. Haugan’s contemporaneously created records reflect a vaccine was administered into his left or right shoulder. Mr. Haugan, and his doctors, have consistently recorded pain in Mr. Haugan’s right shoulder following a vaccination, presumably into his right shoulder. With this persuasive support from medical records created in the months after the vaccination, Mr. Haugan’s

assertion that the vaccine was administered into his right arm carries more weight and credibility.

Therefore, in resolving this matter, it appears that it is more likely than not that Mr. Haugan received his vaccination in his right shoulder.<sup>7</sup>

## 2. Significant Aggravation / Causation

Now that Mr. Haugan's vaccine was found to be administered into his right shoulder, Mr. Haugan is required to establish that the vaccine harmed his shoulder, either by causing an initial injury or by worsening a pre-existing injury. Here, it is appropriate to analyze Mr. Haugan's claim under a significant aggravation claim because Mr. Haugan's medical records establish previous injuries regarding his right shoulder, including a motor vehicle accident in 2006 (exhibit 13) for which he was treated for rotator cuff tendinopathy (exhibit 28), migratory joint pain (exhibit 8 (August 22, 2016) at 512), and right rotator cuff tear (see exhibit 8 (June 6, 2017) at 509). Additionally, Mr. Haugan claimed that the vaccine had significantly aggravated his right shoulder injuries. Pet'r's Reply Br. at 3-4. When the category of claim is unclear, special masters have analyzed the claim as a significant aggravation claim because the elements of a significant aggravation claim overlap with the elements of an initial onset claim. Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 468 (2012), aff'd, 786 F.3d 1373, 1375 (Fed. Cir. 2015).

To be entitled to compensation, Mr. Haugan needed to present sufficient evidence to satisfy the six-prong test for significant aggravation claims adopted in Loving v. Sec'y of Health & Hum. Servs., 86 Fed. Cl. 135 (2009). Under the Loving framework, Mr. Haugan must establish:

- (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the

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<sup>7</sup> Regarding the severity requirement for Mr. Haugan's SIRVA/shoulder injury claim, the Secretary argued that, while Mr. Haugan did seek medical care more than six months from the date of his vaccination (October 31, 2018), Mr. Haugan sought treatment for his right shoulder, which the Secretary maintains is the unvaccinated shoulder. Resp't's Br. at 20. The Secretary has not raised alternative issues related to Mr. Haugan's off-Table SIRVA claim regarding severity. For reasons discussed above regarding the shoulder site of vaccine administration, Mr. Haugan provides persuasive evidence to find that the vaccine was more likely than not administered to his right shoulder.

vaccination if that is also pertinent), (3) whether the person’s current condition constitutes a “significant aggravation” of the person’s condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Id. at 144. Mr. Haugan discussed and analyzed the Loving prongs, in their entirety, in less than a page. Pet’r’s Reply at 3-4. In his view, he has provided sufficient evidence to support his claim for significant aggravation to his right shoulder injury. For the reasons below, the evidence preponderates in his favor.

*a) Althen Prong One / Loving Prong Four - Theory*

The first Althen prong, which corresponds to the fourth Loving prong, requires a petitioner to present a reliable and persuasive medical theory. Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (citing Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). Mr. Haugan reiterated that he has met his burden under prong four of Loving based on the expert reports and opinions provided by Dr. Mostov, Dr. Belfie, and Dr. Robinson. Mr. Haugan advances the following medical theory to connect how a flu vaccine can cause a shoulder injury. “**Medical theory causally connecting a worsened condition.** As previously stated. Three treating physicians, Dr’s Mostov, Belfie and Robinson have made this connection with medical opinion and written testimony provided herein.” Pet’r’s Reply at 3 (emphasis in original). Mr. Haugan’s expert reports are supplemented with a series of about ten case studies regarding SIRVA (exhibit 26) and a medical article about SIRVA. Exhibit 27 (Wiesel & Keeling).<sup>8</sup> In the Wiesel and Keeling article, the authors stated that “The pathogenesis of SIRVA is incompletely understood. The most widely held theory posits that SIRVA occurs when vaccine is injected through the deltoid into underlying nonmuscular tissues, producing a prolonged inflammatory response.” Id. at 733. “Other authors have expanded on this proposed mechanism of injury, noting that if the vaccine is inadvertently injected into the subacromial space of the shoulder, preexisting antibodies within the surrounding tissue may produce a prolonged inflammatory response that causes the symptoms typical of SIRVA.”

