# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 19-0695V**

UNPUBLISHED

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| WINNIFER KINSEY,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: September 26, 2022<br><br>Special Processing Unit (SPU); Causation-in-Fact; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Neuroinflammation |

*James Domengeaux, Domengeaux, Wright, Lafayette, LA, for Petitioner.*

*Claudia Barnes Gangi, U.S. Department of Justice, Washington, DC, for Respondent.*

## ENTITLEMENT DECISION[1]

On May 14, 2019, Winnifer Kinsey filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program")[2] alleging that she suffered "permanent muscle and nerve damage" caused-in-fact by a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine administered on June 20, 2018. Petition at ¶¶ 2, 6, 8. Petitioner later refined her claim, alleging that the Tdap vaccination caused nerve sensitization and/or neuroinflammation, resulting in radicular pain from a previously asymptomatic disc herniation. ECF 31 at 8.

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[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.

For the reasons set forth below, I find Petitioner has failed to establish that the Tdap vaccination caused a nerve injury or neuroinflammation in her right arm. Accordingly, Petitioner's claim is dismissed.

## I. Relevant Procedural History

Approximately one year after the claim's initiation, Respondent filed a Rule 4(c) Report challenging compensation, arguing that Petitioner could not demonstrate that the Tdap vaccine caused "permanent muscle and nerve damage" or significantly aggravated Petitioner's pre-existing disc herniation. ECF No. 27 at 10. Respondent further asserted that Petitioner had failed to demonstrate that she received the relevant vaccination in her *right* arm, when the vaccination record indicates the *left* arm. *Id.* Nine months later, with Petitioner having submitted no new evidence, an Order to Show Cause as to why Petitioner's claim should not be dismissed was issued. ECF No. 28.

On March 23, 2021, Petitioner filed a response to the Order to Show Cause, asserting that the affidavits, medical records, and medical opinions establish that Petitioner received the Tdap vaccination in her right arm and the vaccination caused neuroinflammation resulting in radicular cervical pain from a previously asymptomatic disc herniation. ECF No. 31 at 5-10. Petitioner filed additional exhibits with her response. Ex. 24-28. Respondent filed a response to Petitioner's assertions, incorporating his arguments contained in the Rule 4(c) Report. ECF No. 33. Respondent maintained that Petitioner has not established vaccination in the right arm, nor has Petitioner established that the vaccination caused-in-fact her alleged injury or significantly aggravated her pre-existing disc herniation. ECF 33 at 1.

The matter is now ripe for adjudication.

## II. Issues

At issue is whether Petitioner's June 20, 2018 Tdap vaccination was administered in her right or left arm. And if it was administered in her *right* arm, whether the Tdap vaccination caused-in-fact a neuroinflammation resulting in radicular pain from a pre-existing, asymptomatic disc herniation. As Petitioner alleges an off-Table injury, she must prove by a preponderance of evidence that the subject vaccination caused the alleged injury. § 11(c)(1)(C)(ii).

Both a fact and causation issue exist, with the factual issue to be determined first.

## III. Legal Standards for Fact Finding

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "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." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, 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). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.,* 42 Fed. Cl. 381, 391 (1998). The Court later outlined 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 & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health*

*& Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

## IV. Findings of Fact

Based upon the entire record, I find that Petitioner's June 20, 2018 Tdap vaccine was likely administered in Petitioner's right arm, as she contends. I make this finding after a complete review of the record to include all medical records, affidavits, and additional evidence filed. [3] Specifically, I note the following evidence:

- On the afternoon of June 20, 2018, Petitioner received a Tdap vaccination. The administrator, Nurse Kimberly Jump, documented in a medical record that it was given in the "left deltoid." Ex 15 at 2.

- The day after vaccination, June 21, 2018, Petitioner presented to the emergency department for "post-tetanus vaccination malaise/myalgias." Ex. 3 at 2. Petitioner reported that she had not had a tetanus shot in ten years and was given a tetanus shot the day prior in her "right deltoid area." *Id.* at 7. She reported soreness and aching in her right deltoid area and being very tired. *Id.* During a review of systems, she reported "Mild pain and swelling to the area where the tetanus shot was given to the right deltoid area." *Id.* at 8. Upon examination, Dr. Angie Ragas documented "induration, that is mild is noted, located on the Right deltoid area and the area of the injection. Mild pain on palpation." *Id.* Dr. Ragas assessed Petitioner with "possible mild arthus type reaction to that area." *Id.* at 9. Petitioner was advised to take Tylenol or ibuprofen, use cool compresses, and follow up with her primary care physician ("PCP"). *Id.*

[3] While I have not specifically addressed every medical record, or all arguments presented in the parties' briefs, I have fully considered all records as well as arguments presented by both parties.

