

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1213V

██████████ B.T.,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

*
*
*
*
*
*
*
*
*
*
*
*
*
*
*

Chief Special Master Corcoran

Filed: November 8, 2024

Jessica A. Wallace, Siri & Glimstad, LLP, Aventura, FL, for Petitioner.

Benjamin P. Warder, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION¹

On April 15, 2021, ██████████ B.T. filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”).² Petitioner alleges that he developed an ulnar neuropathy in his right upper extremity from receipt of an influenza (“flu”) vaccine administered to him on September 19, 2018. Petition (ECF No. 1) at 1, 3. The parties have submitted expert reports and offered briefs so that the matter can be resolved via a ruling on the record. *See* Petitioner’s Motion, dated Mar. 26, 2024 (ECF No. 42) (“Mot.”); Respondent’s Opposition, dated May 14, 2024 (ECF No. 44) (“Opp.”); Petitioner’s Reply, dated May 29, 2024 (ECF No. 45). For the reasons stated in more detail below, I deny entitlement.

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 in 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. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter “Vaccine Act” or “the Act”]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Pre-Vaccination Evidence of Limb and Shoulder Issues

Petitioner's pre-vaccination medical history bears on the alleged injury. He had previously experienced several issues relating to his hands and right shoulder that are somewhat consistent with the alleged injury, seeing some of the same treaters who provided assistance after vaccination. (His history also reveals a propensity to seek treatment regularly, and the advice of a large number of different providers).

For example, six years before the vaccination at issue (in October 2012), a magnetic resonance imaging scan ("MRI") of ██████████ B.T.'s right elbow revealed the presence of a large anconeus epitrochlearis accessory muscle, creating a mass effect on the ulnar nerve at the level of the cubital tunnel, and resulting in elbow pain. Ex. 2 at 180. Then, in December 2016, Petitioner had another MRI—this time of his right hand, occasioned by an accident to it that had caused pain. Ex. 17 at 43–16. This second MRI revealed a finger bone contusion plus a likely related muscle sprain. *Id.* Mr. Tacher underwent a third MRI in June 2017 of his right shoulder (and also due to reported pain), and which revealed tendinopathy. *Id.* at 39.

In addition, during the spring and early summer of 2018, ██████████ B.T. had several visits to chiropractor Cole Streets, D.C., of Sports & Spine Chiropractic & Rehabilitation Solutions ("SSCRS"). Ex. 6 at 31–37. He sought chiropractic care to treat "symptoms in the cervical spine described as intermittent aching discomfort that radiates to the head and radiates to the right shoulder." *Id.* at 31. Dr. Street's impressions included cervical dysfunction, impingement syndrome of the right shoulder, cervicgia, and right-hand pain. *Id.* Petitioner obtained additional chiropractic treatment at SSCRS that summer, complaining of right shoulder pain, left-side cervical spine discomfort, and radiating pain from his temporomandibular joint ("TMJ") that radiated to his head. *Id.* at 25–29, 31.

That same summer, ██████████ B.T. also visited a different chiropractor, Scott Weiland, D.C., at Gulf Coast Spine & Sport ("GCSS") for TMJ and persistent right shoulder pain. Ex. 7 at 3–6. Testing revealed normal strength but pain on some movement with tenderness to palpitation ("TTP") of certain right shoulder muscles. *Id.* at 4, 5. Dr. Weiland provided chiropractic physical adjustments but also proposed home exercises. *Id.* at 5–6. His pain remained over the summer, however. *Id.* at 7–9, 10–12. He returned to SSCRS in August–September 2018 to see Dr. Streets, also reporting right shoulder pain, and receiving treatment comparable to what Dr. Weiland provided. Ex. 6 at 25–27.

September 2018 Vaccination

██████████ B.T. (then 44-years old) received the flu vaccine in his right deltoid on September 19, 2018, at a Cape Coral, Florida CVS Pharmacy. Ex. 1 at 2. Two days later (September 21, 2018), Petitioner visited Dr. Streets at SSCRS complaining of constant, *bilateral* shoulder pain at

a 7/10 level. Ex. 6 at 24. The record from this visit (the first post-vaccination) makes no reference to the vaccination event two days prior, and does not contain any representations from Petitioner that the recent vaccination had caused pain or any other immediate symptoms. *Id.* Dr. Streets treated Petitioner with chiropractic manipulation and laser therapy, among other things. *Id.*

One-week post-vaccination, on September 27, 2018, ██████████ B.T. contacted Neuroscience & Spine Associates (“NSA”) to schedule an appointment with neurologist Dr. Igor Levy-Reis, based on a reported referral from another treater. Ex. 2 at 24-7. At this time, Petitioner reported tingling in his feet and hands for one week—although no reference is made in this intake form as to the prior vaccination. *Id.* Then, in early October, he went to Jaffe Sports Medicine (“JSM”) to see physical medicine and rehabilitation specialist, Peter Jaffe, D.O. Ex. 3 at 10–13. ██████████ B.T. now noted his September vaccination, adding that after receiving it he had developed bilateral upper extremity paresthesias, and reported experiencing numbness and pain in his right forearm and hand, all of which were worsening. *Id.* at 10. Petitioner did also acknowledge his prior PT and hand-related treatments. *Id.* at 12.

A neurologic exam performed at Dr. Jaffe’s office revealed bilateral upper and lower paresthesias, but normal reflexes and strength. Ex. 3 at 11. Petitioner underwent an EMG of his upper right extremity at this time which demonstrated evidence of a mild-to-moderate right ulnar compression across the elbow, but no likely cervical radiculopathy. Ex. 8 at 46. Dr. Jaffe proposed that ██████████ B.T. was experiencing “worsening nerve dysfunction sequelae” and possibly “Vaccine[-]induced [Guillain-Barré syndrome].” Ex. 3 at 11, 12 (noting a diagnosis of “nerve dysfunction, right arm”). He prescribed gabapentin, PT, and home treatments, including exercises. *Id.* at 12.

Later that same October and November, Petitioner returned to Dr. Streets, now complaining of right wrist and elbow pain, plus left cervical spine pain. Ex. 6 at 22, 23. Dr. Streets referred him to an orthopedic specialist, but also proposed an MRI to look for evidence of nerve entrapment. *Id.* Petitioner saw that specialist—Dr. David Eichten of Joint Implant Surgeons of Florida (“JISF”)—on November 7, 2018. Ex. 4 at 27–30. ██████████ B.T. reported pain in his right elbow and wrist, radiating down his arm to his hands and beginning six weeks after the September vaccination (meaning later October or early November), due, in his estimation, to the vaccine’s misadministration. *Id.* at 27. Dr. Eichten proposed Petitioner follow up with his practice partner, Dennis Sagini, M.D., for “in[]situ decompression vs transposition of the ulnar nerve.” *Id.* at 30.

On November 9, 2018, ██████████ B.T. had a previously-scheduled appointment at NSA with Dr. Levy-Reis. Ex. 2 at 126–28. He again reported numbness in his right hand beginning at the time of vaccination, due to purported misadministration. *Id.* at 126. And it was claimed that the EMG performed by Dr. Jaffe at an earlier October visit demonstrated ulnar neuropathy. *Id.* Dr. Levy-Reis prescribed a Medrol Dosepak and gabapentin, and ordered an MRI of Petitioner’s right upper extremity and an EMG of his upper extremities. *Id.* at 127. Petitioner also saw Dr. Weiss that same day, reporting right elbow and hand pain in the wake of vaccination and due to

misadministration, with paresthesias beginning two days after vaccination and worsening pain over time. Ex. 7 at 13–15.

