In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1321V

LATOYA MCCOY,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: October 15, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Mark Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner.

Felicia Langel, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE[1]

On October 5, 2020, Latoya McCoy filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"),[2] ECF No. 1 ("Petition"). Petitioner alleges that she experienced left shoulder pain and/or adhesive capsulitis after receiving an influenza ("flu") vaccine on October 8, 2017.

The matter was originally assigned to the Special Processing Unit ("SPU"), based on the assumption that Petitioner had alleged something akin to the Table claim of a shoulder injury

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. Id.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

related to vaccine administration, or "SIRVA," suggesting in turn that it was likely to settle. But intractable fact disputes resulted in the claim's transfer to my docket.

Respondent has now moved to dismiss the claim, arguing that Petitioner cannot meet the SIRVA Table elements, and otherwise has not established a viable causation-in-fact claim. Motion to Dismiss, dated July 24, 2024 (ECF No. 49) ("Mot."). Petitioner opposes the motion, maintaining that she has established a *prime facie* case for a SIRVA-like injury, even if the facts do not meet all of the Table elements. Opposition, dated August 29, 2024 (ECF No. 50) ("Opp.").

Having reviewed the parties' submissions, I hereby determine (as discussed below) that Petitioner has not offered sufficient evidence to meet *either* the Table SIRVA elements or to establish a viable causation-in-fact claim – mainly, although not exclusively, due to the fact that the record preponderates in favor of the conclusion that Petitioner's injury *predated* vaccination. For this reason, Respondent's Motion to Dismiss is granted.

I. Factual Background

Prior to receipt of the flu vaccine, Ms. McCoy had a history of intractable migraines. *See generally* Ex. 3. Petitioner also reported bilateral shoulder pain in 2015 and 2016. *Id.* On October 8, 2017, Petitioner visited a Walgreens pharmacy and received the flu vaccine intramuscularly in her left deltoid. Ex. 9 at 3.

There is no medical record evidence of any claimed immediate vaccine reaction. However, Petitioner filed four declarations to support her claim that she experienced pain and weakness immediately following the vaccine. In the first, Petitioner states that she noticed pain in her left shoulder and arm one week after she received the flu vaccine. *See* Declaration of Latoya McCoy, dated December 14, 2020 (ECF No. 9). In her second declaration, Petitioner explains that she delayed seeking treatment for her arm because of her severe migraines, and the need to prioritize their treatment. *See* Declaration of Latoya McCoy, dated October 28, 2022 (ECF No. 36). Petitioner's daughter also filed a declaration claiming that Petitioner complained of arm pain "shortly after she received the [October 2017] flu vaccine," and required assistance with holiday preparations due to ongoing pain. *See* Declaration of Jondashia Mingo, dated September 14, 2022, filed as Ex. 13 (ECF No. 36-1). And a declaration from Petitioner's work colleague states that Petitioner required assistance at work and missed workdays due to arm pain from "the flu vaccine in October 2017." *See* Declaration of Ashland Edwards, dated September 14, 2022, filed as Ex. 14 (ECF No. 36-2).

Despite the allegations set forth in these declarations, Petitioner's first visit to any physician following receipt of the vaccine occurred on November 30, 2017 – six weeks post-

vaccination. Ex. 5 at 19. At this visit, Petitioner complained to her primary care provider ("PCP") only about cellulitis in her left hand – and did not mention any shoulder pain or related discomfort. *Id.* Then, on February 1, 2018 (now about four months after the vaccination – and two months after her last treater visit), Petitioner went back to her PCP complaining of a tender "knot" in her upper left arm that had been present for about a year (meaning *before* vaccination). *Id.* at 16-17. An ultrasound indicated no abnormalities. *Id.* at 42.

Over the next seven months through September 2018, Petitioner reported to medical providers for treatment of her unrelated migraines on six occasions. Ex. 2 at 11-15; Ex. 5 at 10-14. She never mentioned arm pain at any of these appointments, and sought no independent treatment for that admittedly-distinguishable condition.

Then, on January 7, 2019 (now well over a year after the vaccination date), Petitioner presented to Urgent Care and complained of 4/10 rated pain in her left arm after "getting [a] flu vaccine *3 years ago*." Ex. 2 at 3-4 (emphasis added). On exam, Petitioner displayed reduced range of motion ("ROM") and was diagnosed with bursitis[3] and adhesive capsulitis.[4] *Id.* at 5. One week later, on January 16, 2019, Petitioner followed up with her PCP and reported "left arm pain and weakness for *at least 2 years*," along with "electric" pain in her left bicep since her October 2017 vaccination. Ex. 5 at 8-9 (emphasis added).