- On June 23, 2018, Petitioner returned to the emergency department with complaints of swelling to the posterior aspect of her upper right arm, the area where she had received a tetanus injection. Ex. 4 at 7. Petitioner reported that associated soreness had resolved but redness and swelling began a day prior. *Id.* Petitioner was seen by Dr. Andrew Fuller, who noted "4x3cm area of erythema noted to the right upper arm in the posterior aspect, well demarcated." *Id.* at 8. Dr. Fuller assessed Petitioner with cellulitis and prescribed Petitioner a course of antibiotics. *Id.* Petitioner was advised to return to the emergency department for a re-check in two days or return immediately if her cellulitis worsened. *Id.* at 8-9.

- Petitioner returned to the emergency department on June 25, 2018, with complaints of worsening swelling, erythema, and pain in her right arm. Ex. 5 at 3. Upon examination, "r[igh]t arm swelling and erythema from mid upper arm to elbow, r[igh]t ax[illary] lymphadenopathy" was noted. *Id.* at 4. Petitioner's MRI of her right upper extremity showed cellulitis and myositis changes. *Id.* at 2. Petitioner was assessed with right upper extremity ("RUE") cellulitis and myositis after intramuscular injection. *Id.* Another antibiotic was prescribed Petitioner was advised to follow-up with her PCP. *Id.*

- On July 1, 2018, Petitioner presented to the emergency department for her arm swelling, which "now extended down her entire arm." Ex. 6 at 7. Petitioner reported that she received a tetanus vaccine on June 20th and "since that injection has had pain and swelling with associated cellulitis to her right lateral aspect upper arm." *Id.* Though the cellulitis had improved, Petitioner reported pain with movement of her right arm and paresthesias. She denied right arm weakness. *Id.* Upon examination, the nurse noted "Mild edema to RUE. Sensation and strength intact… no cellulitis or wound to area." *Id.* at 8. Dr. Krieger advised that Petitioner's condition was "most likely post injection complications." *Id.* Petitioner was advised to see a neurologist if her paresthesia persisted. *Id.* A RUE ultrasound was performed and no soft tissue abnormalities were found. *Id.* at 13.

- On July 3, 2018, Petitioner presented to her PCP, Dr. Clinton Sharp, for "pain in [her] right arm after tdap shot." Ex. 7 at 22. Petitioner reported her recent history and emergency visits. *Id.* at 21. She reported that it hurt to abduct her right arm. *Id.* Dr. Sharp noted that Petitioner was right-handed and examined her right arm. *Id.* Dr. Sharp assessed Petitioner with and adverse reaction to Tdap vaccination. *Id.* Prednisone was prescribed. *Id.*

- On August 13, 2018, Petitioner presented to Dr. Sharp for pain in her right arm and in the back of her neck. Ex. 7 at 19. She reported pain travelling down her right arm into her forearm as well as right arm weakness. *Id.* Painful neck flexion was noted. Dr. Sharp assessed Petitioner with cervical arthralgia and radiculopathy of the RUE. *Id.* A cervical MRI was ordered, which showed C4-5 disc herniation and C5-6 foraminal narrowing. *Id.* at 25. Physical therapy and prednisone were prescribed. *Id.* at 19.

- Petitioner presented for a physical therapy evaluation on September 10, 2018. Ex. 21.[4] Petitioner reported "RUE pain and paresthesias dating back to a TDAP injection in June." *Id.* at 1. Petitioner reported one month of cervical pain with insidious onset. *Id.* Objective findings for her cervical region included decreased range of motion, tenderness to palpation, and impaired muscle function. *Id.* at 3.

- On September 21, 2018, Petitioner returned to Dr. Sharp complaining of right arm pain. Ex. 7 at 18. Following examination, Dr. Sharp assessed Petitioner with cervical disc degeneration and radiculopathy. He referred Petitioner to Dr. Justin Owen for a neurosurgery consultation. Ex. 7 at 18.

