In the United States Court of Federal Claims

No. 21-2133
(Filed: September 3, 2025)
(Re-issued: December 9, 2025)[1]

* *
SHERRI PULSIPHER,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.
* *

Isaiah Kalinowski, Fairfax, VA, and *Jimmy A. Zgheib*, White Plains, NY, for plaintiff.

Rachelle P. Bishop, Trial Attorney, United States Department of Justice, Civil Division, for defendant, with whom were *Brett A Shumate*, Assistant Attorney General, *C. Salvatore D'Alessio*, Director, *Heather L. Pearlman*, Deputy Director, and *Colleen C. Hartley*, Assistant Director.

OPINION

BRUGGINK, *Senior Judge*.

In this vaccine appeal, petitioner argues that the Special Master's decision was not in accordance with law regarding her Shoulder Injury Related to Vaccine Administration ("SIRVA") claim. Petitioner first argues that the regulatory provision the Special Master relied upon to deny her Table Injury claim is invalid, because it conflicts with the burden shifting framework of the National Vaccine Injury Compensation Program ("the Vaccine Act"). Petitioner also argues that the Special Master incorrectly

[1] This opinion was originally issued under seal pursuant to Vaccine Rule 18(b) to afford the parties the opportunity to propose appropriate redactions. The opinion appears as in the original because no redactions were proposed.

applied the legal standards set forth in *Althen* in denying her actual causation claim. Because petitioner failed to raise her regulatory challenge before the Special Master, we find she has waived that argument. We also conclude that the Special Master did not err in his application of *Althen*. Accordingly, we deny petitioner's motion for review and affirm the Special Master's decision.

BACKGROUND

I. The Vaccine Act

The Vaccine Act allows individuals to seek compensation from the federal government for injuries caused by certain vaccines. 42 U.S.C. § 300aa-11(b)(1)(A). Injured individuals can file a petition with the Office of Special Masters against the U.S. Department of Health and Human Services ("HHS"), seeking an award for their vaccine-related injuries. 42 U.S.C. § 300aa-11(a)(1). Under the Vaccine Act, a petitioner can recover under two distinct legal frameworks: (a) by establishing a "Table Injury"; or (b) by establishing that their injury was actually caused by a vaccine referenced in the Vaccine Act. 42 U.S.C. § 300aa-11(c)(1)(C). Both frameworks are discussed below.

a. Establishing a Table Injury

A petitioner is presumed to have experienced a vaccine-caused injury if the circumstances of their injury meet the qualifications of the Vaccine Injury Table—a creature of the Vaccine Act. 42 U.S.C. § 300aa-11(c)(1)(C)(i). If a petitioner sufficiently shows she was administered a vaccine listed on the Table, and that she experienced an injury associated with that vaccine within the enumerated time limit, she has established a Table Injury and has a prima facie entitlement to compensation. 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3(a); *Shalala v. Whitecotton*, 514 U.S. 268, 270–71 (1995) ("[A] claimant may establish a prima facie entitlement to compensation . . . by meeting the requirements of what the Act calls the Vaccine Injury Table."). Once a petitioner has established a prima facie Table Injury claim, the burden of proof then shifts to the government to show by a preponderance of the evidence that "the illness, disability, injury, or condition . . . is due to factors unrelated to the administration of the vaccine described in the petition"—in other words, that the petitioner's injury was actually caused by something other than the vaccine at issue. 42 U.S.C. § 300aa-11(a)(1)(B); *Shalala*, 514 U.S. at 270–71.

The Vaccine Act includes a section titled "Qualifications and Aids to

Interpretation" ("QAI"). 42 U.S.C. § 300aa-14(b); 42 C.F.R. § 100.3(c). This section more specifically defines the types of injuries covered under the Vaccine Injury Table and is supposed to be read in conjunction with the Table. 42 U.S.C. § 300aa-14(b). The Vaccine Act allows the Secretary of HHS to promulgate regulations that modify both the Vaccine Injury Table and the QAI. 42 U.S.C. § 300aa-14(c)(1); *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072, 1078 (Fed. Cir. 2020).

Pertinent to the case at hand, in 2017, the Secretary promulgated a regulation adding SIRVA as an eligible Table Injury. 42 C.F.R. § 100.3(a). A petitioner can establish a SIRVA Table Injury by showing that she was administered a seasonal influenza ("flu") vaccine, and that she experienced SIRVA within 48 hours of receiving that vaccine. *Id.* The QAI to that regulation states the following regarding SIRVA:

> A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

b. Establishing Actual Causation

If a petitioner was administered a vaccine listed on the Vaccine Injury Table but has not experienced a Table Injury (e.g., does not meet the QAI criteria for a SIRVA injury), causation is not presumed. *Shalala*, 514 U.S. at

1479; 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Instead, the petitioner can only recover if she shows by a preponderance of the evidence that the Table vaccine was the actual cause of her injury. 42 U.S.C. § 300aa-11(c)(1)(C)(ii). The Federal Circuit articulated the elements for the off-table causation standard in *Althen v. Sec'y of Health & Hum. Servs*. To establish actual causation, the petitioner must show: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Once a petitioner satisfies all three *Althen* prongs, the burden of proof then shifts to the government to show, "also by a preponderance of [the] evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Id.* (internal citation omitted).

II. Factual History

On October 24, 2020, petitioner, Sherri A. Pulsipher, was administered a flu vaccine in her left shoulder at a pharmacy in Las Vegas, Nevada. Ex. 2 at 2–3; Ex. 11 at ¶ 2. She was 66 years old at the time. According to Ms. Pulsipher, within hours of receiving that vaccine, she started experiencing pain and burning in her left shoulder, which increased in intensity over the following weeks and was accompanied by decreased mobility. Ex. 1; Ex. 11 at ¶ 2. There is no evidence that petitioner experienced these left shoulder symptoms prior to vaccination. Petitioner did not immediately seek medical attention for her shoulder, but instead, for several months, self-treated her symptoms through rest and by taking over-the-counter-anti-inflammatories. Ex. 11 at ¶ 3.

The record reflects a factual disagreement as to when petitioner first sought medical assistance for her shoulder pain. According to Ms. Pulsipher's affidavit, she first sought medical assistance for her shoulder from Andrew Rose, a Certified Physician Assistant, on January 25, 2021, three months after the vaccination. *Id.* at ¶ 4. During that visit, petitioner informed Mr. Rose of her left shoulder symptoms, and he administered a steroid injection in Ms. Pulsipher's left shoulder. *Id.* Contrary to Ms. Pulsipher's affidavit, however, the documentation for petitioner's visit with Mr. Rose does not reference any reported issues with her left shoulder—instead referencing a myriad of other unrelated medical issues, including generalized anxiety disorder, insomnia, depression, hypertension, and gastroesophageal reflux disease. Ex. 5 at 31. There is also no medical

documentation supporting petitioner's claim that she received a steroid injection in her left shoulder. *See generally id.* at 29–32.