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<sup>8</sup> Brent B Wiesel & Laura E. Keeling, Shoulder Injury Related to Vaccine Administration, 29 J. AM. ACAD. ORTHOPAEDIC SURGEONS 732 (2021); filed as Exhibit 27.

Id. The authors provide a caveat that “because current research on the pathophysiology of SIRVA is limited to observational studies, it is not possible to definitely prove a relationship between immunization and the onset of SIRVA symptoms. Larger, high-quality studies are needed to further elucidate the pathogenesis of shoulder injury after vaccination.” Id. Special masters have relied upon SIRVA articles to support causation-in-fact cases. See Morris v. Sec’y of Health & Hum. Servs., No. 19-1570V, 2023 WL 5092691, at \*6 (Fed. Cl. Spec. Mstr. July 11, 2023).

The Secretary disputed that Mr. Haugan supported his claim with a medical theory that connects a flu vaccine to how it can cause shoulder injuries. In support of his position, the Secretary relies, in part, on the opinion of Dr. Feeley. Dr. Feeley supports his opinion with the AAOS’s position on the risk of a vaccination causing a shoulder injury.

Immunizations are also very common as many individuals are administered annual influenza vaccinations. The likelihood of first noticing a shoulder problem around the time of an immunization is highly likely. Most of these associations between immunization and shoulder pathology will be coincidental, even if they are perceived as causal.

Exhibit C at 7. Dr. Feeley noted that AAOS estimated that as many as a million people a year might “inaccurately and inappropriately believe they were injured by vaccination each year” because so many older adults are vaccinated for the flu each year and the prevalence of existing, detectable rotator cuff tendinopathy. Id.

Dr. Feeley’s opinion was supported with medical articles. Exhibits C, Tab 1 – Tab 14. These articles broadly cover topics such as rotator cuff disease, biceps sub-pectoral tenodesis, bursitis, frozen shoulder syndrome post-vaccination, and SIRVA. Although the expert provided many medical articles, the Secretary does not meaningfully engage with them or advance them in his brief. See Resp’t’s Br. at 2, 17.

The combination of Mr. Haugan’s treating doctors and the Wiesel and Keeling article, provide sufficient evidence to preponderantly establish a medical theory causally connecting such a significantly worsened condition to the vaccination. Therefore, Mr. Haugan has met his burden under prong one.

*b) Althen Prong Two / Loving Prong Five - Logical Sequence*

Pursuant to Althen, a petitioner must establish “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. A petitioner does not need to present “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect” to satisfy this prong, but may rely on circumstantial evidence and reliable medical opinions. Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1325-26 (Fed. Cir. 2006). In analyzing Althen prong two, special masters are to consider the opinions of the treating physicians who concluded that the vaccine was the cause of a petitioner’s injury. Id. at 1326 (“As far as the second prong in concerned . . . the chief special master erred in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of Ms. Capizzano’s injury. The fact that these physicians’ diagnoses may have relied in part on the temporal proximity of Ms. Capizzano’s injuries to the administration of the vaccine is not disqualifying.”) (citations omitted). Prong two of Althen corresponds with prong five of Loving.

Mr. Haugan supported his Althen prong two / Loving prong five analysis by discussing both his shoulder injury and serum sickness in the same paragraph. Mr. Haugan stated that

**Logical sequence of “cause and effect”.** The onset of a rash was notable and markedly unusual. That was the documented start. As these things go a “wait and see” approach prevailed. Waiting to seek medical advice did not negate documenting the onset. When waiting did not resolve these unusual conditions, Petitioner did resort to medical advice. That was not instant as in medicine these days it takes time to secure an appointment. Medical advice was sought in an attempt to “find out what is going on” (Pet Ex 8 p 99 and Pet Ex 8 p 503).

Pet’r’s Reply at 4 (emphasis in original). Mr. Haugan did not discuss in his brief the logical sequence of cause and effect related to his shoulder injury. His argument for this prong is focused on his serum sickness claim.

However, Mr. Haugan’s primary care physician, Dr. Mostov, opined that Mr. Haugan’s right shoulder pain was a side effect following the high dose influenza vaccination and that it was unlikely that his motor vehicle accident injury

was the cause of Mr. Haugan's right shoulder pain after vaccination. Exhibit 28 at 1. Dr. Mostov opined that the "medical evidence strongly indicates that the symptoms experienced after the influenza vaccine were not related to this previous injury, but, rather, were acute and directly associated with the vaccination process." *Id.* Dr. Mostov's opinion is based on his professional expertise and experiences. In Dr. Mostov's message to Mr. Haugan on March 15, 2019, he stated that his theory "that [Mr. Haugan's] joint/muscle reaction may be related to the flu vaccine are based on my knowledge of and experience with human biology, not based on any cutting edge research. Sorry I do not have any specific references for you." Exhibit 8 at 69; Exhibit 4 at 1.