On November 14, 2018, ██████████ B.T. returned to GCSS for a visit with Dr. Weiland for treatment of persistent nerve pain in his right arm that he associated with his September vaccination. Ex. 7 at 16–17. The next day, he had an appointment at JISF with orthopedic surgeon and hand specialist Dr. Sagini, at which time he reported symptoms and vaccine associations comparable to what he was providing to other treaters at the time. Ex. 4 at 10–15. On examination, Petitioner’s Tinel’s sign³ was negative in the right radial tunnel but positive in the right ulnar groove, and he displayed some pain and weakness with right wrist flexion. *Id.* at 12–13. Dr. Sagini opined that ██████████ B.T. might be experiencing a triangular fibrocartilage complex (“TFCC”) sprain of the right wrist and a healing ulnar nerve neuritis, and provided a direct injection into Petitioner’s hand and wrist which provided some prompt relief. *Id.* at 13–14.

Treatment in 2019 and Beyond

Petitioner has filed medical records memorializing treatment he received in the ensuing three years (2019–21). He continued to seek medical assistance from the same providers he had seen in the months immediately following vaccination, reporting chronic symptoms he associated with his September 2018 vaccination.

In the winter of 2019, for example, ██████████ B.T. saw Dr. Weiland again, complaining of unrelated neck and upper back pain, but also ongoing nerve pain he deemed associated with his vaccination that prior fall. Ex. 7 at 18–20, 21–22, 23–24. He also had several appointments into the spring of 2019 with Dr. Streets at SSCRS, during which he consistently reported right elbow pain. Ex. 6 at 11–19.

In mid-March 2019, ██████████ B.T. went back to Dr. Sagini but saw his physician’s assistant (“PA”), Maria Rienzi, reporting more right hand/wrist/elbow pain. Ex. 4 at 66–70. PA Rienzi noted some wrist range of motion issues and other hand concerns, but did not deem surgery necessary, and recommended that Petitioner undergo an MRI of his right wrist (to rule out a TFCC tear) and right elbow (to rule out a biceps tendon tear versus brachialis tear). *Id.* at 69–70. He saw a new treater at JSM in April 2019, now claiming that the post-vaccination paresthesias he first experienced in his right upper extremity had migrated to his feet (if more moderate in sensation). Ex. 3 at 14–16. The treater confirmed the possibility of a vaccine reaction, and proposed ██████████ B.T. follow up with a PCP to confirm whether he had some kind of flu vaccine sensitivity. *Id.*

The right elbow MRI recommended by PA Rienzi occurred in mid-April, and it revealed an abnormal signal at the biceps tendon insertion that could represent tendinopathy or tendon bursitis. Ex. 8 at 45. On April 17, 2019, Petitioner underwent an MRI of his right wrist, and its

³

“Tinel Sign” is defined as “a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of the nerve.” *Tin el Sign*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=106510> (last visited Nov. 8, 2024).

findings seemed consistent with prior trauma of some kind (but also showed effusion associated with capsulitis/capsulosynovitis or TFCC thinning). *Id.* at 51. Another EMG, performed in early May by Dr. Levy-Reis of NSA, demonstrated a right ulnar sensory neuropathy and isolated decreased recruitment of the hypothenar muscles. Ex. 2 at 214–19. Dr. Levy-Reis also saw [REDACTED]. [REDACTED] B.T. thereafter, on May 9, 2019. *Id.* at 123–25. Based on his reported history and the exam findings and testing, Dr. Levy-Reis opined that Petitioner had experienced a vaccine-induced ulnar neuropathy (adding that there was a lack of clear evidence of right elbow nerve entrapment). *Id.*

That same May, [REDACTED] B.T. returned to Dr. Sagini for consideration of his on-going right wrist and elbow pain. Ex. 4 at 45–50. An examination of his right wrist was positive for TTP over the ECU tendon sheath, and there was paresthesias related to ulnar nerve distribution. *Id.* at 48. Dr. Sagini deemed Petitioner’s presentation to constitute evidence of distal biceps tendinitis of the right elbow and sprain of the right wrist, and prescribing additional medication and pain injections. *Id.* at 49. Toward the end of the month, Petitioner began seeking treatment from the Pain Management Center of Naples, due to his hand and shoulder pain (although his ulnar neuropathy was noted as well). Ex. 13 at 5–8. An MRI performed that month of Petitioner’s cervical spine revealed a number of problems, including bulging discs and stenosis. *Id.* at 12. [REDACTED] B.T. returned to Dr. Levy-Reis in June 2019, repeating his diagnosis of ulnar neuropathy, and adding that “[i]t seems it was triggered by the [flu] injection.” Ex. 2 at 109–11.

Throughout that summer, Petitioner received occupational therapy (“OT”). Ex. 3 at 89–108. A left shoulder MRI performed in August revealed intact rotator cuff tendons, mild peritendinobursitis, and a small effusion. Ex. 8 at 47. Issues with back and shoulder pain also led [REDACTED] B.T. to return to Dr. Levy-Reis in September 2019. Ex. 2 at 83–85. At this time, however, Dr. Levy-Reis declared that the ulnar neuropathy in Petitioner’s right arm had “pretty much resolved.” *Id.* at 83–84.

By the fall, Petitioner continued to complain of left shoulder and right elbow pain, and he received steroid or platelet-rich plasma injections in his bilateral upper extremities. Ex. 2 at 80–82. He followed up with Dr. Sagini at JISF in November, at which time he complained of right wrist and elbow pain (but without right shoulder numbness or tingling). Ex. 4 at 54–58. [REDACTED] B.T. was assessed with right shoulder tendinitis, but Dr. Sagini also noted that OT appeared to have helped Petitioner’s wrist pain and range of motion issues. *Id.* at 57–58. Dr. Sagini also proposed further consultation with a rheumatologist. *Id.* at 58.

At an early December 2019 visit to NSA, Petitioner’s focus was on his difficulties coping with left shoulder pain, and he complained that prior pain treatments had worn off. Ex. 2 at 76–78. He was now assessed with right cubital tunnel syndrome, right distal biceps tendinitis, left AC joint osteoarthritis, and left subacromial impingement with rotator cuff tendinitis. *Id.* at 77, 78. It was proposed that [REDACTED] B.T. consider more invasive treatment, such as ulnar nerve decompression with transposition surgery. *Id.* That same month, Petitioner obtained more pain management treatment at PMCN, and his ulnar nerve injury was addressed, as well as many

possible causes of it. Ex. 13 at 2–4. Petitioner continued to repeat his contention about his elbow-related issues due to vaccine misadministration at a visit to orthopedic hand specialist, Dr. Stephen Helgemo, at the Florida Hand Center (“FHC”) in mid-December 2019. Ex. 10 at 3–5. Dr. Helgemo, however, observed that Petitioner’s right elbow pain might “be coming from the biceps or the brachioradialis [as] both are somewhat obscure problems that really do not have a ready-made solution,” and therefore, more invasive treatment was likely unwarranted. *Id.* at 5.

2020 featured the same efforts by ██████████ B.T. to obtain treatment (both for the injury at issue as well as other conditions) from a wide variety of medical providers. For example, Petitioner returned to Dr. Helgemo in January 2020, and it was now recommended that he undergo decompression surgery. Ex. 10 at 6–7. He subsequently received acupuncture treatment that winter as well. Ex. 15 at 4.