About one month later, on February 22, 2021, Ms. Pulsipher visited Dr. Stephen Kirk, a sports medicine physician. Ex. 6 at 8–11. The documentation for that visit does reference her left shoulder pain. She described her pain as "aching, burning, intermittent, [and] stabbing," and relayed additional symptoms such as "stiffness, tenderness, [and] weakness." *Id.* at 8. Petitioner informed Dr. Kirk that her symptoms started after she received the flu shot in October. *Id.* Upon physical examination of Ms. Pulsipher's left shoulder, Dr. Kirk observed that Ms. Pulsipher's range of motion was mildly restricted in all planes of motion, she was moderately tender in the lateral part of her shoulder and mildly tender in the anterior and posterior parts of her shoulder, and that she experienced mild pain and weakness during the abduction external rotation of her shoulder. *Id.* at 9. After conducting several tests involving the movement of her arm and shoulder, Ms. Pulsipher tested positive for shoulder impingement.[2] *Id.* Dr. Kirk also performed an x-ray of Ms. Pulsipher's left shoulder. *Id.* That x-ray revealed that there was severe narrowing of the glenohumeral joint and that osteophytes (i.e., extra bone growth at the joint) were present at the humeral head. Ex. 6 at 9.

Based on Ms. Pulsipher's physical examination, Dr. Kirk diagnosed petitioner with left shoulder rotator cuff impingement syndrome. *Id.* at 10. Dr. Kirk noted that, although the x-ray supported a potential diagnosis of glenohumeral osteoarthritis, Ms. Pulsipher's "symptoms do not seem to be focal to this presently," and Dr. Kirk thus favored the impingement syndrome diagnosis. *Id.* He also noted, however, that he would "like to see how she does over the course of treatment to see how she responds to the impingement type treatment and whether or not she develops or presents with more glenohumeral pain in the future." *Id.* Dr. Kirk administered a steroid injection into petitioner's subacromial bursa that same day.[3] *Id.* He determined that, if the subacromial bursa injection did not provide Ms. Pulsipher with significant relief, he "would strongly consider injecting the glenohumeral joint." *Id.*

---

[2] These tests are referred to as the Neer, Hawkins-Kennedy, and Empty Can tests. Ex. 6 at 9.

[3] This is a part of the shoulder often associated with impingement syndrome.

On March 8, 2021, petitioner visited Mr. Rose again. The visit was for, among other things, epigastric abdominal pain. Ex. 5 at 25–27. No mention was made of her left shoulder symptoms, and, in fact, upon physical examination, Mr. Rose found "no malalignment or tenderness" to Ms. Pulsipher's joints, bones, and muscles, and found "normal movement of all extremities." *Id.* at 29. Mr. Rose instructed petitioner to avoid alcohol, caffeinated beverages, nicotine products, strenuous exercise, and large meals prior to bedtime. *Id.* The next day, on March 9, 2021, petitioner visited Mr. Rose again for a cough she was experiencing. *Id.* at 22, 24. Petitioner's shoulder symptoms were once again not mentioned. Mr. Rose diagnosed Ms. Pulsipher with acute sinusitis (i.e., a sinus infection) and prescribed an antibiotic and cough suppressant. *Id.* at 25.

On April 14, 2025, petitioner visited the Mesa View Regional Hospital Emergency Department for her epigastric abdominal pain. Ex. 7 at 16. Again, no shoulder symptoms were mentioned. Additionally, the emergency department physician, Dr. Jarrod Johnson, found "[f]ull, normal range of motion" during his physical examination. *Id.* Petitioner was administered and prescribed medication and was discharged that same day. *Id.* at 19.

On April 21, 2021, petitioner began seeing another Certified Physician Assistant, Rodney Briggs, at the Mesa View Medical Group. Ex. 5 at 15. During her initial appointment with Mr. Briggs, petitioner reported various symptoms, including "[f]atigue, muscle cramps, generalized pain, headaches, confusion, memory impairment, [and] imbalance." *Id.* at 17. She also reported her epigastric issues but did not report any abdominal pain. *Id.* Petitioner's shoulder symptoms were not specifically mentioned, and Mr. Briggs recorded "normal movement of all extremities" during his physical exam. *Id.* at 18. Mr. Briggs scheduled Ms. Pulsipher for a follow-up appointment on May 4, 2021 with Dr. Soon Kim, a general surgeon at the Mesa View Medical group, regarding her epigastric condition. *Id.* At that appointment, no shoulder symptoms were mentioned. During Dr. Kim's routine physical examination of petitioner's joints, bones, and muscles, Dr. Kim recorded "no malalignment or tenderness and normal movement of all extremities." *Id.* at 8–10.

On May 5, 2021, petitioner returned to Dr. Kirk regarding her shoulder pain. She informed Dr. Kirk that the injection to her subacromial bursa "didn't help her at all" and wanted to "see what she should do next[.]" Ex. 6 at 55. Dr. Kirk's physical examination of Ms. Pulsipher's left shoulder

was substantially the same as his examination in February—although his overall diagnosis differed. *Id.* at 55–56. Because the subacromial bursa injection failed to provide significant relief to Ms. Pulsipher's shoulder pain, he considered glenohumeral osteoarthritis as the probable "primary source of her pain," and considered impingement syndrome to be a "lesser diagnosis," although he did not completely remove impingement syndrome as a potential diagnosis, as petitioner "still ha[d] some pain and weakness on abduction external rotation." *Id.* at 56. Dr. Kirk and Ms. Pulsipher discussed a variety of treatment options, including an injection of the glenohumeral joint space; however, petitioner wanted a more advanced diagnostic of her shoulder before moving forward. *Id.* Dr. Kirk referred Ms. Pulsipher for an MRI of her left shoulder. *Id.*

An MRI of petitioner's left shoulder was conducted on May 13, 2021. *Id.* at 53–54. The radiologist, Dr. Don Williams, found, among other things, tendonitis in the rotator cuff, profound circumferential degeneration of the labrum in the glenohumeral joint, small glenohumeral osteophytes, and a small inferior clavicular head osteophyte. *Id.* There were no findings of subacromial bursitis (i.e., inflammation of the subacromial bursa). Ex. 6 at 54. Dr. Williams's impressions was that petitioner was experiencing severe glenohumeral osteoarthritis, mild-to-moderate tendonitis in the rotator cuff area, mild tendonitis near the front of her shoulder blade, and moderate acromioclavicular osteoarthritis. *Id.* Dr. Kirk reviewed Ms. Pulsipher's MRI results with Dr. Williams and met with petitioner that same day. *Id.* at 49–52, 54.

After reviewing Ms. Pulsipher's MRI results, Dr. Kirk's assessment was that petitioner had severe glenohumeral osteoarthritis and rotator cuff tendonitis. *Id.* at 51. He advised her that "the most appropriate next step in her treatment is to surgically treat the shoulder. A reverse shoulder replacement would be the most appropriate treatment choice given the severe arthritis and rotator cuff pathology present." *Id.* A reverse shoulder replacement surgery was subsequently scheduled with Dr. Todd Parry, an orthopedic surgeon. *Id.*

Ms. Pulsipher underwent shoulder replacement surgery on June 16, 2021. Ex. 5 at 160. Although Dr. Kirk advised petitioner to undergo surgery due, in part, to her glenohumeral osteoarthritis, the pre- and postoperative diagnosis on Dr. Parry's operative report only mentioned "rotator cuff arthropathy." *Id.* Approximately two weeks later, at the postoperative follow-up appointment, petitioner reported "progressively less pain over the last

several weeks," and that "[s]he has worked with the physical therapist . . . as per the protocol and made reasonable progress," although she was still using a shoulder sling. Ex. 6 at 94. At petitioner's six-week follow-up appointment, she reported "not taking any pain medication," and that she was "moving [her] shoulder a little more the past few days." *Id.* at 99. Ms. Pulsipher was advised she could "discontinue use of the sling but continue to be cautious in regard to her activities." *Id.* at 101.