Mr. Haugan's treating doctors also opined consistently that Mr. Haugan's vaccination was the reason for Mr. Haugan's significantly aggravated shoulder injury. Mr. Haugan's expert, Dr. Belfie, opined that Mr. Haugan "spent a considerable amount of time with right shoulder disability and participated in physical therapy for greater than 6 months for return of normal function to his right shoulder . . . . Prior to his influenza vaccination, he had no shoulder problems." Exhibit 25 at 1.

In his expert report, Dr. Belfie stated that "there has been no objective data that demonstrates flu vaccine injections cause conditions such as rotator cuff tears or adhesive capsulitis." Exhibit 25 at 1. Dr. Belfie was concerned about Mr. Haugan's shoulder and ordered an MRI. *Id.* Dr. Belfie opined that the MRI "demonstrated rotator cuff tear pathology. It is highly unlikely that this flu vaccination injection resulted in the aforementioned rotator tear cuff." *Id.* Dr. Belfie concluded that the influenza vaccination caused Mr. Haugan's shoulder pain and disability for a finite period of time and has since resolved without further disability. *Id.* at 2. In Dr. Belfie's opinion, Mr. Haugan's right shoulder pain and disability were caused by the influenza vaccination, based on a logical sequence of cause and effect. Dr. Belfie's opinion is based on his expertise and experiences.

The Secretary's expert, Dr. Feeley, addressed Mr. Haugan's shoulder injury claim following vaccination. Dr. Feeley noted that shoulder injuries following vaccinations tend to involve shoulder bursitis and reports of pain occur "almost immediately after the injection," generally within the first 48 hours. Exhibit C at 7.

Dr. Feeley noted that Mr. Haugan did not report to a physician until a considerable time after vaccination, and that Mr. Haugan did not have considerable loss of motion in his shoulder. *Id.* Dr. Feeley also commented that Mr. Haugan had a history of concerns with his right shoulder, including a history of a partial rotator cuff tear, recurrent pain noted in 2014, and a request for PT for his right

shoulder just prior to his vaccination. Id. at 8. Mr. Haugan disputed that the PT was for his right shoulder and stated it was for his left shoulder. Pet'r's Br. at 3; Exhibit 8 (October 29, 2018) at 118.

Dr. Feeley also emphasized that Mr. Haugan's right shoulder MRI demonstrated mild arthritis, and there was no mention of bursitis. Exhibit C at 7. Dr. Feeley concluded that

the influenza vaccine that was administered into Mr. Haugan's left shoulder on October 31<sup>st</sup>, 2018 is not the source of his right shoulder pain. While he has some symptoms that are consistent with right shoulder pain, he also has a history of prior shoulder pain that included seeing a shoulder and upper extremity specialist in the past, requesting PT for his shoulder prior to his vaccination, MRI finding that are non-specific in nature with the exception of mild glenohumeral cartilage degeneration (which is not a SIRVA based injury), and a record indicating that the injection was placed in the opposite arm.

Id. at 10. Dr. Feeley supported his opinion with over 10 articles related to post-vaccination shoulder injuries. Exhibits C, Tab 1 – Tab 14. While the Secretary's expert has supported his report with relevant medical literature that adds to the soundness and credibility of his opinion, the Secretary does not marshal any of these articles in his response brief. Whereas, Mr. Haugan's treating doctors' opinions posit a logical sequence of cause and effect between Mr. Haugan's vaccination and his significantly aggravated shoulder injury that provide ample support for Mr. Haugan to meet his burden. As his treating physicians, Mr. Haugan's experts' opinions deserve considerable weight. With the support of these treating physicians, Mr. Haugan preponderantly established his burden under Althen prong two / Loving prong five. Althen prong three / Loving prong six are discussed next.

*c) Althen Prong Three / Loving Prong Six - Temporal Relationship*

The next element concerns the timing of the aggravation. The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the "onset of" the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013). The anticipated interval

largely derives from the offered theory. Langland v. Sec’y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013).