In the early spring, Petitioner saw physiatrist Sebastian Klisiewicz, D.O., at Integrative Rehab Medicine (“IRM”). Ex. 8 at 61–62. ██████████ B.T. was assessed with right arm pain and numbness, ulnar neuropathy, radial neuritis, right lateral wrist instability, and thinning of the TFCC. *Id.* at 61. It was proposed that Petitioner undergo nerve hydrodissection⁴ of the right radial nerve and right ulnar nerve, along with a prolotherapy⁵ injection of the right lateral wrist. *Id.* Both procedures were performed at IRM on March 23, 2020. *Id.* at 38–41.

Thereafter, however, Petitioner continued to experience elbow pain, and Dr. Klisiewicz assessed him in April with right arm pain and numbness since Petitioner’s receipt of the flu vaccine, plus right-sided ulnar neuropathy, right-sided radial neuritis, right-sided distal biceps peritendinitis/bursitis, right-sided lateral wrist instability, and thinning of the right-side TFCC. Ex. 8 at 35–38. ██████████ B.T. was instructed to focus on a home exercise program. *Id.* He returned to Dr. Klisiewicz in early May, reporting that the pain in his right arm had decreased, and he received a steroid injection directed at the right radial and ulnar nerves. *Id.* at 2–5. Later that month, Dr. Klisiewicz again saw ██████████ B.T., and performed elbow laser therapy on his right ulnar nerve. *Id.* at 11–13. Dr. Klisiewicz also that month administered PRP prolotherapy and perineural injections into Petitioner’s bilateral AC joints and the radial collateral ligament of his right wrist. *Id.* at 6–7, 14–26.

At an appointment with Dr. Helgemo of FHC in July, Petitioner noted he continued to experience elbow pain, among other things, and ulnar nerve decompression surgery was discussed.

⁴ “Nerve hydrodissection” is defined as “a technique used when treating nerve entrapments, [and] involved the injection of an anesthetic, saline, or 5% dextrose in water to separate the nerve from the surrounding tissue, fascia, or adjacent structures.” NIH National Library of Medicine, *Ultrasound-Guided Nerve Hydrodissection for Pain Management: Rationale, Methods, Current Literature, and Theoretical Mechanisms*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414936/> (last visited Nov. 8, 2024).

⁵ “Prolotherapy” is defined as “an injection-based complementary and alternative medical (CAM) therapy for chronic musculoskeletal pain.” NIH National Library of Medicine, *Prolotherapy in Primary Care Practice*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831229/> (last visited Nov. 8, 2024).

Ex. 10 at 8–9. It was noted, however, that nerve tests had “not shown anything except maybe neuropathy on one [test],” and there was no “real area of tenderness” in Petitioner’s right elbow, although Dr. Helgemo was able to palpate the ulnar nerve, which was sensitive above the elbow. *Id.* at 8–9. Dr. Helgemo stated that he did not believe that surgery was “really clearly indicated,” recommending instead right hand-oriented OT. *Id.* at 9. Dr. Helgemo added that because the tingling and numbness in Petitioner’s right had had largely stopped, the “primary impetus” to perform an ulnar nerve decompression surgery was no longer present. *Id.* Additional EMG testing of ██████████ B.T.’s right upper extremity performed by Dr. Jaffe in August 2020 revealed moderate- to-severe ulnar compression across the right elbow, but no evidence of cervical radiculopathy. Ex. 16 at 21.

Petitioner sought a second opinion on the propriety of surgery that same August, at the University of Miami Hospital and Clinics (“UMHC”) with neurosurgeon Ian Cote, M.D. Ex. 9 at 8–11. Dr. Cote noted that ██████████ B.T. had previously undergone EMGs confirming a diagnosis of compressive ulnar neuropathy at the elbow, and his exam revealed right-hand sensory deficiencies. *Id.* He deemed Petitioner’s ulnar neuropathy to be likely “secondary to a congenital abnormality in the form of an accessory anconeus muscle belly.” *Id.* at 10. But Dr. Cote did recommend a surgical procedure—“an ulnar nerve neurolysis and decompression at the elbow”—to which ██████████ B.T. expressed a willingness to undergo. *Id.*

Toward the end of August, Petitioner saw yet another orthopedic surgeon and hand specialist, Dr. Elizabeth Ouellette, again complaining of right elbow pain. Ex. 11 at 12–16. After an extensive physical examination, Dr. Ouellette opined that ██████████ B.T. was suffering from compartment syndrome of the right upper arm (secondary to the vaccination event from 2018), ulnar nerve entrapment at the right elbow, tear of the TFCC of the wrist, brachial plexopathy without trauma, and injury of the radial nerve in the upper right arm. *Id.* Dr. Ouellette proposed a surgical plan for release of the plexus at the axilla and radial nerve at the triangular space of the right upper extremity—the procedure was performed on September 18, 2020. *Id.* at 16, 18–19. Petitioner experienced some post-surgical shoulder pain, but otherwise recovered well from the procedure.

Records filed with respect to treatment ██████████ B.T. received in 2021 (which cease that spring) underscore his continued efforts to seek relief for the panoply of shoulder/arm/hand symptoms he had experienced, but do not provide illumination as to causation. Petitioner did, however, continue to inform treaters that his discomfort began at the time of his September 2018 vaccination. *See, e.g.,* Ex. 17 at 55–60 (documenting March 2021 visit to sports medicine/regenerative orthopedic specialist); Ex. 16 at 8–13 (documenting visit to physical medicine and rehabilitation specialist). Despite some lingering symptoms, Petitioner’s condition was generally deemed improved, and treaters largely recommended medication or non-invasive treatments to manage any continued pain or sensory issues. *See, e.g.,* Ex. 16 at 30 (documenting follow-up EMG performed in April 2021, which revealed mild ulnar neuropathy at Petitioner’s right elbow with new evidence of denervation, peripheral neuropathy, myopathy, radiculopathy,

radial neuropathy, brachial plexopathy, or carpal tunnel syndrome); Ex. 18 at 15–18 (noting follow-up examination performed by Dr. Ouellette in April 2021 revealed full range of motion and strength, plus resolution of compartment syndrome, and other than some mild wrist discomfort, [REDACTED] B.T. reported decrease in numbness and overall improvement).

II. Expert Reports

A. *Petitioner's Expert — Dr. Carlo Tornatore*

Dr. Tornatore, a board-certified neurologist, prepared two written reports for Petitioner in support of the contention that his ulnar neuropathy was vaccine-caused. Report, dated Dec. 15, 2022 (ECF No. 31-1) (“Tornatore First Rep.”); Report, dated Aug. 26, 2023 (ECF No. 36-1) (“Tornatore Supp. Rep.”).