Petitioner underwent post-operative physical therapy for her shoulder between July 27, 2021 and September 2, 2021. *See generally* Ex. 8. At her last recorded appointment, she reported that "her shoulder is doing better." Ex. 8 at 47. Her physical therapists noted that petitioner "has less fatigue after completing her exercises showing an increase in endurance," that her "[upper extremity] strength has also increased but remains limited," and that "[s]he had a slight increase in pain when performing [internal rotations] with [a] strap that decreased once the exercise was complete." *Id.*

On September 7, 2021, at petitioner's three-month post-operative follow-up with Dr. Parry, petitioner stated that she was "'totally amazed' at her results thus far." Ex. 6 at 107. It was recorded that she "shows great motion in the shoulder, having worked hard in physical therapy. X-rays taken today show that the components are perfectly aligned. She is well informed, is doing well, and will follow up . . . at the one year postop mark." *Id.* Petitioner's affidavit conforms with this information, as she states that, at the three-month mark, she was "generally satisfied with [her] progress." Ex. 11 at ¶ 16.

Unfortunately, at petitioner's one-year post-op visit with Dr. Parry, she reported that "her shoulder has been causing her a lot of pain the last few months[,] [s]he does not remember injuring it at all," and that "[t]he pain radiates into the neck and down the arm." Ex. 10 at 6. A physical examination of her shoulder showed "a well-healed scar with no heat, redness or soft tissue swelling," but that there was "weakness with internal and external rotation." *Id.* at 8. An x-ray of petitioner's left shoulder showed that, despite petitioner's recorded symptoms, the "prosthesis appear[ed] well fixated without concern for loosening" and there was "no evidence of acute fracture or dislocation." *Id.* Although Ms. Pulsipher was prescribed an anti-inflammatory and was recommended to once again attend physical therapy, she did not attend any further physical therapy sessions (she continued to perform at-home exercises, however). *Id.*; Ex. 11 at ¶¶ 17–19.

Petitioner claims that she continues to experience pain and dysfunction in her left shoulder "to this day," and that she has "difficulty with activities of daily living involving [her] left shoulder." Ex. 11 at ¶ 19. Despite the treatment she has received, she believes that her "left shoulder will never be the same again." *Id.*

III. Procedural History

Ms. Pulsipher filed her petition in the Office of Special Masters on November 4, 2021, requesting compensation under the Vaccine Act for SIRVA allegedly caused by the flu vaccine. The parties filed their respective expert reports and medical literature between August 9, 2023, and February 23, 2024.

a. Petitioner's Expert Opinion

Petitioner's expert, Dr. Uma Srikumaran, Associate Professor in the Department of Orthopedic Surgery at Johns Hopkins University, stated in his expert report that the record supports Ms. Pulsipher's SIRVA claim under both legal frameworks of the Vaccine Act. Ex, 12 at 1, 5, 8–9.

First, Dr. Srikumaran stated that both Ms. Pulsipher's medical records and sworn statements satisfy all four QAI requirements of a SIRVA Table Injury claim. *Id.* at 5. He highlighted that there was no indication from Ms. Pulsipher's medical records that she had any prior history of pain or dysfunction in her left shoulder. *Id.* Additionally, her pain is consistently documented as limited to her left shoulder. *Id.* Although petitioner's appointment with Mr. Rose in January did not reference any shoulder pain or steroid injection, Dr. Srikumaran credited petitioner's affidavit that her symptoms occurred within 48 hours of vaccination. *Id.* Moreover, although her appointment with Mr. Rose occurred several months after Ms. Pulsipher was administered a flu vaccine, Dr. Srikumaran noted that "the vast majority of patients do not have their pain . . . evaluated within 48 hours," and that "[m]ost people are hopeful things will improve with time and basic measures and try several over the counter remedies for many weeks or months before seeking professional evaluation." *Id.* at 6.

In addressing the last requirement of a SIRVA Table Injury—that petitioner must show that no other condition or abnormality is present that would explain the symptoms—Dr. Srikumaran acknowledged the petitioner's underlying glenohumeral osteoarthritis, and that the "condition takes decades to develop." Ex. 12 at 7. He opined, however, that her

glenohumeral osteoarthritis did not explain her symptoms, as "it was completely asymptomatic prior to her vaccination." Instead, the administered vaccination "caused, or 'triggered,' a previously asymptomatic chronic condition to become painful." *Id.* at 7–8.

Second, Dr. Srikumaran stated that petitioner's claim also meets the requirements for actual causation. *Id.* at 8. Dr. Srikumaran's medical theory of causation was that Ms. Pulsipher received the flu vaccine inadvertently near the subacromial bursa, which resulted in an inflammatory reaction, causing bursitis. *Id.* at 8–9. Bursitis then led to the activation of painful glenohumeral arthritis, which had previously been asymptomatic. *Id.*

To support his medical theory, Dr. Srikumaran pointed to a 2010 article involving research from the Department of Health and Human Services and the University of Kentucky School of Medicine, showing that 46% of Vaccine Act claims involving shoulder pain and dysfunction between 2006 and 2010 also involved vaccines that were administered high in the deltoid, and 93% of those patients experienced pain and limited range of motion within 24 hours of vaccine administration. Ex. 12 at 11. He also cited a 2007 article by Bodor and Montalvo, showing two cases of "shoulder pain, decreased range of motion, and weakness after vaccine injection," in which "both cases involved injections 'high' . . . into the deltoid muscle with symptoms beginning two days after injection." *Id.* at 10; Ex. 12, Tab D. The authors to that study hypothesized that the administered vaccine "was injected into the subacromial bursa, 'causing a robust local immune and inflammatory response.'" Ex. 12, Tab D at 2. Dr. Srikumaran then went on to cite a host of scientific literature supporting the notion that vaccines—in particular, the poor administration of vaccines—have "the potential for inducing a prolonged immune-mediated inflammatory reaction," leading to the "[r]isk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations." Ex. 12 at 8–9; *see also* Ex. 12, Tab A.

In his attempt to connect vaccine-caused inflammation to arthritis, Mr. Srikumaran cited one 1962 study, the Dumonde study, where an immunological reaction caused by the injection of antigenic material in rabbits produced arthritis. Ex. 12 at 9, 11; Ex. 12, Tab G; Ex. 14 at 4. Dr. Srikumaran, however, admitted that "[t]he production of arthritis in rabbits secondary to an immunological reaction observed and documented in the Dumonde study is the only of its kind to demonstrate production of arthritis as the result of antigenic material." Ex. 14 at 4.