Mr. Haugan disputed that even though he waited over 40 days to seek medical attention that he has met his burden under prong six.

**Temporal relationship between vaccination and significant aggravation.** Respondent notes “no medical attention was sought” for 41 days. Already explained it takes weeks to secure a medical consultation appointment. For the shoulder it took lifting heavy objects to stand up and take notice. For the joints it took time as well to be sure something was truly amiss.

Pet’r’s Reply at 4 (emphasis in original).

The medical record shows that Mr. Haugan messaged his primary care provider, Dr. Mostov, on December 16, 2018 (46 days after vaccination) and complained that “about four days ago” his left little finger started to suddenly swell. Exhibit 8 at 106-107. On January 15, 2019 (76 days after vaccination), Mr. Haugan again messaged Dr. Mostov and raised his first post-vaccination complaint related to his shoulders, stating that his shoulders were getting more painful and that the pain below his right shoulder was worse than his left. Exhibit 8 at 95.

However, even though Mr. Haugan waited to raise his right shoulder complaints, the records memorialize Mr. Haugan’s complaints of his shoulder pain occurring earlier than his appointment. For example, the following chart follows the chronology of Mr. Haugan’s earliest complaints related to his right shoulder, post-vaccination.

<u>Date</u>	<u>Note</u>	<u>Exhibit</u>
10/31/2018	Mr. Haugan received his flu shot.	Ex. 1 at 2
12/2/2018	Mr. Haugan takes a trip to the Big Island in Hawaii.	Ex. 22 at 2
12/2/2018 (affidavit signed on 1/5/2020)	Ms. Haugan states that “[Mr. Haugan] also complained about his right shoulder and could not lift a suitcase in the luggage bin of an airplane as he usually could.” “These	Ex. 10 (Ms. Haugan’s affidavit)

	collective symptoms all happened right after the flu shot.”	
12/16/2018	Mr. Haugan messaged Dr. Mostov that his left little finger started to swell.	Ex. 8 at 106-107
1/13/2019	Mr. Haugan described to Dr. Mostov that his shoulders were more painful and that the pain below his right shoulder was worse than his left and described this these symptoms as “all new.”	Ex. 8 at 95
1/15/2019	Mr. Haugan messaged Dr. Mostov about his shoulders, stating that his shoulders were getting more painful and that the pain below his right shoulder was worse than his left.	Ex. 8 at 95
2/20/2019	Mr. Haugan stated that his right shoulder continued to be irritated and said that it “started after my flu shot 10/31/2018.”	Ex. 8 at 88
3/14/2019	Mr. Haugan explained to Ms. Rejon that he had right shoulder pain since the flu vaccine in October 2018.	Ex. 2 at 34
3/20/2019	Mr. Haugan told his physical therapist, Ms. Stringer, that he had right shoulder pain symptoms that began on October 31, 2018.	Ex. 2 at 34

Mr. Haugan addressed why he deferred seeking treatment from a medical provider and stated that

The delay in securing medical advice is understandable given getting an appointment is typically weeks out, shortened by holiday schedules. Discomfort and associated pain was not constant – only in certain movements (i.e. heavy overhead lifting). A “wait and see” approach was adopted until it did not resolve which is when medical attention was sought.

Pet'r's Br. at 3. While the exact timing of onset of Mr. Haugan's shoulder pain is unclear, he consistently reported to his doctors that the pain started well before his first doctor appointment.

Mr. Haugan's experts did not provide an opinion regarding onset or specify a "timeframe for which it is medically acceptable to infer causation" or that the "onset of" the disease occurred in this medically acceptable time period. However, in the Wiesel and Keeling article that Mr. Haugan filed, the authors stated that

The symptomatic hallmark of SIRVA is shoulder pain that occurs within 1 to 2 days of vaccination in previously asymptomatic shoulder. Unlike shoulder pain that commonly occurs after vaccination, the pain associated with SIRVA does not resolve within 1 week. In one series, the onset of pain was noted within 24 hours of injection in 93% of patients, with 54% of patients reporting pain immediately after vaccination. Hesse et al reported a mean time from immunization to presentation of 15 days, despite the onset of pain typically occurring within 24 hours of vaccination.

Exhibit 27 (Wisel & Keeling) at 735.

The Secretary disputed that Mr. Haugan experienced an onset of his symptoms during a timeframe that is medically acceptable to infer causation. Dr. Feeley opined that shoulder injuries following vaccinations tend to involve shoulder bursitis and reports of pain occurring "almost immediately after the injection," generally within the first 48 hours. Exhibit C at 7. Dr. Feeley also noted that Mr. Haugan did not report to a physician until a considerable time after vaccination, and that Mr. Haugan did not have considerable loss of motion in his shoulder. Id.