Dr. Tornatore graduated from Cornell University with a Bachelor of Arts and Sciences in Neurobiology, and attended Georgetown University Medical Center, where he received a Master of Science in Physiology. *Curriculum Vitae*, filed as Ex. 21 (ECF No. 39-1) (“Tornatore CV”) at 1. He subsequently graduated from medical school at Georgetown University School of Medicine, completing a residency in the Department of Neurology at Georgetown University Hospital. Tornatore CV 1–2. Dr. Tornatore also completed a fellowship in Molecular Virology at the National Institute of Health in Bethesda, Maryland. *Id.* at 2. He has published multiple articles addressing cell biology and pathology of demyelinating disorders. *Id.* at 6–15. Currently, Dr. Tornatore serves as Professor and Chairman of the Department of Neurology at Georgetown University Medical Center, Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital in Washington, D.C., and Executive Director of the Multiple Sclerosis Patient Centered Specialty Home. Tornatore First Rep. at 1. Currently, Dr. Tornatore follows approximately 124 patients with inflammatory neuropathies, myopathies and disorders of the neuromuscular junction. Tornatore CV at 3. Over the course of his career, he has been involved with the care of approximately thousands of patients who present with mononeuropathies and polyneuropathies. *Id.*

First Report

Dr. Tornatore first provided a detailed summary of Petitioner’s prior medical history and the pertinent facts as they relate to the alleged vaccine-related injury before setting forth his opinion. *See generally* Tornatore First Rep. at 2–14. Dr. Tornatore opined that Petitioner’s “onset of symptoms [is] consistent with a right ulnar injury at the level of the elbow two days after receiving an influenza vaccination in the vicinity of the right ulnar nerve.” *Id.* at 14. He further explained that Petitioner had a pseudocyst of the distal scaphoid as a result of a pre-vaccination wrist injury, in addition to a congenital abnormality of the accessory anconeus muscle at the elbow, which according to Dr. Tornatore, “may have made [REDACTED] [B.T.] more susceptible to an ulnar neuropathy due to a mis-administered vaccination.” *Id.* at 14–15.

To support the conclusion that a mis-administered vaccination can result in an ulnar neuropathy, Dr. Tornatore relied upon several items of literature. Tornatore First Rep. at 15; H. Kim et al., *Upper Limb Nerve Injuries Caused by Intramuscular Injection or Routine Venipuncture*, 12 *Anesthesia & Pain Medicine* 103 (2017), filed as Ex. 19, Tab 1 (ECF No. 31-2) (“Kim”); S. Geiringer & J. Leonard, *Injection-Related Ulnar Neuropathy*, 70 *Arch Phys Med Rehabil* 705 (1989), filed as Ex. 19, Tab 2 (ECF No. 31-3) (“Geiringer”); V. Salanga & J. Hahn, *Traumatic Ulnar Neuropathy from Jet Injection: Case Report*, 19 *J Trauma* 283 (1979), filed as Ex. 19, Tab 3 (ECF No. 31-4) (“Salanga”).

Kim described two cases of an injection-related ulnar neuropathy following vaccination, and noted several mechanisms that might account for its development, including “1. Direct trauma to nerve fibers from the needle; 2. Compression of nerve fibers by the injected material, either intraneural or extraneural; 3. Hematoma caused by injection leading to nerve compression; 4. Direct toxic effect of injected material on nerve fibers; [or] 5. Toxic effect of injected material on surrounding tissues, leading to fibrosis or small vessel thrombosis, with a delayed secondary effect on nerve.” Kim at 103. As Dr. Tornatore pointed out, both patients discussed in Kim had been injected on the left by a right-handed nurse, and thus “[c]ombined with a ‘sidearm’ delivery, [such] positioning likely facilitated missing the deltoid completely, skirting medial to the triceps long head, and entering the medial-lying neurovascular bundle.” Tornatore First Rep. at 17; Kim at 106. Dr. Tornatore also proposed that Kim provided additional support for ██████████ B.T.’s onset of symptoms beginning forty-eight hours post-vaccination, since the “[m]igration of the injected material from its original location is one explanation for the delayed onset of symptoms, 30 minutes in one case, several hours in the other.” *Id.*

Dr. Tornatore further opined that if Petitioner were suffering from a congenital abnormality of the accessory anconeus muscle at the elbow, “then the migration of the injected material/vaccine and [] or a hematoma, could [have] indeed resulted in compression of an already compromised ulnar nerve at the elbow.” Tornatore First Rep. at 18. In fact, several of Petitioner’s EMG/NCS studies indicated “a significant aggravation of a pre-existing condition,” according to Dr. Tornatore, thus corroborating this possibility. Tornatore First Rep. at 18.

To conclude his first report, Dr. Tornatore argued that “there are scientifically recognized reasons why an improperly administered influenza vaccination could result in an ulnar neuropathy above the elbow.” Tornatore First Rep. at 19. He further emphasized the notion that such an injury is more likely to occur in an individual who might present with an “anatomical predisposition to developing ulnar neuropathy above the elbow.” *Id.* Based on the medical records and facts herein, Dr. Tornatore opined that ██████████ B.T.’s receipt of the flu vaccine on September 19, 2018, was “improperly administered, [and thus] aggravating [his] congenital propensity for development of ulnar neuropathy above the elbow.” *Id.*

Supplemental Report

Dr. Tornatore's second report began by briefly describing the concept of "double crush syndrome" as it relates to the case herein. Tornatore Supp. Rep. at 3. As he explained, "[i]n [Petitioner's] case, there was a second injury above the elbow from the misplaced vaccination," and this second injury likely exacerbated the *existing* injury at the elbow. *Id.* at 4. Double crush syndrome can be defined as "the coexistence of dual compressive lesions along the course of a nerve," and can be further demonstrated via an animal model described in an item of literature. *Id.* at 5; K. Nemoto et al., *An Experimental Study on the "Double Crush" Hypothesis*, 12 J. Hand Surgery 552, 558 (1987), filed as Ex. 20, Tab 4 (ECF No. 36-5) ("Nemoto") (clamping sciatic nerve of dogs at either a single or two sites, and finding that where the nerve was compressed at proximal and distal sites, complete conduction block was seen in 50 percent of the nerves at six weeks, and motor nerve conduction velocity was reduced to 66 percent). Dr. Tornatore maintained that Nemoto "emphasizes the point that two low grade compressions along the nerve trunk are worse than one such compression[,] but also that the damage of the dual compression exceeds the expected additive damage caused by each isolated compression." Tornatore Supp. Rep. at 5.

Moreover, Dr. Tornatore maintained that Nemoto supports the notion that "[compression] can result in permanent symptomatic injury to the nerve distal to the proximal point of injury long after the proximal injury has resolved." Tornatore Supp. Rep. at 5; Nemoto at 558; *see also* A. Schmid & M. Coppieters, *The Double Crush Syndrome Revisited – A Delphi Study to Reveal Current Expert Views on Mechanisms Underlying Dual Nerve Disorders*, 16 Manual Therapy 557 (2011), filed as Ex. 20, Tab 5 (ECF No. 36-6) (identifying fourteen mechanisms associated with a first nerve disorder that may predispose to the development of another nerve disorder, four of which were considered highly plausible (*i.e.*, impaired axonal transport, ion channel up or downregulation, inflammation in the dorsal root ganglia, and neuroma-in-continuity)). In further elaboration of the double crush concept, Dr. Callaghan also cited, but did not discuss in detail, four cases discussing ulnar double crush. Tornatore Supp. Rep. at 5; M. Akyuz et al., *Electromyography and Ultrasonography in the Diagnosis of a Rare Double-Crush Ulnar Nerve Injury*, 92 Arch Phys Med Rehabil 1914 (2011), filed as Ex. 20, Tab 6 (ECF No. 36-7); B. Corder et al., *Subacute Ulnar Nerve Compression Neuropathy following Hand Crush Injury in the Setting of Intracanal Accessory Abductor Digiti Minimi: A Double Crush Phenomenon*, J. Hand Surgery Global Online 1 (2023), filed as Ex. 20, Tab 7 (ECF No. 36-8).