Dr. Srikumaran then went on to explain how petitioner's case conformed with his medical theory of causation. According to Dr. Srikumaran, petitioner's initial symptoms were not only consistent with left shoulder impingement syndrome, but also with subacromial bursitis (although he also mentions that impingement syndrome is a generalized term and can be secondary to, among other things, glenohumeral arthritis as well). Ex. 12 at 13; Ex 14 at 4. During petitioner's initial appointment with Dr. Kirk, she was administered a steroid injection to her subacromial bursa, which addressed her bursitis—evidenced by the fact that her May 13 MRI findings found no subacromial bursitis in her left shoulder. Ex. 14 at 2. Despite the fact the steroid injection was successful in reducing petitioner's subacromial inflammation, during the time between vaccine administration and the steroid injection, the inflammation in her subacromial bursa spread to her glenohumeral joint, which activated her preexisting yet asymptomatic glenohumeral arthritis. *Id.* According to Dr. Srikumaran, this explains why petitioner was still feeling pain in her shoulder after the steroid injection to her subacromial bursa, as well as Dr. Kirk's second diagnosis, favoring glenohumeral osteoarthritis over impingement syndrome as the likely diagnosis. *Id.*

b. Respondent's Expert Opinion

Respondent's expert, Dr. Geoffrey D. Abrams, Professor of Orthopedic Surgery at the Stanford School of Medicine, stated that petitioner's medical record and history "confirmed diagnosis of shoulder arthritis [as] a more likely source of her shoulder pain than SIRVA." Ex. A at 1, 4. In support of his conclusion, Dr. Abrams noted that "[s]houlder arthritis is a very common cause of shoulder pain, with an increasing incidence as patients age and is seen most commonly in those over 50 years of age." *Id.* at 4. Arthritis development, especially in the shoulder, "is a slow process and takes years for clinical symptoms to express themselves." *Id.* He mentioned that, although there is indeed a period where arthritis is present prior to symptoms, "everyday activities (i.e., carrying groceries, sleeping on the shoulder, and other normal activities which patients do not recognize as traumatic) can initiate pain from shoulder arthritis." *Id.* As a result, "it is exceedingly common (the great majority) for patients with underlying arthritis as a cause of their shoulder pain to not recall any specific event which they can attribute to the onset of their symptoms." *Id.*

Moreover, in response to Dr. Srikumaran's medical theory connecting vaccine-caused inflammation to arthritis pain, Dr. Abrams stated, "the ability

of a vaccination to 'trigger' symptoms related to arthritis is not a known clinical entity," and that "a vaccination would be unlikely to affect the intra-articular space of the shoulder, where the arthritis is located," because "the rotator cuff . . . provides a barrier between the subacromial and intra-articular spaces." *Id.* at 5; Ex. C at 2–3. Dr. Srikumaran also cited a position statement from the American Academy of Orthopedic Surgeons ("AAOS"), stating that "vaccination administered to the shoulder is unlikely to cause or contribute to common shoulder pathologies such as . . . glenohumeral arthritis." Ex. A-3 at 3; Ex. A at 7–8.

Regarding Ms. Pulsipher's medical record, Dr. Abrams pointed out that petitioner's first visit to a health care provider post-vaccination produced no documentation regarding her shoulder symptoms or any administered steroid injection to petitioner's shoulder. Ex. A at 5–6. Although Dr. Abrams stated that he has seen medical record errors before, he also stated that "[t]he chance that the provider not only failed to record that the petitioner reported shoulder pain as well as also failed to report that an injection was given is improbable." *Id.* at 6. Additionally, though it is possible that those who experience SIRVA may not seek medical care for their shoulder pain within the first 48 hours, it is unusual for a patient to not seek medical care for their pain for several months after the occurrence. *Id.* Instead, Dr. Abrams suggested that petitioner's recounting of the circumstances surrounding her vaccination are likely "susceptible to distortion," as "memory has proven unreliable in recollection of facts surrounding an event, particularly as the duration of time passes from the event occurrence," potentially resulting in the "retrospective attribution of musculoskeletal pain to some prior event." *Id.* at 7.

Dr. Abrams noted that it was not until petitioner's visit with Dr. Kirk on February 22, 2021 that her shoulder symptoms and steroid injection were first recorded; and although Dr. Kirk recorded an initial diagnosis of impingement syndrome, according to Dr. Abrams, positive examination findings of impingement syndrome are not only independently associated with bursitis, but also with pre-existing arthritis. *Id.* at 4–5; Ex. C at 3–4.

Dr. Abrams also stated that "the mechanism of SIRVA centers around injection of antigenic material into the subacromial space, with resulting inflammation (and therefore clinical symptoms) in the shoulder area," but that there was no indication from petitioner's MRI that there was any significant tearing in her rotator cuff that could have possibly allowed any inflammation in the subacromial space to affect the arthritis-affected space.

Ex. C at 2. Furthermore, petitioner claimed she did not experience any pain relief from the steroid injection administered by Dr. Kirk, which Dr. Abrams asserted contradicts a SIRVA diagnosis. *Id.* at 3–4. According to Dr. Abrams, with such an injection, one would "expect to see at least some inflammatory reaction or 'bursitis' . . . on the MRI"; however, petitioner's MRI results indicated "no subacromial/subdeltoid bursitis." Ex. A at 5; Ex. 6 at 54. Alternatively, the February 22 (pre-injection) and May 5 (post-injection) appointments with Dr. Kirk consistently showed petitioner's mild range of motion, the February 22 x-ray of petitioner's shoulder showed small osteophytes present (which Dr. Abrams described as the "hallmark of joint arthritis"), and the May 13 MRI findings showed "severe glenohumeral osteoarthritis," which all support the opinion that petitioner's shoulder pain was independently caused by her pre-existing osteoarthritis. Ex. A at 4–5.

c. Parties' Arguments

Before the Office of Special Masters, petitioner argued that she had demonstrated a Table Injury, because (1) she had no history of pain, inflammation or dysfunction in her left shoulder before receiving the flu vaccination; (2) the onset of her pain occurred within 48 hours of vaccine administration; (3) her symptoms were limited to the left shoulder; and (4) no other condition or abnormality was present that would explain her symptoms.

Regarding the last QAI prong, petitioner argued that, although medical evidence of petitioner's underlying osteoarthritis was present, it did not wholly explain petitioner's shoulder symptoms, as the progression of arthritis symptoms is slow and the medical records in this case show petitioner experienced sudden shoulder symptoms after vaccination. Thus, according to petitioner, Dr. Srikumaran's explanation of events—that the vaccination caused an inflammatory reaction which triggered petitioner's arthritis symptoms—is more consistent with the medical record.

Petitioner alternatively claimed recovery under an actual causation theory. First, petitioner stated that Dr. Srikumaran's medical theory (*Althen* prong one) is sound, because it is generally accepted that administering a vaccine inadvertently into the rotator cuff can cause an inflammatory response; and because it is widely recognized that osteoarthritis may cause no symptoms until aggravated by another event. Second, to support a logical sequence of cause and effect (*Althen* prong two), petitioner pointed to Dr. Srikumaran's opinion that petitioner likely experienced inflammation due to

inadvertent administration of the flu vaccine near her subacromial bursa, causing bursitis, which eventually aggravated her previously asymptomatic osteoarthritis. Third, petitioner claimed that a proximate temporal relationship (*Althen* prong three) exists between the vaccination and her injuries, arguing that her records demonstrate that she consistently placed the onset of her condition within 48 hours of vaccination and reported the onset of her symptoms "after" or "suddenly after" the October 24, 2020 vaccination.