An electromyography ("EMG") test performed on April 24, 2019, showed cubital tunnel syndrome[5] in both of Petitioner's arms. Ex. 4 at 18-22. On May 29, 2019, Petitioner saw a neurologist and was diagnosed with cervical radiculopathy (pinched nerve). *Id.* at 4. She was referred to physical therapy and attended seven sessions. *See generally* Ex. 11.

On June 20, 2019, Petitioner's orthopedist noted that her cubital tunnel syndrome did not explain her left shoulder issue. Ex. 6 at 10. MRIs and X-rays of Petitioner's left shoulder revealed a large, calcific deposit in the supraspinatus tendon, tendinopathy, and bursitis. *Id.* at 11.

[3] "Bursitis" is defined as "inflammation of a bursa [fluid-filled sac] occasionally accompanied by a calcific deposit in the underlying tendon." *Bursitis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=7315&searchterm=bursitis (last visited Oct. 8, 2024).

[4] "Adhesive capsulitis" is defined as "adhesive inflammation between the joint capsule and the peripheral articular cartilage of the shoulder with obliteration of the subdeltoid bursa, characterized by shoulder pain of gradual onset, with increasing pain, stiffness, and limitation of motion. Called also adhesive bursitis and frozen shoulder." Adhesive capsulitis, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=62985&searchterm=adhesive+capsulitis (last visited Oct. 8, 2024).

[5] Cubital tunnel syndrome occurs when the ulnar nerve, which passes through the cubital tunnel (a tunnel of muscle, ligament, and bone) on the inside of the elbow, becomes inflamed, swollen, and irritated." *Cubital tunnel syndrome*, University of Rochester Medical Center Health Encyclopedia, https://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=85&ContentID=P00908 (last visited Oct. 8, 2024).

Petitioner's orthopedist diagnosed her with "[l]eft arm lateral deltoid pain, status post injection, now 2 years out." *Id.* at 10, 75-77. On August 9, 2019, Petitioner underwent surgery on her left shoulder for calcific tendinosis removal, a tear repair, and a rotator cuff repair. Ex. 6 at 52-53. After surgery, Petitioner attended twelve PT sessions. *See generally* Ex. 10. At the October 21, 2019 PT session, Petitioner reported that her shoulder felt "good." *Id.* at 41.

Petitioner reported to her PCP in October 2019 and April 2020 for a rash and allergic rhinitis, but did not mention her left arm at either of these appointments. Ex. 5 at 3-6.

II. Petitioner's Expert – Dr. Michael Katz

Dr. Katz,[6] an orthopedic surgeon, prepared a single written report on behalf of Petitioner. *See* Report, dated May 15, 2024, filed as Ex. 18 (ECF No. 48-1) ("Katz Report"). Dr. Katz opines that it is more likely than not that the administration of the flu vaccine caused the nascent and degenerative changes in Petitioner's left shoulder to become symptomatic and disabling. Katz Report at 7.

In his report, Dr. Katz proposes that the pain and weakness in Petitioner's left arm began almost immediately after she received the flu vaccine in October 2017. Katz Report at 5. Dr. Katz explains that Petitioner likely waited to seek treatment because she was hoping the pain would resolve on its own and was preoccupied with her severe migraines. *Id.* In Dr. Katz's opinion, Petitioner's shoulder pain and eventual need for surgery was causally linked to the flu vaccine. *Id.* at 7.

Dr. Katz goes on to explain that a SIRVA injury is the result of an inflammatory effect from vaccine administration into the subdeltoid bursa. Katz Report at 6. He then opines that a logical sequence of cause and effect exists to support the conclusion that the flu vaccine was the reason for Petitioner's SIRVA. *Id.* Dr. Katz also argues that there is a proximate temporal relationship between the flu vaccine and the Petitioner's injury. *Id.* He explains that studies show an onset of symptoms occur immediately, within 2-8 hours, or within 48 hours following receipt of a vaccine. *Id.* According to Dr. Katz, Petitioner's onset of symptoms is consistent with this, and it is no surprise that she delayed seeking medical attention, as this is common among individuals injured by vaccination. *Id.* In Dr. Katz's view, the sequence of events and onset of symptoms supports a conclusion that the flu vaccine caused Petitioner's shoulder injury. *Id.* at 7.