Dr. Tornatore thus opined that there are recognized scientific principles that exist to support a double crush scenario as explanatory herein of Petitioner's injury. Tornatore Supp. Rep. at 6. As he detailed, "1. [REDACTED] B.T. had long standing compression of the ulnar nerve at the elbow due to congenital accessory anconeus muscle (*i.e.*, the first crush of a potential double crush syndrome); and 2. Following the misplaced injection of the influenza vaccine in the upper arm, the second component of the double crush, symptoms of ulnar nerve dysfunction at the elbow, became evident due to the disruption of the axoplasmic flow proximally from the vaccine site." Tornatore Supp. Rep. at 6.

The second part of the supplemental report was devoted to responding to comments made by Respondent's expert, Dr. Callaghan. Tomatore Supp. Rep. at 6–10. Dr. Tomatore noted that Dr. Callaghan acknowledged that Petitioner's October 2012 MRI results had revealed the existence of an accessory anconeus muscle, and he disputed Dr. Callaghan's minimization of the role that this kind of anatomical predisposition could have in the development of an ulnar neuropathy seen two days post-vaccination. *Id.* at 6. Dr. Tomatore instead insisted that he had adequately demonstrated, via the referenced literature, that an anatomical predisposition can become symptomatic through a double crush scenario. *Id.* He further addressed Dr. Callaghan's assertion that an injection in the deltoid, and/or other areas of the upper arm would be incapable of causing an ulnar nerve injury elsewhere. *Id.* Dr. Tomatore argued that not only had Dr. Callaghan "ignore[d] the fact that [REDACTED] B.T. reported receiving the vaccination below the deltoid," but that the diagrams referenced in Geiringer demonstrated "how anatomically it would be possible to cause injury to the ulnar nerve in the upper arm from a misplaced injection." *Id.*; see also Geiringer at 705 (Fig. 1), 706 (Figs. 2, 3).

In response to Dr. Callaghan's comment that "[v]accination is [] unlikely a cause of Petitioner's ulnar neuropathy, given the many flares of his symptoms over the years," Dr. Tomatore argued instead that Dr. Callaghan "misse[d] the point that the [flu] vaccine led to the significant aggravation of the ulnar neuropathy at the elbow via a double crush syndrome and subsequent changes to the physiology of the ulnar nerve at the elbow." Tomatore Supp. Rep. at 8. He further explained that when the ulnar nerve undergoes such changes, "they will continue to be periodically symptomatic[,] independent of any further injury proximally[,] given the ongoing compression from the accessory anconeus muscle." *Id.*

Dr. Tomatore then briefly addressed Dr. Callaghan's criticisms of referenced case reports. Tomatore Supp. Rep. at 8. Dr. Callaghan argued that the case reports documenting traumatic injury of the ulnar nerve post-vaccination documented only injuries significantly higher than the elbow, but Dr. Tomatore maintained that were such an injury the *second* incident in a double crush scenario, then symptoms relating to the previous compression as a result of the accessory anconeus muscle injury (*i.e.*, the first incident in a double crush scenario) could occur. *Id.* He further opined that such a scenario was illustrated in Nemoto. *Id.* In addition, Dr. Tomatore also disagreed with Dr. Callaghan's statement that "[w]hile case reports and series are valuable tools in flagging areas for future study, they are anecdotal and provide low-level evidence compared to other study designs." Callaghan Rep. at 8; Tomatore Supp. Rep. 9. In fact, he maintained, "[t]he Institute of Medicine was very clear about the value of case reports that demonstrate strong mechanistic evidence" which according to Dr. Tomatore, is exactly what the three case reports he referenced in his first report do—illustrate a vaccine/injection-related ulnar injury from misplaced injections. Tomatore Supp. Rep. at 9.

B. *Respondent's Expert – Dr. Brian Callaghan*

Dr. Callaghan, a neuromuscular specialist in treatment of neuropathies like ulnar mononeuropathy, prepared one written report on behalf of Respondent. Report, dated Apr. 21, 2023 (ECF No. 33-1) (“Callaghan Rep.”). Dr. Callaghan opines that Petitioner’s clinical course is consistent with a diagnosis of ulnar neuropathy at the right elbow caused by compression rather than vaccination. *Id.* at 9.

Dr. Callaghan graduated from the University of Michigan with a Bachelor of Science, and attended the University of Pennsylvania Medical Center, where he received his medical degree. He subsequently graduated from the University of Michigan with a Masters in Science in Clinical Research Design and Statistical Analysis. *Curriculum Vitae*, filed as Ex. B (ECF No. 33-3) (“Callaghan CV”) at 1. Thereafter, Dr. Callaghan completed an internship and residency at the University of Pennsylvania Medical Center in Preliminary Medicine and Neurology, respectively. Callaghan CV at 1. He also completed fellowships in Neuromuscular and the Center for Healthcare Research and Transformation Policy at the University of Michigan. *Id.* Dr. Callaghan is board certified by the American Board of Psychiatry and the American Board of Electrodiagnostic Medicine. *Id.* He has published more than 130 articles and medical book chapters, with a majority focusing on neuropathy, and including the appropriate diagnostic evaluation and treatment of neuropathy. *Id.* at 14–24. Currently, Dr. Callaghan serves as an Associate Professor of Neurology at the University of Michigan. *Id.*; Callaghan Rep. at 1.

Dr. Callaghan began his report summarizing the pertinent medical history and facts of Petitioner’s case. *See generally* Callaghan Rep. at 1–6. He then opined on Petitioner’s overall diagnosis—stating that based on Petitioner’s various test results, a clear diagnosis of right ulnar neuropathy at the elbow was indicated. *Id.* at 7. Of note, Dr. Callaghan emphasized that Petitioner underwent five EMG/NCS studies, three of which revealed “clear localization of the elbow.” *Id.*; Ex. 2 at 214; Ex. 3 at 14, 21. While Petitioner’s MRI of his right elbow did not reveal impingement, Dr. Callaghan noted that Petitioner’s neurologist documented “mild impingement of the ulnar nerve at the right elbow” in his report, and that Petitioner’s ultrasound demonstrated “clear evidence of compression at the elbow.” Callaghan Rep. at 7; Ex. 2 at 59. Moreover, an MRI performed in October 2012 (and thus years before the relevant vaccination) revealed the accessory anconeus muscle, which according to Dr. Callaghan is known to make an individual susceptible to compression of the ulnar nerve at the elbow. Callaghan Rep. at 7.

Ulnar neuropathy of the elbow, explained Dr. Callaghan, “is almost always secondary to compression or stretch of the nerve within the cubital tunnel.” Callaghan Rep. at 7; A. Cambon-Binder, *Ulnar Neuropathy at the Elbow*, 107 *Orthopaedics & Traumatology: Surgery and Research* 1 (2021), filed as Ex. A, Tab1 (ECF No. 33-2) (“Cambon-Binder”). Although Dr. Callaghan allowed for the possibility that an “injection into the elbow could cause an ulnar neuropathy at that situs, [an] injection at the shoulder cannot,” because “[t]he deltoid, where vaccinations are administered, and the elbow are anatomically far apart.” Callaghan Rep. at 7–8. Dr. Callaghan also

criticized Dr. Tornatore’s opinion that the flu vaccine could have aggravated [REDACTED] B.T.’s “congenital propensity” to develop an ulnar neuropathy above the elbow—noting that “[t]here is no evidence that the flu vaccine, or any vaccine, can cause an ulnar neuropathy at the elbow.” *Id.* at 8. All case reports offered for this proposition involved specific injuries occurring at places on the arm well above the elbow. *Id.*; Salanga at 2. In addition, Kim (which Dr. Tornatore highlighted) not only affirmed the rarity of ulnar neuropathies caused by injection, but does not even specify “vaccine-related” injection as a possible cause. *Id.*; Kim at 103, 106 (stating that “[i]njection-related ulnar nerve injury seems to be relatively rare,” and finding that only 2 of 645 patients with ulnar nerve injuries analyzed over a thirty year period were thought to possibly have incurred the injury due to injection).