Before the Special Master, respondent countered that petitioner cannot recover under a Table Injury claim, because the record does not establish that her pain began within 48 hours of vaccination. Although petitioner signed an affidavit alleging that she started feeling her shoulder symptoms within 48 hours of vaccine administration, she did not report her shoulder pain to Mr. Rose until January 25, 2021—more than 3 months post-vaccination. Moreover, respondent pointed out that petitioner's medical encounter with Mr. Rose showed no documentary evidence of shoulder complaints or treatment. It was not until her first appointment with Dr. Kirk on February 22 that there was documentary evidence showing her shoulder complaint and subsequent treatment. Petitioner also had a number of medical appointments in which she did not mention her shoulder symptoms, instead raising a variety of other medical issues, including, among other things, depression, sinus infection, and epigastric pain. Thus, respondent argued that petitioner's affidavit regarding the onset of her symptoms within the 48-hour window and the circumstances of her initial appointment with Mr. Rose should be given less deference due to its contradiction by the documentary evidence.

Respondent also argued that petitioner has not established the fourth QAI requirement for a SIRVA Table Injury claim—that no other condition or abnormality is present that could explain petitioner's symptoms—because petitioner's arthritis independently explains her symptoms. Respondent referenced petitioner's x-ray and MRI findings that confirmed petitioner's moderate-to-severe osteoarthritis, including the presence of osteophytes, which could not have developed within only several months of vaccination. Moreover, petitioner's lack of relief from her shoulder symptoms after receiving the subacromial steroid injection and her MRI finding of "[n]o subacromial/subdeltoid bursitis" points away from SIRVA. According to respondent, petitioner's physical exam findings pre- and post-steroid injection both show "mild" restriction on all planes, suggesting the cause of her shoulder pain was the same between both visits.

Regarding petitioner's alternative actual causation theory for recovery, respondent asserted that petitioner has not established a persuasive or reliable medical theory under *Althen* prong one. This is because, where, as with petitioner, the rotator cuff is largely intact, it is unlikely that any inflammation in the subacromial bursa would spread to the intra-articular space (where petitioner's osteoarthritis is located), as the two spaces are separated by the rotator cuff. Although respondent recognized the existence of medical literature supporting the fact that vaccination can cause inflammation, respondent claims that petitioner fails to cite any credible medical literature linking vaccine-caused inflammation to arthritis. In fact, the AAOS specifically refutes this theory. Thus, respondent claimed petitioner's medical theory is without any indicia of reliability.

Respondent also claimed that, even if petitioner's medical theory is sound, under *Althen* prong two, petitioner has failed to establish a logical sequence of events comporting with that medical theory. This is because petitioner's MRI failed to show any signs of bursitis; the steroid injection in petitioner's left shoulder offered no pain relief; petitioner's rotator cuff was intact; both Dr. Kirk and Dr. Williams attributed petitioner's shoulder pain to osteoarthritis; and the parties agree that osteoarthritis is a slow-developing condition, that petitioner had osteoarthritis before her vaccination, and that it is exceedingly common for arthritis symptoms to be triggered by everyday activities.

For *Althen* prong three, respondent claimed that petitioner had not established a proximate temporal relationship between her vaccination and her alleged injury. Although petitioner alleges her shoulder symptoms began within 48 hours of receiving the flu vaccine, the medical record does not support this notion. Respondent highlights that petitioner first reported her symptoms several months after the vaccination. As a result, respondent argued that petitioner had not satisfied by a preponderance of the evidence her actual causation theory.

d. Special Master Findings

Special Master Daniel T. Horner filed his decision on April 24, 2025, ruling against petitioner under both frameworks of compensation. *See generally Pulsipher v. Sec'y of Health & Hum. Servs.*, No. 21-2133V, 2025 WL 1364203 (Fed. Cl. Spec. Mstr. Apr. 24, 2025).

In finding that petitioner failed to establish a SIRVA Table Injury, Special Master Horner found that, even if petitioner met the second QAI

criterion—that pain occurred within the 48-hour time period—she did not meet the fourth QAI criterion—that no other condition or abnormality could explain petitioner's symptoms. *Id.* at *11. More specifically, Special Master Horner determined that petitioner had not "preponderantly demonstrated that the pattern of onset she experienced is incompatible with glenohumeral osteoarthritis being the explanation for her symptoms irrespective of her vaccination." *Id.* According to Special Master Horner, this was because of the following evidence: Dr. Kirk concluded that glenohumeral osteoarthritis was the more likely cause of petitioner's shoulder pain; signs of impingement syndrome are not specific to bursitis and may be caused by other conditions, including osteoarthritis; petitioner's physical exam findings between February 22, 2021, and May 5, 2021 were substantially the same, indicating the same condition was present in both instances; and that arthritis symptoms can occur as a result of normal everyday activities, which patients may not recognize as the trigger of their pain. *Id.* Because petitioner had failed to satisfy the fourth QAI criterion for a SIRVA injury, she could not recover under a Table Injury claim. *Id.* at *10–11.

Special Master Horner also found that petitioner had not established actual causation under *Althen* prongs one and two. *Id.* at *11. He recognized that petitioner may satisfy prong one—that petitioner proffer a reputable medical theory—"without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory." *Pulsipher*, 2025 WL 1364203 at *11 (citing *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009)). He also noted, however, that a petitioner must nonetheless "provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Id.* (quoting *Boatman v. Sec'y of Health and Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019)). After reviewing the medical literature submitted by petitioner, he noted that only 5.2% of SIRVA claimants have MRI findings of glenohumeral arthritis, and he determined that, "it does not suffice without more to demonstrate that glenohumeral arthritis is a pain generator among these individuals, rather than an incidental finding." *Id.* at *12; Ex. 12, Tab K at 5.

Special Master Horner further noted that the 1962 Dumonde study is the "only study of its kind to demonstrate production of arthritis as the result of antigenic material." *Pulsipher*, 2025 WL 1364203 at *12. Moreover, the specific type of arthritis provoked in that study, according to its authors, bore "a striking resemblance to rheumatoid arthritis," which is an autoimmune

condition—not a degenerative condition (such as osteoarthritis). *Id.* As a result, Special Master Horner found that "Dr. Srikumaran has not substantiated that the Dumonde findings are informative with respect to osteoarthritis." *Id.* Moreover, Special Master Horner stated that, even if the Dumonde study was some evidence supporting the connection between an antigenic injection and osteoarthritis, this would still not support petitioner's medical theory, because, as Dr. Abrams points out, the subacromial bursa and glenohumeral joint are still separated by the rotator cuff. *Id.* at *12. Thus, petitioner did not satisfy prong one of *Althen*. *Id.* at *13.