- On October 1, 2018, Petitioner presented to Dr. Justin Owen for a neurosurgical evaluation with the chief complaint of "right arm/back and neck pain." Ex. 13 at 5. Petitioner reported that pain in her right triceps area began "immediately following a Tdap shot." *Id.* She reported pain in her shoulder and symptoms radiating down to the hand and fingers on occasion. *Id.* Dr. Owen and his physician's assistant performed a neurological exam and reviewed Petitioner's MRI imaging. *Id.* at 6. Dr. Owen concluded that Petitioner's pain was not radiculopathic considering the onset, location, and distribution of her complaints in conjunction with her imaging. *Id.* He noted that Petitioner's pain was not consistent with the "very mild C4-5 right-sided neural foraminal stenosis." *Id.* "It does not conform to any particular neural distribution." Dr. Owen felt that it could be a shoulder issue and offered a referral to an orthopedist. *Id.*

- On October 8, 2018, Petitioner presented to Dr. Frederick Keppel, an orthopedist, for her arm pain. Ex. 22[5] at 4. Petitioner reported right arm pain for four months associated with a Tdap injection, which "caused an infection, muscle, and tissue damage." *Id.* Petitioner reported constant pain though

[4] Petitioner incorrectly labelled this exhibit as "Pl Ex #20." It is Petitioner's 21st exhibit.

[5] Petitioner incorrectly labelled this exhibit as "Pl Ex #21." It is Petitioner's 22nd exhibit.

prednisone and naproxen provided some relief. *Id.* Upon examination, some weakness was noted on extension of the elbow. *Id.* at 11. There was subjective numbness over the radial aspect of the hand. *Id.* Dr. Keppel ordered a nerve conduction test and noted "Patient had tetanus injection near radial nerve site mid humerus (sic) rule out radial nerve injury also rule out carpal tunnel syndrome." *Id.* at 8.

- Following a normal nerve conduction test on October 30, 2018, Petitioner returned to Dr. Keppel November 19, 2018. Ex. 22 at 35. Dr. Keppel noted the absence of any evidence of an injury to the peripheral nerves or radial nerve. *Id.* He noted that Petitioner had good range of motion in her neck, with good extension and flexion. *Id.* Dr. Keppel also noted that petitioner's cervical disc disease at C4-5, with foraminal stenosis on the right and disc herniation on the left "does not correlate with her symptoms." *Id.* Dr. Keppel referred Petitioner back to Dr. Owen.

- Petitioner returned to Dr. Owen on December 6, 2018, reporting the same symptoms and noting that Dr. Keppel did not believe her symptoms were a shoulder issue. Ex. 13 at 3. Dr. Owen noted that petitioner's pain over the back of her arm "would be most consistent with the C7 distribution over the triceps musculature." *Id.* Dr. Owen again reviewed Petitioner's cervical MRI which showed a C4-5 foraminal stenosis that "[he] would not rate as severe." *Id.* at 4. He explained C5 radiculopathy symptoms which Petitioner disagreed with. *Id.* Dr. Owen felt surgery would be unreasonable and recommended epidural steroid injections. *Id.*

- On February 15, 2019, Petitioner presented to neurologist, Dr. Stephen Rynick, for her neck and right arm pain with intermittent tingling. Ex. 9 at 1. Petitioner associated her right arm symptoms with her Tdap vaccination. *Id.* Dr. Rynick reviewed the imaging, noted foraminal stenosis on the right at C4-5 and assessed Petitioner with cervical radiculopathy. He also noted that "there does not appear to be any focal peripheral nerve injury related to the injection." *Id.*

- Petitioner received a cervical epidural steroid injection on March 15, 2019 from Dr. Rynick. Ex. 11 at 1-2. She reported inadequate relief from the injection and returned on May 3, 2019, complaining of numbness in her hand. Ex. 13 at 1. Dr. Rynick found cervical foraminal compression on the right with diminished sensation in Petitioner's right radial forearm. He referred Petitioner back to Dr. Owen for neurosurgical consultation. *Id.*

- On May 23, 2019, Petitioner presented to Dr. Sharp due to acute neck pain following a motor vehicle accident. Ex. 12 at 2. He prescribed painkillers and ordered x-rays. *Id.* He noted Petitioner's cervical disc degeneration.