Dr. Callaghan then briefly addressed whether the medical record itself supported causation. Callaghan Rep. at 8. While Petitioner’s neurologist had in fact considered a potential causal relationship between his receipt of the flu vaccine and his subsequent development of ulnar neuropathy, Dr. Callaghan deemed it “misleading” for Dr. Tornatore to claim contemporaneous treaters supported causation, noting that Petitioner’s orthopedist, hand specialist physician, and neurosurgeon all embraced the diagnosis of an ulnar mononeuropathy attributable to compression at the elbow. *Id.* Moreover, Dr. Callaghan stressed that “the many flares of [Petitioner’s] symptoms over the years” undermined vaccine causation further. *Id.* He deemed the recurrence of flare-ups “clearly” due to existing compression at the right elbow. *Id.*

Finally, Dr. Callaghan addressed the medical acceptability of timing of onset in this case. In his view, “an onset of symptoms [two] days after [Petitioner’s] receipt of the flu vaccination, and intermittent symptoms initially” were “not compatible” with a vaccination-triggered traumatic injury at the ulnar nerve. *Id.* Instead, such an injury would typically occur almost *immediately* following injection, and associated symptoms would be more likely to present as persistent. *Id.* To bulwark his opinion, Dr. Callaghan noted that even the medical literature relied upon by Dr. Tornatore supported a symptom onset within several hours—not two days as the case herein. *Id.* Geiringer & Leonard at 705.

III. Procedural History

As noted above, this case was initiated in April 2021, a little over three years ago, and assigned to a different special master. Shortly thereafter, it was reassigned to me in February 2022. Respondent filed his Rule 4(c) Report contesting entitlement in July 2022. Report, dated July 19, 2022 (ECF No. 25). The parties began the process of obtaining expert reports, with the final report from Dr. Tornatore filed on November 1, 2023. I proposed a briefing schedule for a ruling on the record, and the matter is ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner argues that he has presented sufficient evidence—medical records and a medical opinion from an expert in the field of neurology—as to how the flu vaccine he received on September 19, 2018, caused him to suffer from ulnar neuropathy. Mot. at 27. Prior to his receipt of the flu vaccine on September 19, 2018, Petitioner had regularly received chiropractic care, and while many of these visits documented [REDACTED] B.T.'s complaints of bilateral extremity pain and cervical pain, none of these records referenced the presence of right elbow pain. *Id.* at 29. Petitioner further notes that medical records suggest that he suffered from a congenital abnormality in the form of an accessory anconeus muscle belly, which Dr. Tornatore opined meant that [REDACTED] B.T. had an anatomical predisposition to ulnar compression across the elbow—making him susceptible to a vaccine-caused injury. *Id.* at 30; Tornatore First Rep. at 13–14. In addition, Petitioner emphasized the significance of evidence of misadministration, citing medical literature discussing the mechanisms in which a mis-administered vaccination can cause an ulnar neuropathy. Mot. at 31; Tornatore First Rep. at 15–17; Geiringer at 705–06; Kim at 106. Thus, based upon the filed medical records, Dr. Tornatore's opinion, and the associated medical literature, Petitioner maintains that he has provided preponderant evidence to satisfy his burden under *Althen* prong one. Mot. at 34.

Next, Petitioner argued that he established a logical sequence of cause and effect that the flu vaccine did cause his ulnar neuropathy. *Id.* at 34. In so asserting, Petitioner notes several instances where treating physicians and providers documented a concern for his receipt of the flu vaccine as causal of his right ulnar neuropathy. *Id.*; Ex. 3 at 29; Ex. 2 at 14–16, 110, 125, 128; Ex. 11 at 12. Moreover, Petitioner emphasizes that the treating physicians and providers who did document the flu vaccine as likely causal were all specialists in the areas of physical medicine and rehabilitation. Mot. at 36. Petitioner further disagrees with Respondent's interpretation of Dr. Cote's August 2020 diagnosis and assessment of [REDACTED] B.T.'s injury, arguing that Petitioner's congenital abnormality in the accessory anconeus muscle was asymptomatic prior to his receipt of the vaccination, and that Dr. Cote noted this abnormality as not providing any clarification as to what caused or triggered it becoming symptomatic. *Id.* at 37.

Finally, Petitioner contends that he has established a proximate temporal relationship between his receipt of the flu vaccine and his right ulnar neuropathy. *Id.* at 38. Here, Petitioner explains that his medical records provide support for an onset of approximately two days post-vaccination. *Id.*; Ex. 3 at 10–13; Ex. 6 at 23; Ex. 4 at 27–30; Ex. 2 at 126–28. Petitioner also relies on several items of medical literature cited by Dr. Tornatore to further demonstrate the various mechanisms by which a vaccine-related ulnar neuropathy can occur, as well as why a two-day onset would be medically acceptable. Mot. at 38. While Respondent argues that the literature cited to by Dr. Tornatore indicates “the greatest delay” in onset of symptoms as occurring no more than several hours after an alleged trigger, Petitioner maintains that [REDACTED] B.T.'s medical records

include reports of immediate pain when he received his flu vaccine. *Id.* at 39; Ex. 2 at 121. Such immediate pain evidences “direct trauma to the nerve fibers from the needle and the worsening pain, numbness, tingling, weakness and other symptoms may have resulted from any one of the mechanisms that result from migration of the injured material.” Mot. at 39.

Respondent

Respondent first argues that Petitioner has not produced reliable evidence that the flu vaccine can cause ulnar neuropathy. Opp. at 28. He maintains that Dr. Tomatore’s opinions are not supported by a reputable scientific or medical explanation, but instead are “based on the assumption that the flu vaccine ██████████ [B.T.] received on September 19, 2018, was administered improperly.” *Id.* at 29. Moreover, Dr. Tomatore presumes that Petitioner’s alleged pre-vaccination pseudocyst in his right distal scaphoid and a congenital abnormality of the accessory anconeus muscle at the right elbow rendered Petitioner susceptible—but without reliable scientific evidence to substantiate this supposition. *Id.*; Tomatore First Rep. at 14–15. Respondent also criticizes Dr. Tomatore’s reliance on the concept of “double crush syndrome” as an explanation for Petitioner’s development of an ulnar neuropathy above the elbow—arguing that Dr. Tomatore’s reasoning (as well as literature offered in support) is flawed and has “no specific relevance to the facts presented in this case.” Opp. at 30.

For example, Geiringer discussed two patients who developed mild ulnar neuropathies following “sidearm” vaccine administration in their upper arms. Yet 1) the vaccines used in the Geiringer study were different than what Petitioner received; 2) there is no medical evidence to suggest that Petitioner received the vaccine in question in a “sidearm” position; and 3) the onset of Petitioner’s symptoms occurred much later (two days) than what was reported for the studied individuals. Geiringer at 1–2; Opp. at 30–31. A different article, Salanga, discussed an injury to the proximal portion of the ulnar nerve due to a jet injection. There, a thirty-year-old woman received the swine flu vaccine, at which time she noted immediate onset of an “electrical” shock from the site of vaccination. Salanga at 1. Salanga’s authors opined that the women’s injury was a result of her arm being faultily held “with too much rotation” and due to a lack of protective underlying subcutaneous tissue which rendered her ulnar nerve more vulnerable to injury. *Id.* at 2. But Salanga is not relevant herein, since Petitioner did not receive the vaccine in question via a jet injection, and the medical records do not document Petitioner feeling any sort of sudden shock at the site of vaccination—or that Petitioner developed any sort of palpable mass on his right upper arm post-vaccination. Opp. at 32.