The first complaints raised by Mr. Haugan, 46 days after his vaccination, referred to his swelling in his left pinky and did not discuss any problems related to his right shoulder. Exhibit 8 at 106-107. Mr. Haugan first raised complaints about his right shoulder 76 days after vaccination. Id. at 95. While Mr. Haugan delayed seeking treatment immediately after his vaccination, the records from his treating doctors and affidavits support his claim that his shoulder injuries started fairly shortly after his vaccination on October 31, 2018. Mr. Haugan also provided medical literature regarding timing of onset of shoulder pain and vaccination within a timeframe for which it is medically acceptable to infer causation. Exhibit 27 (Wisel & Keeling) at 735 (reporting a "mean time from immunization to presentation of 15 days, despite the onset of pain typically occurring within 24

hours of vaccination”). Accordingly, Mr. Haugan provided preponderant evidence to support his claim that he has met his burden under Althen prong three / Loving prong six. Thus, he is entitled to compensation under the Vaccine Act if he can meet his burden under prongs one through three of Loving.

*d) Loving Prongs One - Three*

Under the first three prongs of Loving, Mr. Haugan must establish

- (1) the person’s condition prior to administration of the vaccine, (2) the person’s current condition (or the condition following the vaccination if that is also pertinent), [and] (3) whether the person’s current condition constitutes a “significant aggravation” of the person’s condition prior to vaccination[.]

Loving v. Sec’y of Health & Hum. Servs., 86 Fed. Cl. 135, 144 (2009). For a detailed breakdown of Mr. Haugan’s condition prior to the administration of the vaccine, refer to section I.A. In sum, regarding Loving prong one, Mr. Haugan averred that prior to his vaccination, his right shoulder injuries had largely abated. With respect to Loving prong two and Mr. Haugan’s current condition (or his condition following the vaccination), Mr. Haugan describes that

In addition to a chest rash at onset, the right shoulder as well as several joints were significantly aggravated after the vaccine injection. This is demonstrated in the medical records, physical therapy records and treating physicians. Old injuries in ankle, feet and hands significantly flared up after the injection attributed to serum sickness and/or serum sickness-like adverse reactions. Also note there were old injuries in hands, ankles, and feet but all independent – never flared up at the same time. Petitioner notes an extemporaneous comment to Dr[.] Mostov[.] Medical advice was sought in an attempt to “find out what is going on” (Pet [E]x 8 p 99 and Pet Ex 8 p 503) because of the frustration of finding a cause. Things were getting worse not better.

Pet’r’s Reply at 4.

In relation to the third Loving prong, Mr. Haugan asserted that he has demonstrated significant aggravation of his right shoulder injury. The third prong of the Loving test “does not require a petitioner to demonstrate an expected outcome and that her current-post vaccination condition was worse than such

expected outcome,” but rather, only requires a “comparison of the person’s pre-vaccination condition with the person’s current post-vaccination condition. Sharpe v. Sec’y of Health and Hum. Servs., 964 F.3d 1072, 1081 (Fed. Cir. 2020).

Mr. Haugan highlights his “[i]nability to lift a suitcase and associated pain” as new. Pet’r’s Reply at 4. He states that his “wife had to help me get [the suitcase] in the overhead bin. Petitioner is right-handed and the right is the [dominant]-lifting arm.” Id. Mr. Haugan describes that it was a significant aggravation of his “shoulder pain, shoulder immobility, joint inflammation and pain.” Id. Mr. Haugan has preponderantly established his condition before the vaccine, his condition after the vaccine, and demonstrated a significant aggravation of his injury, in accord with prongs one through three of Loving.

As such, Mr. Haugan has met his burden establishing that he is entitled to compensation for his shoulder injury.

#### V. Conclusion

Regardless of the causes of Mr. Haugan’s right shoulder and serum sickness injuries, the medical records show that his injuries have caused him a tremendous amount of trouble. As evident in the medical records and consistent with Mr. Haugan’s treating physicians and experts, Mr. Haugan has preponderantly established that he is entitled to compensation for his right shoulder injury. However, Mr. Haugan has not established, by a preponderance of the evidence, that he is entitled to compensation for his serum sickness claim. A separate order regarding damages will issue.

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master