- Petitioner returned to Dr. Owen on June 11, 2019. Ex. 14 at 1. Dr. Owen noted that Petitioner's condition had progressively worsened over the last year and Petitioner had recently been involved in a motor vehicle accident resulting in worsening back pain and mild right-sided radiculopathy. *Id.* at 1. He did not believe the accident affected her neck. *Id.* Upon examination, he found "very faint but noticeable weakness of right-sided grip strength, right-sided biceps and right-sided shoulder abduction compared to the left." Ex. 14 at 2. He again reviewed Petitioner's cervical MRI from August of 2018 and this time felt that cervical discectomy and fusion at C4-5 and C5-6 would be appropriate. *Id.* at 2.

- On June 18, 2019, Petitioner followed-up with Dr. Owen to discuss the surgery he recommended. Ex. 23[6] at 1. Dr. Owen documented that his review of Petitioner's cervical MRI from August of 2018 differed from the official radiology report—he believed Petitioner had "*severe* right-sided neural foraminal stenosis at the C4-5 level" and "*moderate* right-sided neural foraminal stenosis at the C5-6 level." *Id.* at 1 (emphasis added). He felt that the neural foraminal stenosis "correlate[s] very nicely" to Petitioner's symptoms. *Id.* Petitioner requested further discussion prior to the surgery. *Id.* at 2.

- On July 9, 2019, Petitioner returned to Dr. Owen with severe pain from her neck down through her right arm. Ex. 18 at 2. Petitioner wished to proceed with the C4-5 surgery. *Id.* at 2, 4. Petitioner's recent MRI, taken on June 26, 2019, showed a herniated disc at C4-5 and displacement of anterior nerve roots causing severe stenosis. *Id.* at 4.

The records taken in their totality overwhelmingly support Petitioner's contention that the June 20, 2018 Tdap vaccination was administered in her *right* arm. The only medical record indicating otherwise is Petitioner's initial vaccination record, prepared by Nurse Kimberly Jump. Ex. 15 at 2. While there is an affidavit from Nurse Jump dated December 4, 2019, affirming the vaccination record, Nurse Jump provided no reason or context for why she would independently remember the location of Petitioner's Tdap vaccination more than a year later. Ex. 20 at 2. Nurse Jump only restated what was contained in the initial administration record. *Id.*

[6] Petitioner incorrectly labelled this exhibit as "Pl Ex #22." It is Petitioner's 23rd exhibit.

As such, Petitioner's reports of a right arm vaccination the *very next day* and thereafter support a finding that the vaccine was likely administered in her right arm. At Petitioner's emergency visit on June 21, 2018, Petitioner reported that a Tdap vaccine had been administered in her right arm and she felt soreness and aching in the area. Ex 3 at 7. Petitioner also reported that she had not received a tetanus shot in ten years as a reason for her concern. *Id.* It would be highly unlikely for an individual to misremember or misreport where one received a non-annual vaccination merely one day later, particularly while seeking treatment. After this visit, Petitioner also continued to consistently relate her right arm pain to the vaccine. Ex. 4 at 7; Ex 5 at 3; Ex 6 at 7; Ex. 7 at 22; Ex. 9 at 1; Ex. 13 at 5; Ex. 21 at 1; Ex. 22 at 4. Accordingly, there is record support for Petitioner's contention about the situs of administration beyond her own allegations. Thus, while the vaccine administrator documented and affirmed the contrary, and although that initial document warrants some weight, a greater amount of preponderant evidence supports the alternative conclusion.

However, while I accept Petitioner's assertion that the vaccine was administered in her right arm, Petitioner alleges an off-Table claim and has failed to show how her condition was caused-in-fact or significantly aggravated by the vaccination. I find Petitioner has failed to satisfy the *Althen/Loving* prongs necessary for entitlement and the matter must be dismissed.

## V. Legal Standards for Off-Table Claims

### a. Standards for Causation

To receive compensation in the Vaccine Program for an off-Table claim, a petitioner must prove that they suffered an injury actually caused by a vaccine. *See* Section 13(a)( )(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*, 440 F.3d at 1320.

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) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, 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 and is discussed in turn along with the parties' arguments and my findings.

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.

However, the Federal Circuit has repeatedly stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must overall meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the type of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to 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). No one "type" of evidence is required. 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." *Andreu*, 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must each reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon*, 941 F.3d at 1359–60.

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).