Otherwise, Respondent maintains, Dr. Tomatore only has provided irrelevant examples “[i]nstead of providing instances in the medical literature and in his opinions that supported his [overall] theory,” therefore, failing to produce preponderant evidence that the flu vaccine can cause ulnar neuropathy. *Id.* at 33.

Next, Respondent argues that Petitioner has failed to demonstrate a logical sequence of cause and effect that the flu vaccine did cause his ulnar neuropathy. *Id.* at 35. Respondent acknowledges that ██████ B.T., throughout his clinical course, consistently stated *his belief* that his vaccination was mis-administered. *Id.* at 36; *see also* Ex. 4 at 27 (reporting that the flu vaccine was given “the wrong way” at 11/7/18 visit with orthopedic surgeon, Dr. Eichten); Ex. 7 at 13 (documenting 11/9/2018 visit with chiropractor, Dr. Weiland, and noting Petitioner’s complaint that his flu vaccine was placed “into his tricep[s] area instead of his deltoid area”). Respondent also acknowledges that Petitioner’s statements regarding this mis-administration of his flu vaccine were maintained in the medical records, which according to the Federal Circuit, are considered generally “trustworthy” as they “contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions,” where “accuracy has an extra premium” Opp. at 36–37 (citing *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1382 (Fed. Cir. 2021)). However, Respondent contends, Petitioner is not medically qualified to opine as to whether his flu vaccine, or any vaccine, was mis-administered, and the medical records containing such representations do not arise from “the firsthand observations of ██████ B.T.’s] treating physicians. Opp. at 37.

Regarding Dr. Tornatore’s assertion that the compression of Petitioner’s ulnar nerve at the right elbow was asymptomatic prior to his receipt of the flu vaccine, Respondent maintains that ██████ B.T.’s October 2012 MRI results (six years prior to vaccination) revealed “a large anconeus epitrochlearis accessory muscle creating a mass effect on the ulnar nerve at the level of the cubital tunnel.” *Id.*; Ex. 2 at 180. Because the clinical indication for this MRI was “[e]lbow pain,” Respondent argues that the compression of Petitioner’s ulnar nerve was not likely “asymptomatic” prior to his receipt of the flu vaccine. Opp. at 38. Rather, as Dr. Callaghan noted, “almost always” ulnar neuropathy at the elbow is secondary to compression or extension of the nerve within the cubital tunnel. *Id.*; Cambon-Binder at 1–3. Moreover, there was an absence of any evidence indicating that Petitioner had an ulnar nerve injury *above* the elbow—while ██████ B.T.’s four EMGs “precisely localized” an injury to his right elbow. Opp. at 38; Ex. 8 at 46; Ex. 2 at 214–19; Ex. 16 at 21, 30. Accordingly, compression at the right elbow *alone* was the most likely cause of Petitioner’s injury. Opp. at 41.

Lastly, Respondent argues that Petitioner has failed to offer preponderant evidence of a medically acceptable timeframe between his receipt of the flu vaccine and the alleged onset of his ulnar neuropathy. *Id.* at 43–44. A symptoms onset of two days post-vaccination, as well as “intermittent symptoms initially,” is “not compatible with [P]etitioner’s receipt of the flu vaccine causing traumatic injury to his right ulnar nerve.” *Id.*; Callaghan Rep. at 8. Rather, and as Dr. Callaghan emphasized, a majority of occurrences for traumatic injury typically take place immediately following vaccination, and thus “symptoms ‘would be expected to be constant.’” *Id.*

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).⁶ There is no Table claim for an ulnar neuropathy injury, and therefore Petitioner can only advance a causation-in-fact claim.

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.”

⁶ 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).

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.

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. 17-792V, 2022 WL 2678877 (Fed. Cl. Spec. Mstr. June 17, 2022), *mot. for review den’d*, Dkt. No. 79 (Fed. Cl. Oct. 27, 2022), *aff’d* 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); *Veryzerv. 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. Standard for Significant Aggravation Claim

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 *Whitcotton 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 counterparts, 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 a “factor unrelated” 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.

C. *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.

D. *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”).

E. *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”).

F. *Resolution of Claim on Written Record*

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 determination 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

The parties agree on the diagnosis of an ulnar neuropathy to explain Petitioner's symptoms. *See, e.g.*, Callaghan Rep. at 7. They therefore only dispute the *cause* of that injury—and specifically its relationship to the demonstrated, preexisting accessory anconeus muscle condition that Petitioner unquestionably possessed.

Although claimants have in the past sought compensation for alleged vaccine-caused ulnar neuropathies, there are very few written reasoned decisions addressing causation in the context. But at least one petitioner successfully established entitlement under *Althen* for this kind of injury. *See Salazar v. Sec'y of Health & Hum. Servs.*, No. 15-817V, 2021 WL 319393 (Fed. Cl. Spec. Mstr. Jan. 5, 2021) (finding that Petitioner established by preponderant evidence that she sustained a right ulnar neuropathy caused by her October 2, 2014, receipt of the flu vaccine). That decision provides good guidance herein—but it also underscores why entitlement is not appropriate in this matter.

In *Salazar*, a petitioner with no relevant prior history of injury (unlike the present case) received a right-sided vaccination. She experienced an immediate reaction and pain, evidence of which was concretely memorialized in the relevant medical records. *Salazar*, 2021 WL 319393, at *5. Relying on a theory comparable to what is offered herein, the *Salazar* petitioner maintained that a pre-existing asymptomatic condition (cubital tunnel syndrome) had been “unmasked” by the vaccine's misadministration, resulting in nerve injury. *Id.* at *9–11. Importantly, the petitioner submitted direct proof that she was asked to bend her arm 90 degrees at the elbow, place her hand on her hip, and flex forward, *at the time of* vaccine administration. *Id.* at *5. *Id.* The special master deemed all three *Althen* prongs met. *Id.* at *18–22.

Salazar provides helpful guidance, but is distinguishable from the present case in several important regards. For example, the record in this case clearly establishes that Petitioner had a

documented history of right limb pain and issues. Thus, as late as the same month as vaccination, Petitioner was receiving treatment for these complaints. *See* Ex. 6 at 25–27 (discussing visit to SSCRS with Dr. Streets on 9/7/2018, and documenting pain in Petitioner’s right shoulder in which chiropractic manipulation, laser therapy, and release techniques and soft tissue mobilization were provided).

In addition, the *Salazar* petitioner was easily able to substantiate independent medical record evidence that the vaccine had been mis-administered. *Salazar*, 2021 WL 319393, at *18. Here, by contrast, although Petitioner may have *reported* misadministration, these contentions are not well-substantiated even if contemporaneous records contain evidence of Petitioner’s representations. *See, e.g.*, Exs. 2 at 126 and 4 at 27. *Salazar* also involved documented *immediate* pain—again, somewhat unlike this case, where Petitioner (an individual who readily sought treatment for comparable issues) had at least two medical treater visits in the immediate post-vaccination timeframe, but without complaining of any vaccine administration-related sequelae. *See* Exs. 2 at 247 and 6 at 24. Finally— and perhaps most importantly—Petitioner herein clearly possessed a preexisting condition at his elbow that even Petitioner’s expert agrees played a role in his injury (as opposed to a subclinical condition that was unmasked by vaccination).