III. Procedural History

As noted above, this case was initiated in October 2020 and was assigned to the SPU on April 5, 2021. After Respondent filed his Rule 4(c) Report contesting Petitioner's right to

[6] Petitioner did not file a CV for Dr. Katz.

compensation (ECF No. 32), I issued a Show Cause Order instructing Petitioner to submit any supplemental material or briefing explaining why the claim should not be dismissed for insufficient evidence. ECF No. 33. Petitioner filed a response on October 31, 2022. ECF No. 40 ("Brief"). On September 27, 2023, the case was reassigned to my chambers due to its increasing complexity (ECF No. 41), and on May 14, 2024, Petitioner filed Dr. Katz's expert report. Two months later, on July 24, 2024, Respondent filed a Motion to Dismiss, arguing that Petitioner has not proven by preponderant evidence that the flu vaccine caused her arm injury. The parties subsequently briefed dismissal, and the matter is now ripe for resolution.

IV. Parties' Arguments

A. *Respondent's Motion to Dismiss*

Respondent contends that Petitioner cannot meet all three prongs of the causation test set by *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Mot. at 6-7.

Respondent first argues that Petitioner has not alleged a cognizable injury. Mot. at 6. Petitioner has described (in her earlier brief) "an arm injury that eventually limited her range of motion along with a granuloma from the injection itself." *Id.* at 7 (citing Brief at 6). But this is not a defined and/or recognized injury, as required for an off-Table claim, and would not otherwise meet the qualifications for a SIRVA Table injury. *Id.* at 6-7 (referencing 42 C.F.R. § 100.3(c)(10)). Respondent gives particularly short shrift to a possible Table claim based on these facts, noting that the record establishes that Petitioner did not suffer onset of pain within 48 hours of vaccine administration, her pain and reduced ROM were not limited to the shoulder in which the vaccine was administered, and that there *are* other conditions or abnormalities present that would explain her symptoms. *Id.* at 7 n.3.

Respondent then turns to the *Althen* prongs applicable to a possibly-remaining non-Table claim. Respondent argues that Petitioner's medical theory – that the flu vaccine can cause SIRVA, when a previous vaccine introduced into the shoulder joint gives rise to antibodies in the synovial tissues that are related to the effects of a subsequent vaccination – is vague at best and does meet the standard for a reliable theory under *Althen* prong one. Mot. at 7. Petitioner also has not established a logical sequence of cause and effect under *Althen* prong two, despite the allegations set forth in the four declarations she filed and her social media posts.[7] *Id*. Petitioner did not link the flu vaccine to her shoulder injury until she presented to Urgent Care on January 7, 2019, fifteen months post-vaccination – and worse, complained of left arm pain after "getting [a] flu vaccine *3 years ago*," which would have been long before October 2017. Ex. 2 at 3-4. Also, a June 2019 notation by Petitioner's orthopedist stating, "[l]eft arm lateral deltoid pain, status post injection,

[7] On March 1 and September 26, 2019, Petitioner posted on social media that she had experienced two years of arm weakness and pain due to the 2017 vaccination. *See generally* Ex. 12 (ECF No. 35).

now 2 years out,' reflects only a possible temporal association and does not imply vaccine causation. Mot. at 8 (citing Ex. 6 at 11).

Respondent concludes by arguing that Petitioner has failed to present preponderant evidence of a proximate temporal relationship between the flu vaccination and her left arm pain under *Althen* prong three. Mot. at 8. Although Petitioner's declarations suggest she experienced an immediate reaction to the vaccine, this is in stark contrast to her medical records – when Petitioner visited her PCP for right hand cellulitis, 53 days post-vaccination, she failed to mention any arm pain. Ex. 5 at 19. In fact, Petitioner did not report left arm pain until February 1, 2018, and at that time noted a different problem: a knot in her upper arm that had been there for about one year, and hence before the October 2017 vaccination. Ex. 5 at 17. It is possible, in fact, that Petitioner's reported timelines are jumbled because she was actually referring to an even earlier, 2016 flu vaccine that is not the subject of this case. Mot. at 8 (referencing Ex. 1 at 5). Because the timing of Petitioner's arm pain pre-dates the vaccination at issue, she cannot establish a proximate temporal association. *Id.* at 9.