However, medical records and/or statements of a treating physician's views 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 also 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 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, 356–57 (2011), *aff'd without opinion*, 475 F. App'x. 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 also coincide 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), r*econs. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 2013 WL 1896173 (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 review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

**b. Standards for Significant Aggravation**

Where a petitioner alleges significant aggravation of a preexisting condition, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *Loving v. Sec'y of Health & Hum. Servs*., 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Hum. Servs.,* 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which require establishing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

*Loving*, 86 Fed. Cl. at 144; see also W.C., 704 F.3d at 1357 (holding that "the Loving case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

In *Sharpe v. Sec'y of Health & Hum. Servs*., 964 F.3d 1072 (Fed. Cir. 2020), the Federal Circuit further elaborated on the *Loving* framework. Under Prong (3) of the *Loving* test, the Petitioner need not demonstrate an expected outcome, but merely that her current-post vaccination condition was worse than pre-vaccination. *Sharpe*, 964 F.3d at 1081. And a claimant may make out a prima facie case of significant aggravation overall without eliminating a preexisting condition as the potential cause of her significantly aggravated injury (although the Circuit's recasting of the significant aggravation standard still permits Respondent to attempt to establish alternative cause, where a petitioner's showing is enough to make out a prima facie case and thereby shift the burden of proof to Respondent). *Id.* at 1083.

## VI. Parties' Arguments

### a. Petitioner[7]

Petitioner asserts a significant aggravation claim, acknowledging a pre-existing herniation or degenerative disc, but submitting that "it was the receipt of the injection itself…that activated this 'nerve sensitization'/'neuroinflammation' that caused the abrupt radicular event and the need for surgery." ECF No. 31 at 3. In short, Petitioner alleges that the Tdap vaccine caused her to experience radicular pain due to neuroinflammation. *See id.*

Petitioner primarily relies on a letter from Dr. Owen to satisfy the *Althen/Loving* prongs. *See* ECF No. 31 at 6. Specifically, Petitioner highlights the following passage in Dr. Owen's October 9, 2019 letter:

> [P]etitoner's pain and resultant treatment related to this pain is, more likely than not, casually related to the immunization injection as evidenced by the close temporal relationship between the onset of her pain and the receipt of the injection itself, as well as the insidiously-progressive nature of the pain's onset which suggests more of a "nerve sensitization" process rather than an abrupt event (such as sudden disc herniation). The injection did not cause the patient's disc herniation; in fact I believe it is likely that the disc herniation preceded the injection, but was asymptomatic prior to her receiving the injection. However, I believe that the injection caused a reaction within the nerve branches into which the immunization was injection which "sensitized" the nerve and caused her to feel radiculopathic

[7] In addition to the records outlined above, Petitioner submitted a letter from Dr. Owen dated October 9, 2019, additional medical records relating to her right arm swelling, updated MRI results, updated medical records from Dr. Rynick from November 2019 through September 23, 2020, and photographs of her right arm. Ex. 19; Ex. 24; Ex. 26; Ex. 27; Ex. 28.

> pain from nerve abutment at C4/5 and what had previously been an asymptomatic disc herniation. There is no other reasonable or scientifically-plausible explanation for the nature of her pain as it is likely related to her disc herniation, especially since the immunization occurred into the same dermatome as that which is supplied by the CS nerve root (and affected by the C4/5 disc herniation").

ECF No. 31 at 6-7, citing Ex. 19 at 2. Petitioner asserts that Dr. Owen's opinion "ranks premier in contrast to the others delineated" based on his treatment of Petitioner, with the other treating physicians (Drs. Keppel, Rynick, and Sharp) being mere "peripheral physicians." ECF No. 31 at 6-7. Petitioner does not provide a mechanism for the neuroinflammation described by Dr. Owen, but rather states, "it is rudimentary that all vaccines can cause neuroinflammation." ECF No. 31 at 8. "Identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." *Id.* at 10.

Overall, Petitioner asserts that she has satisfied the six *Loving* prongs because: I) she was asymptomatic for radicular pain prior to the vaccination; II & III) she "began the long road of radicular symptoms with no intervening or superseding causes to break the chain" after the vaccination; IV) "Dr. Owen's opinion as set forth above reasonable as to causation;" V) that a logical sequence has been proven in this matter; and VI) "there is no doubt as to the proximal temporal relationship between the vaccination and the manifestation of the radicular symptomatology" and "no natural course of the pre-existing condition that would reasonably explain plaintiff's manifestation of radicular symptoms at the C5-6 distribution solely based on pre-existing condition of herniation/degeneration." ECF No. 31 at 9-10.