Regarding the second *Althen* prong—establishing a logical sequence of cause and effect—Special Master Horner found that "the same reasoning that prevents petitioner from meeting the Table requirements . . . equally hinders her demonstration of causation-in-fact." *Id.* His analysis emphasized that "treating physician opinions carry significant weight," and that the treating physician in petitioner's case, Dr. Kirk, "never opined that her condition was vaccine caused" and "explicitly opined that petitioner's osteoarthritis was the more likely cause of her pain." *Id.* Even if Dr. Srikumaran's medical theory of causation was generally correct regardless of Dr. Kirk's opinion, Special Master Horner contemplated "whether any sequence of cause and effect would be possible in petitioner's own case, given that she had no full thickness rotator cuff tear that could potentially expose the glenohumeral space to the inflammatory response purportedly beginning within the subacromial space." *Id.* Thus, petitioner did not satisfy *Althen* prong two either. *Id.* at *14.

e. Appeal to this Court

Petitioner filed her motion for review of Special Master Horner's decision on May 27, 2025, arguing that the Special Master's decision was not in accordance with law. In support of her motion, petitioner first argues that the regulation the Special Master relied upon in denying petitioner's Table Injury—the fourth QAI criterion for a SIRVA Table Injury—was promulgated without authority, as it conflicts with the burden-shifting framework of the Vaccine Act. Petitioner next argues that the Special Master applied the wrong legal standard in *Althen* prong one by allegedly requiring petitioner to provide medical literature to support her medical theory and in *Althen* prong two by requiring petitioner to show in her chain of causation that the flu vaccine was the sole or superseding cause over osteoarthritis for her shoulder symptoms.

Respondent filed its response to petitioner's motion on June 25, 2025, arguing that: (1) petitioner waived her statutory authority argument, because it was not first raised before the Office of Special Masters; (2) the Secretary, in any event, acted within his authority in promulgating the fourth QAI criterion; (3) even in the event the Secretary exceeded his authority, the petitioner has no meaningful relief, as the court cannot sever the fourth criterion from the rest of the rule; (4) Special Master Horner did not require petitioner to provide medical literature but merely reviewed the medical literature provided by the parties; and (5) Special Master Horner did not require petitioner to show that the flu vaccine was the sole or superseding cause of her shoulder symptoms.

On August 6, 2025, we directed petitioner to file a reply solely addressing whether petitioner waived her statutory authority argument before this court, given that she had not first raised it before the Office of Special Masters. Petitioner filed her reply on August 13, 2025, claiming that she had indeed raised that argument before the Office of Special Masters, and that, even if it had not been raised below, waiver is discretionary and ought not be applied in these circumstances. Oral argument was held on August 18, 2025.

DISCUSSION

I. Jurisdiction and Standard of Review

The Court of Federal Claims has jurisdiction under 42 U.S.C. § 300aa-12(d)(3)(A) to review decisions made by the Office of Special Masters regarding petitions under the Vaccine Act. *See also Shaw v. Sec'y of Health & Hum. Servs.*, 609 F.3d 1372, 1375 (Fed. Cir. 2010); *Terran ex rel. Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1307 (Fed. Cir. 1999). We may set aside findings of fact or conclusions of law made by the special master that we find "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B); *see also Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 867–68 (Fed. Cir. 1992). The special master's determinations of law are reviewed *de novo*, *Demore v. Sec'y of Health & Hum. Servs.*, 175 Fed. Cl. 756, 760 (2025), and the special master's findings of fact are reviewed for clear error. *Rus v. Sec'y of Health & Hum. Servs.*, 129 Fed. Cl. 672, 678 (2016). In doing so, we may issue our own findings of fact and conclusions of law or remand the petition to the special master for further action. 42 U.S.C. § 300aa-12(e)(2)(B)–(C).

After reviewing the record before us, we cannot grant petitioner's

motion. We reject her Table Injury claim, because petitioner failed to raise her statutory authority argument before the Special Master. We reject her actual causation claim, because she has not demonstrated that Special Master Horner erred in his application of *Althen*.

II. Petitioner Has Waived Her Statutory Authority Argument

Petitioner first argues that the fourth QAI criterion for a SIRVA Table Injury was promulgated by the Secretary without authorization, because the provision conflicts with the burden of proof framework contemplated by the Vaccine Act. More specifically, as the provision requires petitioner to show that "[n]o other condition or abnormality is present that would explain the patient's symptoms," petitioner is essentially required to prove that the vaccine actually caused her symptoms in order to show a valid SIRVA Table Injury. According to petitioner, a requirement to prove actual causation for a Table Injury runs contrary to the Vaccine Act, because meeting the vaccination, injury, and timeframe requirements of the Injury Table is intended to create a *presumption* of causation. The QAI is only supposed to limit the scope of what constitutes an injury under the Act, not increase the petitioner's burden of proof. Under the Table Injury framework, it is not until the burden of proof shifts to the government that the *government* must prove that petitioner's symptoms were actually caused by "factors unrelated to the administration of the vaccine." Thus, according to petitioner, Special Master Horner's decision regarding petitioner's failure to establish a Table Injury, which wholly relied on the provision at issue, should be set aside, as it was not in accordance with law.

We note that respondent makes several substantive counterarguments to petitioner's statutory authority argument. As a threshold matter, however, we must first address respondent's procedural counterargument—that petitioner waived her statutory authority argument by not first raising it before the Special Master. For the reasons below, we agree with respondent that the issue was not preserved and is therefore waived.

Rule 8(f) of the Vaccine Rules makes it clear that "[a]ny fact or argument not raised specifically in the record before the special master will be considered waived and cannot be raised by either party in proceedings on review of a special master's decision." Vaccine Rule 8(f)(i). Indeed, consistent with this rule, the Federal Circuit has routinely held that arguments not made before the special master are waived on appeal. *Davis v. Sec'y of Health & Hum. Servs.*, 409 F. App'x 342, 344 (Fed. Cir. 2011) ("Because

[petitioner] points to nothing in the record establishing that [her] arguments . . . were adequately presented to the special master, we decline to consider those arguments on appeal."); *Weddel v. Sec'y of Dep't of Health & Hum. Servs.*, 23 F.3d 388, 390 n.2 (Fed. Cir. 1994) ("The government correctly observes that [petitioner] failed to raise before the [s]pecial [m]aster the . . . arguments they now press."); *Jay v. Sec'y of Dep't of Health & Hum. Servs.*, 998 F.2d 979, 983 n.4 (Fed. Cir. 1993) (finding that, because petitioner did not raise an issue before the special master, "[w]e thus conclude, as did the Claims Court, that it was abandoned."). This court's holdings are consistent. *E.g.*, *Austin v. Sec'y of Health & Hum. Servs.*, 141 Fed. Cl. 268, 277 (2018), *aff'd*, 818 F. App'x 1005 (Fed. Cir. 2020); *Hellenbrand-Sztaba v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 222, 225 (1996), *aff'd*, 106 F.3d 426 (Fed. Cir. 1997); *McMillan v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 357, 358–59 (1992).

The general rule that a court will not consider issues not first raised at the initial adjudicatory forum is rooted in sound policies:

> It ensures finality in litigation by limiting the appealable issues to those a lower court had an opportunity to, and did, address. The rule also conserves judicial resources because it prevents parties from undoing a lower court's efforts—sometimes spanning years of litigation—based on an error that a lower court could have considered and corrected. In the same regard, the rule discourages parties from inviting an alleged error below only to raise it on appeal.