B. *Petitioner's Response*

Petitioner argues that she has alleged a cognizable injury and maintains she has proffered sufficient evidence of causation under all three *Althen* prongs for the case to go forward. Opp. at 4-5. Petitioner clarifies the nature of her claim, alleging that she suffered from adhesive capsulitis with left shoulder pain and a loss of ROM – in effect, a SIRVA (even if she cannot meet all of the Table elements) that can be analyzed as a non-Table claim. *Id.* at 3.

Thus, after receiving the flu vaccine, Petitioner experienced immediate soreness in her arm, that progressively worsened into a presentation that Dr. Katz concluded was consistent with SIRVA. Opp. at 4. According to Dr. Katz, the flu vaccine triggered symptomatic and disabling degenerative changes in her shoulder. *Id*. Petitioner argues that Dr. Katz's expert report supports all three *Althen* prongs. *Id.* at 6. She also acknowledges some delay in treatment but blames her preexisting debilitating migraines as the reason. *Id.* at 5. Once Petitioner started new medications in November 2018, her migraines improved, and she felt well enough to seeks treatment for her shoulder injury. *Id.* (citing Ex. 5 at 31). In conclusion, Petitioner argues that the medical record, social media posts, and declarations all point to the flu vaccine as the cause of her arm injury. *Id.* at 6.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—

corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8]

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "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*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

[8] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and

carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony

surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the

weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are

used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Resolution of Matter Without Hearing*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

Petitioner appears to argue that she experienced an injury that is often thought to fall under the SIRVA umbrella – adhesive capsulitis, also known as "frozen shoulder", with left shoulder pain and a loss of range of motion. Opp. at 3. Although she maintains enough evidence exists to at least justify the case going forward, review of the record reveals a claim that cannot succeed, whether analyzed as a Table SIRVA or as a causation-in-fact matter.

Although Petitioner does not formally attempt to show that she can meet the SIRVA Table elements, Respondent is correct that the existing record reveals such a claim would not be tenable. The Table Qualifications and Aids to Interpretation ("QAI") for SIRVA require a petitioner alleging a SIRVA to affirmatively establish the following: (1) no history of pain, inflammation, or dysfunction of the affected shoulder prior to intramuscular vaccine administration; (2) pain occurs within 48 hours of the vaccine administration; (3) pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (4) no other condition or abnormality is present that would explain Petitioner's symptoms. *See* 42 C.F.R. § 100.3(b)(10).

Here, Petitioner complained of bilateral shoulder pain in the years leading up to the vaccine. *See generally* Ex. 3. Thus, there is already *some* evidence of a "history of pain" that could explain her alleged post-vaccination injury. In addition, the record reveals pain and other complaints outside of the relevant shoulder. Thus, in January 2019, Petitioner reported "electric pain" in her left biceps, limited ROM in her left shoulder and elbow, and weakness from her shoulder to her hand. Ex. 5 at 8-9. An EMG later performed on April 24, 2019, showed that Petitioner had cubital tunnel syndrome, resulting from nerve compression at the elbow. Ex. 4 at 18-22.

In addition, when Petitioner visited a P.A. in May 2019, she complained of back and neck pain, and the doctor diagnosed her with *cervical radiculopathy*, which occurs when a pinched nerve in the neck leads to pain that can spread into the arms –an express SIRVA exclusionary factor. *Id.* at 3; 42 C.F.R. § 100.3(b)(10)(iv). And during a PT session in June 2019, Petitioner's physical therapist noted that there was palpable adhesion near Petitioner's left biceps with severe pain on palpitation. Ex. 11 at 43. Thus, Petitioner's medical records show that her pain extended well beyond her shoulder; indeed, it appears her entire arm, particularly her elbow and bicep, were affected. This is not a case where such non-shoulder complaints can be differentiated from the SIRVA. *Compare Masters v. Sec'y of Health & Hum. Servs.*, No. 20-1640V, 2023 WL 9424779 at *4 (Fed. Cl. Spec. Mstr. Dec. 18, 2023) (finding Petitioner's sole report of neck soreness and radiating pain to be inconsequential when left shoulder pain was the focus of Petitioner's complaints).