**b. Respondent**

Respondent submits that Petitioner has failed to satisfy the *Althen/Loving* prongs necessary to establish entitlement. Respondent cites the lack of an expert report and that Petitioner "has not offered a reputable scientific or medical theory establishing that the Tdap vaccine can cause 'permanent muscle and nerve damage' or significantly aggravate a preexisting disc herniation."[8] ECF No. 27 at 10. Respondent takes issue with Petitioner's use of Dr. Owen's opinion, stating that Dr. Owen "has provided no support for this proposed theory" and questioning why Dr. Owen would recommend surgery to improve Petitioner's radiculopathy if the pain was caused by nerve sensitization. *Id.* at 10; ECF No. 33 at 4-5. Further, Respondent submits Petitioner's other treating physicians, Drs.

[8] Respondent also argues that a significant issue to establishing causation is the situs of vaccination. Since I have already resolved situs issue in favor of Petitioner, this argument will not be further addressed.

Sharp and Rynick, did not believe the Tdap vaccination to be related to Petitioner's cervical disc disease or radiculopathy. *Id.* at 11-12. Respondent also submits that Petitioner has failed to show an appropriate temporal relationship, nor established that her condition is not a result of the natural course of her preexisting condition. *Id.*

## VII. Analysis

Petitioner ultimately alleges a significant aggravation claim of radicular pain and therefore must satisfy the six *Loving* prongs. While some are not credibly disputed,[9] it is unquestionably the case that three cannot be met – and therefore Petitioner has failed to satisfy all of the *Althen/Loving* prongs necessary for entitlement.

### a. *Althen* Prong I/*Loving* Prong IV

Petitioner has not provided a medical theory supported by preponderant evidence that would establish that the Tdap vaccine "can cause" sufficient neuroinflammation to aggravate radicular pain. Respondent correctly notes Petitioner's failure to provide an expert report, and that Petitioner inadequately relies on Dr. Owen's letter alleging nerve sensitization and/or neuroinflammation. *See* ECF No. 27 at 10. While Dr. Owen maintains that "the immunization occurred into the same dermatome as that which is supplied by the CS nerve root," he provides no substantiation for how a Tdap vaccination causes nerve sensitization and/or neuroinflammation in the nerves affected by a C4-5 foraminal stenosis. Ex 19 at 2. Petitioner asserts that "it is rudimentary that all vaccines can cause neuroinflammation," citing no sources, and submits that Dr. Owen's opinion "is reasonable as to causation." ECF No. 31 at 8, 9. This is conclusory – and falls well short of the preponderant level of evidence required to meet Petitioner's burden.

### b. *Althen* Prong II/*Loving* Prong V

Petitioner has also failed to preponderantly establish that the Tdap vaccine "did cause" neuroinflammation sufficient to aggravate her underlying injury.

Petitioner again relies on Dr. Owen's opinion, maintaining that it "ranks premier" in comparison to all other treating physicians. ECF No. 31 at 6-7. In fact, that opinion contradicts Dr. Owen's records, and fails to address Petitioner's full medical history.

[9] The first prong, that Petitioner did not have radicular pain in her neck and right arm prior to her June 2018 vaccination, is not in dispute. Neither is the second prong - Petitioner's post-vaccination condition (as of 2020) of radicular pain in her neck and right arm is established.

In his letter, Dr. Owen states that he first began treating Petitioner on June 11, 2019. Ex. 19 at 1. However, Dr. Owen first saw Petitioner in *October 2018* and completed a full neurological evaluation at that time. Ex. 13 at 5. Further, his 2018 treatment records contradict his letter. At the October 2018 visit, Dr. Owen reviewed Petitioner's August 2018 MRI and found "very mild C4-5 right-sided neural foraminal stenosis" and that her pain "does not conform to any particular neural distribution." *Id.* at 6. He concluded that Petitioner's pain was not radicular. *Id.* When Petitioner retuned on December 6, 2018, Dr. Owen continued to opine that Petitioner's pain was not consistent with a C4-5 foraminal stenosis, and in fact noted that Petitioner's pain would be consistent with the C7 nerve distribution. Upon reviewing her MRI again, he found her C4-5 foraminal stenosis to not be severe. Ex. 13 at 3. Despite the above, Dr. Owen opines in his letter that Petitioner's pain conforms "most closely to C5 and/or C6 distribution" and that the injection "sensitized the nerve and caused her to feel radiculopathic pain from nerve abutment at C4/5" Ex. 19 at 1, 2. He does not explain the aforementioned inconsistencies.[10]

Furthermore, Dr. Owen does not address Petitioner's motor vehicle accident, which occurred shortly before Petitioner's June 11, 2019 appointment. Ex. 14 at 1. Dr. Owen wrote that the accident "did not affect her neck," yet Petitioner's medical records show that the accident *caused acute neck pain* (as well as back pain and mild right-sided radiculopathy). Ex. 12 at 2; Ex. 14 at 1. It was only after this motor vehicle accident that Dr. Owen recommended the C4-5 and C5-6 surgeries and that the updated MRI showed a herniated disc at C4-5 with severe foraminal stenosis. Ex. 14 at 2; Ex. 18 at 4. Dr. Owen concludes that there is "no other reasonable or scientifically plausible explanation for the nature of [Petitioner's] pain," yet he does not consider or discuss how a motor vehicle accidence would affect Petitioner's foraminal stenosis and how Petitioner's condition may have naturally evolved and progressed. Ex. 19 at 2.

Dr. Owen's deficient opinion should also be weighed against other contrary evidence, including conflicting opinions among the relevant physicians. See *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012). Dr. Sharp continually assessed Petitioner with cervical degenerative disc disease and radiculopathy; he did not attribute the vaccination to these issues. Ex 7 at 18, 19. Dr. Keppel, an orthopedist, conducted a nerve conduction test and noted the absence of any injury to peripheral nerves or radial nerve. He also noted that Petitioner's symptoms did not correlate with a C4-5 foraminal stenosis. Ex. 22 at 35. And Dr. Rynick, another neurologist, assessed Petitioner with cervical radiculopathy and noted no focal

[10] Additionally, on June 18, 2019, Dr. Owen once again reviewed Petitioner's August 2018 MRIs and found "*severe* right-sided neural foraminal stenosis at the C4-5 level" and "*moderate* right-sided neural foraminal stenosis at the C5-6 level." *Id.* at 1 (emphasis added), contrary to his prior records. Ex. 23 at 1. It is unclear how Dr. Owen could see "very mild" stenosis in an MRI but then see "severe" stenosis in the same MRI several months later. His inconsistent records devalue his subsequent opinion.

peripheral nerve injury related to the vaccination. Ex. 9 at 1. Petitioner has continued to see Dr. Rynick since 2019, and his assessment has continued to be cervical radiculopathy, treating Petitioner with epidural steroid injections. *See generally,* Ex. 27.

Dr. Owen (and Petitioner) fail to address these conflicting assessments, in which Petitioner's other treating physicians attribute her symptoms to her cervical degenerative disc disease. Dr. Owen fails to address the objective testing showing no injury to Petitioner's peripheral nerves and radial nerve as well. Despite being given ample opportunity to file additional evidence, Petitioner has not provided any further support. Considering the entire record, including all the treating physicians' opinions, I find Dr. Owen's opinion about the "did cause" prong inadequate and outweighed by other compelling evidence. The record does not support the contention that the Tdap vaccine injured Petitioner.

### c. *Althen* Prong III/*Loving* Prong VI

Petitioner has not established by preponderant evidence a medically-acceptable temporal relationship between the vaccination and onset of her alleged significant aggravation. While Petitioner experienced a reaction involving cellulitis within a few days of the vaccination (which resolved by August 2018), no timeline for Petitioner's alleged nerve sensitization and/or neuroinflammation has been defined or explained. Petitioner did not offer literature of testimony regarding the expected post-vaccination onset of any comparable condition. Dr. Owen merely opines that there is a "close temporal relationship" (something that is never by itself sufficient in the Program), and provides no further proof that the onset of Petitioner's neuroinflammation occurred within an appropriate amount of time after her Tdap vaccination. The record evidence of some initial vaccine reaction has not otherwise been credibly linked to the primary injury alleged in this case.

## VIII. Conclusion

Based on the entire record, I find that Petitioner has failed to provide preponderant evidence that the Tdap vaccination caused a nerve injury, nerve sensitization, and/or neuroinflammation in her right arm.

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Because Petitioner has made no such showing, she is not entitled to compensation. **Petitioner's claim is hereby DISMISSED.** In the absence of a

timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this Decision.[11]

**IT IS SO ORDERED.**

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

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.