HTC Corp. v. IPCom GmbH & Co., KG, 667 F.3d 1270, 1281–82 (Fed. Cir. 2012).

In her reply brief here, petitioner argues that she indeed raised the statutory authority issue before the Special Master, quoting the following language from her reply brief before the Special Master:

> "[I]n presenting her prima facie case under the Vaccine Injury Table, petitioner does not bear any burden of proving causation generally or to show that her shoulder pathology can be directly related to her vaccination as causal. It would be incompatible with the very idea of the Vaccine Injury Table to hold petitioner to a burden of proving causation to establish a Table Injury."

Pet'r's Reply Br. at 4, *Pulsipher v. Sec'y of Health & Hum. Servs.*, No. 21-2133V, 2025 WL 1364203 (Fed. Cl. Spec. Mstr. Apr. 24, 2025) (quoting *Lang v. HHS*, No. 17-995V, 2020 WL 7873272, at *13 n.9 (Fed. Cl. Spec. Mstr. Dec. 11, 2020)).

According to petitioner, although her filings before the Office of Special Masters do not explicitly mention the issue of statutory authority, the statutory authority argument she brings before us is a logical extension of the language used above—not a completely new argument.[4] We disagree.

Petitioner primarily relies on this court's decision in *Spahn v. Sec'y of Health & Hum. Servs.*, 138 Fed. Cl. 252 (2018). In *Spahn*, before the special master, the respondent argued that the special master had an independent duty to determine reasonable attorneys' fees and costs and requested that the special master "exercise his discretion" in doing so. *Id.* at 260–61 (internal citations omitted). On the respondent's appeal to this court, the respondent argued that the special master abused his discretion in determining a reasonable award for the petitioner, because he failed to make an independent finding regarding the reasonableness of fees and costs. *Id*. Respondent also argued on appeal, however, that the special master's independent duty to determine reasonable fees and costs is rooted in Supreme Court and Federal Circuit caselaw. *Id.* at 261. The petitioner argued the respondent had waived his caselaw argument under Rule 8(f), as that specific argument was not first raised before the special master. *Id.* We rejected petitioner's argument, however, writing that, although respondent did not specifically raise the additional supporting caselaw before the special master, "the Secretary's argument in this regard simply expands upon the core argument that the Secretary did present to the special master." *Id.*

We find petitioner's reliance on *Spahn* misplaced, as the statutory authority argument petitioner presents now is not rooted in the same "core argument" brought before the Special Master. Petitioner did indeed articulate the following legal standard: a petitioner generally has no obligation to prove causation when establishing a prima facie Table Injury. Petitioner cited this

[4] "While 'a waiver may occur if a party raises a new issue on appeal . . . [a] waiver will not necessarily occur . . . if a party simply presented new or additional arguments in support.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1359–60 (Fed. Cir. 2008) (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1370–71 (Fed. Cir. 2002)).

standard, however, *in support* of her argument that she satisfied the fourth QAI criterion for a SIRVA Table Injury—not that the criterion was promulgated contrary to statutory authority. In the very next paragraph of petitioner's reply brief, she quotes the fourth criterion, and states that the court must "conduct a 'holistic examination of a petitioner's complete clinical presentation' and assess whether the preponderant evidence shows 'either (a) that her history is entirely free of, for example, clinical evidence of [osteoarthritis], or (b) if not, that the [osteoarthritis] would not explain her symptoms.'" Pet'r's Reply Br. at 4, *Pulsipher v. Sec'y of Health & Hum. Servs.*, No. 21-2133V, 2025 WL 1364203 (Fed. Cl. Spec. Mstr. Apr. 24, 2025) (quoting *Durham v. HHS*, No. 17-1899V, 2023 WL 3196229, at *14 (Fed. Cl. May 2, 2023)). She then claimed, after going through the medical history, that she met the fourth criterion, as "no other condition or abnormality wholly explains [p]etitioner's post vaccination left shoulder symptoms independent of vaccination." *Id.* at 7.

Claiming that the fourth QAI criterion for a SIRVA Injury was promulgated without authority and unlawfully relied on by the Special Master is not merely an extension of petitioner's core argument mentioned above. Rather, it is a new argument addressing a completely different issue on appeal.

Petitioner next relies on the Federal Circuit's decision in *Terran ex rel. Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1310–11 (Fed. Cir. 1999), as well as our decision in *GHS HMO, Inc. v. United States*, 76 Fed. Cl. 339, 368–72 (2007), *aff'd*, 536 F.3d 1293 (Fed. Cir. 2008), in arguing that challenges to a regulation's statutory authority are exempt from the waiver doctrine. The issue in *Terran*, however, was whether the Vaccine Act required a petition challenging a regulation to be filed within 60 days of its promulgation (it did not)—not whether a petitioner presenting a regulatory challenge is exempt from raising their argument before the trial court first. *Terran*, 195 F.3d at 1310–11.[5]

[5] The cases petitioner includes in her following string cite are similarly unhelpful. *Pub. Citizen v. Nuclear Regul. Comm'n*, 901 F.2d 147, 150–53 (D.C. Cir. 1990) (addressing whether petitioner's challenge was barred by a statutory time limit); *N.L.R.B. Union v. Fed. Lab. Rels. Auth.*, 834 F.2d 191, 195–97 (D.C. Cir. 1987) (same); *Nat. Res. Def. Council v. Nuclear Regul. Comm'n*, 666 F.2d 595, 601–03 (D.C. Cir. 1981) (same); *Functional Music, Inc. v. F.C.C.*, 274 F.2d 543, 546–47 (D.C. Cir. 1958) (same); *Eagle-Picher*

Likewise, in *GHS HMO*, the issue was not whether a party could raise a new legal issue on appeal but whether contractors could object to a mandatory contract provision, incorporating an invalid regulation, after contract award and performance (which we ruled they could). *GHS HMO*, 76 Fed. Cl. at 368–72. Moreover, the general rule petitioner cites from that case pertaining to waiver is limited to contract law: "if government officials make a contract they are not authorized to make, in violation of a law enacted for the contractor's protection, the contractor is not bound by estoppel, acquiescence, or failure to protest." *Id.* at 370. Furthermore, our reasoning for that case partly relied on the fact that the plaintiffs' objections to the contract provision at issue before award would have been futile, because the agency had already overridden similar objections from other interested parties in its rulemaking process. *Id.* at 372. Here, there is no indication that petitioner's challenge to the fourth SIRVA QAI criterion would have been similarly futile before the Special Master.[6]

Petitioner next argues that, depending on the facts and circumstances of the case, we have discretion in deciding when to apply the waiver doctrine. Petitioner primarily relies on the Federal Circuit's decision in *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792 (Fed. Cir. 1990). That case, however, is of no aid to petitioner. Petitioner specifically relies on the Federal Circuit's language that the waiver doctrine "is, of course, not governed by a rigid rule but may as a matter of discretion not be adhered to where circumstances indicate that it would result in basically unfair procedure." *Id.* at 800. The court in that case, however, decided *not* to apply its discretion to hear the unraised issue, noting that the plaintiff "had a full opportunity" to raise the issue before the lower court, but "[i]t chose not to do so." *Id.* at 800. As in *Becton Dickinson*, we decline to hear petitioner's statutory authority

---

Indus., Inc. v. U.S. E.P.A., 759 F.2d 905, 911–19 (D.C. Cir. 1985) (addressing whether petitioner's challenge was either moot or barred by a statutory review period).