Most detrimental to Petitioner's claim, however, is the timing of the onset of symptoms. For (as noted above) the evidence not only preponderates against a finding that her onset began within 48 hours of receipt of the flu vaccine (as the Table requires), but supports the conclusion that any shoulder-specific issues more likely than not *preceded* vaccination. Thus, the first two times she *ever* reported shoulder pain (at treatment visits, it bears noting, that occurred well after the October 2017 vaccination), Petitioner identified pre-vaccination onset dates. *See e.g.*, Ex 5 at 16-17 (February 1, 2018 visit); Ex. 2 at 3-4 (January 7, 2019 visit); Ex. 5 at 8 (January 16, 2019 visit).

To overcome this record, Petitioner offers four witness statements[9] and two social media posts. But this evidence is unconvincing, taken on its own terms. Petitioner's first social media post, for example, places the onset of symptoms *before* the October 2017 flu vaccine, while the second post says nothing about onset. *See* Ex. 12.[10] Furthermore, the witness statements (all of which were filed and created years after Petitioner received the vaccine), lack record corroboration, and do not explain why Petitioner reported onsets before vaccination. Petitioner's self-described timeline, as detailed in the medical records, is confusing and inconsistent, and certainly does not support a finding that her symptoms began *after* the October 2017 vaccination.[11]

[9] Petitioner's first declaration (ECF No. 9) was filed in December 2020. Petitioner's second declaration (ECF No. 36), the declaration from her colleague (ECF No. 36-2), and the declaration from her daughter (ECF No. 36-1) were filed in October 2022.

[10] In the first social media post, from March 1, 2019, Petitioner claims she has been experiencing two years of arm pain due to the flu vaccine (which would be March *2017*). Even if the reference to "two years" is taken broadly, this is still only weakly supportive of her onset contentions. In the second social media post, from September 26, 2019, Petitioner warns against the flu vaccine generally. *See* Ex. 12 (ECF No. 35).

[11] I also do not give significant weight to Petitioner's arguments that her debilitating migraines caused her to delay treatment. Opp. at 5. Although it is reasonable to contend that concerns about a more pressing health issue might lead an individual to downplay other legitimate health matters, statements Petitioner made to medical treaters *when she did*

This otherwise is not a case in which witness statements merit greater weight than medical records, or where the statements provide missing context or add details that add nuance to the disputed onset issue. When reviewing evidence in a case, special masters (already empowered to weigh evidence) may give greater weight to medical records. *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952, *958 (Fed. Cir. 2011). As this court explained in *Cucuras v. Sec'y of Health & Human Servs.*:

> "[t]he Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight. *United States v. United States Gypsum Co.*, 333 U.S. 364, 396, 68 S.Ct. 525, 92 L.Ed. 746 (1948) .... Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." 993 F.2d 1525, 1528 (Fed.Cir.1993).

The foregoing is true even though witness statements can be offered to vary or supplement medical record evidence, and although records are not "presumptively" correct. *Kirby*, 997 F.3d at 1383. In this case, the statements in Petitioner's declarations conflict with the contents of Petitioner's medical records – but no compelling reason has been provided by Petitioner not to favor the contemporaneous record and what it suggests about onset.

Because Petitioner cannot preponderantly show her pain did not precede vaccination,[12] she cannot succeed under any form of the claim, Table or not. This by itself is grounds for the claim's dismissal – although it is not the only reason to find the claim is not tenable. For even if I merely determined a Table claim could not be advanced, I would still be able to find that a causation theory could "work." Dr. Katz's opinion largely seeks to argue that Petitioner experienced a SIRVA, despite all of the fact issues pointed out above with that conclusion. Opp. at 4. His conclusory opinion does not set forth a reliable theory for how the flu vaccine could cause or worsen a shoulder injury given the facts, or some kind of condition involving Petitioner's presentation, which went well beyond her complaints of shoulder pain.

---

seek treatment for her shoulder place the onset of symptoms before receipt of the 2017 flu vaccine. Thus, these delay explanations do not account for such symptoms reporting.

[12] The Vaccine Act does permit petitioners to attempt to establish that vaccination worsened a condition or illness that preceded a vaccine's administration. 42 U.S.C. § 300aa–11(c)(1)(C)(i) -(ii). But Petitioner has not raised a significant aggravation claim in this case or in the present briefing, and Dr. Katz does not propose that the vaccine aggravated an existing shoulder injury.

CONCLUSION

Claimants must carry their burden of proof. Because Petitioner cannot show by preponderant evidence that the flu vaccine likely caused her shoulder injury, I deny entitlement.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[13]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[13] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.