Althen Analysis

Taking the above into account, I cannot find entitlement established under *Althen*. *Salazar* certainly supports the conclusion that a misadministered flu vaccine “can cause” an ulnar neuropathy, whether or not due to the downstream impact of vaccination or directly as a result—and since Petitioner’s theory seems consistent with what was offered in that case, I can find the first prong to have been preponderantly satisfied. But a claimant must satisfy all *three* prongs to obtain entitlement, and he cannot do so on this record. *Dobrydnev v. Sec’y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).

First, Petitioner cannot demonstrate that the flu vaccine “did cause” his ulnar neuropathy—*i.e.*, that it was likely a substantial factor in his injury. Here, the preexisting muscle injury (first observed in 2012) is the obstacle. Ex. 2 at 180. Dr. Callaghan (who clearly possesses more first-hand expertise in evaluating this specific sort of neuropathy than Dr. Tomatore) provided a persuasive reading of the medical record, and in so doing demonstrated a lack of evidence that the initial vaccination likely produced the kind of injury that could impact the preexisting issue, consistent with the theory Dr. Tomatore proposed. Callaghan Rep. at 8. As a result, although there is some record evidence suggesting that several of Mr. Tacher’s treating physicians considered his receipt of the flu vaccine to have caused his right ulnar neuropathy, the medical records *themselves* simply do not establish the presence of a separate, above-the-elbow injury due to a mis-administered vaccine. Indeed, and as pointed out in Dr. Callaghan’s report, Petitioner underwent five EMG studies—four of which “precisely localized” Mr. Tacher’s injury *at* the elbow, not above. *See* Ex. 2 at 134; Ex. 3 at 14, 21; Ex. 16 at 30. And I do not give great weight to Petitioner’s subjective contentions that the vaccination was itself injurious—especially since he did not

immediately report this to be the case (and this matter involves an individual who regularly sought treatment for any limb-related concerns he had).

It is thus instead more likely that Petitioner’s post-vaccination elbow symptoms related *solely* to his preexisting elbow-specific muscle problem. While it is no doubt the case that a Vaccine Act claimant need not *disprove* an alternative explanation for an injury, he must address evidence in the record undermining the conclusion that the vaccine played a substantial role in his injury. *Exum v. Sec’y of Health & Hum. Servs.*, No. 21-1513V, 2024 WL 4291116, at *14 (Fed. Cl. Spec. Mstr. Aug. 29, 2024) (citing *Strone v. Sec’y of Health & Hum. Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) (“[t]he special master is entitled to consider the record as a whole . . . and no evidence should be embargoed from the special master’s consideration simply because it is also relevant to another inquiry under the statute.”)). That has not been successfully done here. Even if Dr. Tornatore’s “double crush scenario” theory has some scientific reliability, I cannot conclude on this record that the vaccination constituted a second intervening instance of a “crush” leading to exacerbation of Petitioner’s preexisting condition.

The timing of Petitioner’s injury under *Althen* prong three has also not been shown to be medically acceptable. Case reports relied upon by Dr. Tornatore to support his causation theory involved instances of more obvious and immediate vaccine-related pain (*i.e.*, within thirty minutes to several hours), whereas Mr. Tacher’s alleged injury most likely occurred approximately forty-eight hours post-vaccination, in Dr. Tornatore’s estimation. First Tornatore Rep. at 17; See Geiringer at 705. But Dr. Callaghan persuasively established that a traumatic injury due to vaccination sufficient to result in a downstream neuropathy of the kind asserted herein would typically occur *immediately* following receipt of a vaccine, and that associated symptoms would also be expected to mirror that timeline.

Loving Analysis

My determination is the same under a *Loving* analysis—which could arguably be applied herein, based on a construction of the claim in which Petitioner’s preexisting accessory anconeus muscle injury is alleged to have been worsened due to vaccination. First, the record does not fully support the conclusion that Petitioner’s condition *actually* worsened post-vaccination. The third *Loving* prong requires an examination of Petitioner’s pre- and post-vaccination conditions, and a determination of whether Petitioner’s current condition constitutes a “significant aggravation” of his pre-vaccination condition. *Loving*, 86 Fed. Cl. at 144. Under the Vaccine Act, a “significant aggravation” is “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” Section 33(4).

Medical records filed herein, however, clearly demonstrate Petitioner’s frequent visits regarding bilateral shoulder and right limb issues to multiple treating physicians over the span of several years prior to receiving the flu vaccine—and many more thereafter. Petitioner regularly

complained of limb-related pain and neuropathic issues, pre- and post-vaccination, and the tempo of these complaints was consistent throughout (even though he identified the vaccination as an inflection point). Thus, on September 21, 2018 (two days post-vaccination), [REDACTED] B.T. saw Dr. Streets at SSCRS reporting “constant, throbbing, non-radiating pain in his left and right shoulders” but noting further that he had no significant changes in his health history since his last visit on September 7, 2018, and with respect to his “overall health symptoms.” Ex. 6 at 24. And Dr. Streets employed the same treatment methods (*i.e.*, chiropractic manipulation, laser therapy, and release technique and instrument assisted soft tissue mobilization) from prior appointments to address Petitioner’s current concerns. *Id.*

Similarly, [REDACTED] B.T. underwent EMG/NCS testing on October 2, 2018, during a visit with Dr. Jaffe at JSM—the results of which revealed only a mild to moderate right ulnar neuropathy. Ex. 3 at 21. As noted in Dr. Callaghan’s report, subsequent EMG/NCS testing several years later, on April 7, 2021, *also* demonstrated a mild right ulnar neuropathy at the elbow but with noted improvement from previous testing done on August 10, 2020. Callaghan Rep. at 6; Ex. 16 at 30 (documenting EMG/NCS results revealing a moderate to severe right ulnar neuropathy at the elbow); *see also* Ex. 2 at 86 (documenting visit with Dr. Reis on September 5, 2019, which noted Petitioner’s right ulnar mononeuropathy was resolving, with only *some* tenderness of the right elbow) (emphasis added). These intermittent flare ups, as persuasively explained by Dr. Callaghan, reflect the effects of the existing compression at his right elbow, but do not largely support the conclusion that overall Petitioner was in fact suffering from a worsened condition post-vaccination.

Of course, as a general matter it is not especially difficult for a claimant to prove the first three *Loving* prongs, given the Circuit’s treatment of them in *Sharpe*. And therefore, the mere fact that Petitioner’s pre-vaccination accessory anconeus muscle injury was not giving him trouble, but clearly did post-vaccination, might be sufficient to meet this prong, despite my overall view of the record. But the same flaws discussed above with respect to *Althen* prongs two and three would also apply to their *Loving* counterparts (*Loving* prongs five and six). For even if *Salazar’s* reasoning supports the determination that a vaccine that was improperly administered could (via Dr. Tornatore’s embrace of the double crush theory) worsen his elbow-associated pre-vaccination muscle condition, it has not been preponderantly demonstrated that in this case the vaccine *did* worsen it, or that this occurred in a medically acceptable timeframe. Petitioner’s overall presentation, pre-existing health issues, non-specific nature of early complaints, and the lack of preponderant evidence of a first “hit” caused by the vaccine all undermine the conclusion that his subsequent ulnar neuropathy was worsened by vaccination.

CONCLUSION

Claimants must carry their burden of proof. Because Petitioner cannot show by preponderant evidence that his injury was caused by the vaccination preceding it, 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.⁷

IT IS SO ORDERED.

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

⁷ 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.