[6] Petitioner also briefly argues in her reply brief that she had "no reason to focus on the illegitimacy of the offending language in 42 C.F.R. § 100.3(c)(10)(iv), because there was no indication that the Special Master would rule against her on that basis." Pet'r's Reply Br. at 4. Petitioner's obligation, however, was to either meet the regulatory test or challenge its application. She chose only to do the former, and it is now too late to choose the latter on review.

argument, because there is nothing in the record to suggest petitioner did not have a full opportunity to raise it before the Special Master.[7]

In sum, in accordance with longstanding precedent, as well as the rules of this court, petitioner has waived her argument regarding the validity of the fourth SIRVA QAI criterion, and we thus decline to address it.[8] Because we find that waiver applies, we need not address respondent's other counterarguments on the issue.

III. The Special Master did not Err in His Application of *Althen*

Petitioner next argues that the Special Master's application of *Althen* was flawed under both prongs one and two. Petitioner's prong one argument is that the Special Master erred in rejecting petitioner's medical theory by requiring petitioner to support her theory with medical literature. Respondent counters that the Special Master did not require petitioner to support her

---

[7] Petitioner also relies on the Federal Circuit's decision in *Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317 (Fed. Cir. 2020). The issue in that case was whether an argument raised and denied before this court on summary judgment but not raised in a subsequent motion for judgment as a matter of law could be heard on appeal. *Id.* at 1320–21. The Federal Circuit decided not to apply the waiver doctrine to the appellant's argument, noting that "this is not a typical waiver scenario in which we are asked to 'consider an issue not passed upon below'" and placed significant weight in the fact that "the issue . . . was fully briefed, argued, and decided below." *Id.* at 1322 (quoting *Singleton v. Wulff*, 428 U.S. 106, 120 (1976)). Contrary to *Ericcson*, petitioner does not raise an already argued issue on appeal—but a completely new issue.

[8] Petitioner argues at the end of her reply brief that "principles of fundamental fairness" must be applied by the court when weighing the application of the waiver doctrine. It is clear, however, that the "principles of fundamental fairness" petitioner relies on apply to the admission of evidence. *Horner for Horner v. Sec'y of Health & Hum. Servs.*, 35 Fed. Cl. 23, 26–29 (1996) (holding principles of fundamental fairness required reopening the evidentiary record to consider "newly found" evidence); *see also* Vaccine Rule 8(b)(1) ("In receiving evidence, the special master . . . must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties."). No such evidentiary admissibility concern exists here.

medical theory with medical literature, but "thoroughly and thoughtfully analyzed the medical literature provided and determined that the record evidence failed to support petitioner's theory." Resp't's Resp. Br. at 16.

We agree with respondent. To establish actual causation, petitioner must first "show a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278 (internal citation omitted). The medical theory must demonstrate a "'logical sequence of cause and effect' . . . supported by 'reputable medical or scientific explanation[,]' i.e., 'evidence in the form of scientific studies or expert medical testimony.'" *Id.* (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed.Cir.1992)). A medical theory "need only be 'legally probable, not medically or scientifically certain." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed.Cir.1994)). Likewise, a petitioner is "not required to show that the theory is generally accepted, and [s]he may demonstrate h[er] theory without resort to medical literature or epidemiological studies." *Bechel v. Sec'y of Health & Hum. Servs.*, 168 Fed. Cl. 602, 617 (2023); *see also Althen*, 418 F.3d at 1280 ("[B]y requiring medical literature, it contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof."). We note, however, that "the medical theory must nonetheless be sound and reliable for a petitioner to prevail," and the special master's evaluation of a petitioner's medical theory "is both a fact-specific inquiry and an exercise of his or her judgment to determine the relative weight of the evidence presented 'in a field bereft of complete and direct proof of how vaccines affect the human body.'" *Bechel*, 168 Fed. Cl. at 618 (quoting *Althen*, 418 F.3d at 1280).

Petitioner's medical theory is that the inadvertent administration of the flu vaccine near her subacromial bursa resulted in inflammation, leading to bursitis in that area, which subsequently triggered symptoms in petitioner's pre-existing yet asymptomatic osteoarthritis in her glenohumeral joint. In support of this theory, petitioner cites, in part, SIRVA injury claim statistics between 2010 and 2016, as well as the 1962 Dumonde study linking the injection of antigenic material in rabbits to the development of arthritis. Regarding petitioner's use of medical literature, we do not find that the Special Master required petitioner to resort to medical literature in establishing her medical theory, but, rather, that the Special Master reviewed the medical literature *submitted by petitioner* and determined that it did not support petitioner's theory.

In his decision, Special Master Horner was unconvinced by the SIRVA claim statistics petitioner cites, as those statistics only show that 5.2% of SIRVA claims between 2010 and 2016 showed MRI findings of glenohumeral arthritis. Additionally, the authors of that publication noted that many of the recorded MRI findings, including for glenohumeral arthritis, "are common in patients with and without shoulder pain and may not be related to vaccination." Ex. 12, Tab K at 6. We cannot say the Special Master erred in concluding that these statistics show no more than incidental findings of osteoarthritis.

Nor was the Special Master unreasonable in discounting the Dumonde study. The study was conducted over 60 years ago, and even Dr. Srikumaran acknowledged that it "is the only study of its kind to demonstrate production of arthritis as the result of antigenic material." Ex. 14 at 4. Even assuming the reliability of the Dumonde study, Special Master Horner correctly points out that the authors of the study state that the induced arthritis bears a "striking" resemblance to rheumatoid arthritis, which is a distinct condition from the osteoarthritis suffered by petitioner. Ex. 12, Tab G at 16.

Moreover, the Special Master determined that Dr. Srikumaran's medical theory does not sufficiently link the flu vaccination to petitioner's shoulder injury. He found that Dr. Srikumaran's medical theory does not account for the fact that, because the rotator cuff operates as a barrier between the subacromial bursa (injection site) and the glenohumeral joint (osteoarthritis site), it is unlikely that, even if petitioner experienced inflammation at the injection site, that inflammation would have spread to the glenohumeral joint, thereby aggravating petitioner's preexisting osteoarthritis. Given that petitioner's medical records show that she had an intact rotator cuff, it was not unreasonable for the Special Master to conclude that petitioner's medical theory failed to causally connect the vaccination to her injury.

Because the Special Master correctly applied prong one, and because the petitioner must establish all three *Althen* prongs to succeed on her actual causation claim, we need not address the parties' arguments under prong two.

CONCLUSION

Overall, petitioner has failed to establish that the Special Master's decision was not in accordance with law. Because petitioner failed to raise her statutory authority argument before the Special Master, we find that argument waived. We also do not find that the Special Master erred in his

application of *Althen*. As a result, we deny petitioner's motion for review and affirm the decision below. The Clerk of Court is directed to enter judgment accordingly.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge