

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 6, 2022

ANTHONY ABELS,	*	PUBLISHED
	*	
Petitioner,	*	No. 18-558V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH	*	Entitlement; Influenza (“Flu”) Vaccine;
AND HUMAN SERVICES,	*	Brachial Neuritis.
	*	
Respondent.	*	
	*	

Bridget McCullough, Muller Brazil, LLP, Dresher, PA, for petitioner.
Sarah Duncan, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

I. INTRODUCTION

On April 18, 2018, Anthony Abels (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”), 42 U.S.C. § 300aa-10 *et seq.* (2012).² Petitioner alleges that he suffered brachial neuritis as the result of an influenza (“flu”) vaccination administered on October 6, 2016. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating that “this case is not appropriate

¹ Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is 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 Ruling 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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

for compensation under the [Vaccine] Act.” Respondent’s Report (“Resp. Rept.”) at 2 (ECF No. 23).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner has provided preponderant evidence that his flu vaccine caused his brachial neuritis, satisfying petitioner’s burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

II. ISSUES TO BE DECIDED

The parties agree that petitioner received the flu vaccine in question on October 6, 2016. Joint Submissions, filed Feb. 16, 2022, at 1 (ECF No. 96). There are two factual issues. First, the vaccination record does not identify the site of vaccination.³ Second, while the parties agree that petitioner “suffered from brachial neuritis,” they dispute the onset of symptoms. Petitioner contends “that the initial onset of his symptoms occurred two days after [] vaccination . . . and [r]espondent argues that petitioner’s symptoms pre-dated his vaccination.” Id.

In addition to the factual issues to be resolved, the parties also dispute causation. Specifically, they dispute the following:

- a. Whether the flu vaccine can cause brachial neuritis (Althen Prong One);
- b. Whether petitioner’s brachial neuritis was caused by the receipt of the October 6, 2016, flu vaccination (Althen Prong Two); and
- c. Whether the onset of petitioner’s brachial neuritis began within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medical acceptable to infer causation-in-fact (Althen Prong Three).

Joint Submissions at 1.

The factual issues identified above will be addressed and resolved in the context of the undersigned’s discussion and analysis of causation.

III. BACKGROUND

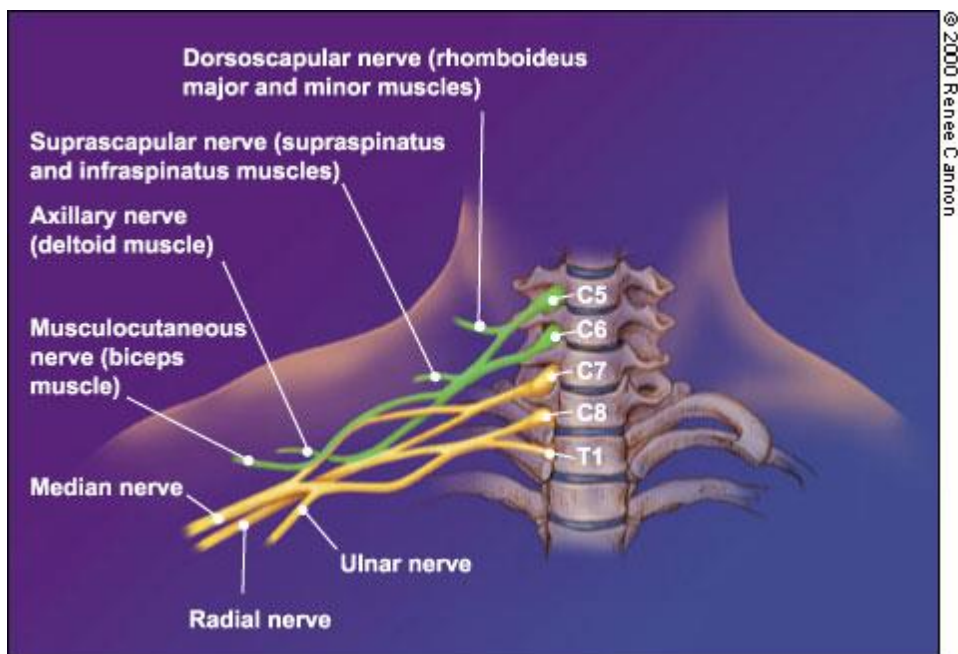
A. Medical Terminology

Acute brachial neuritis is an “uncommon disorder characterized by severe shoulder and upper arm pain followed by marked upper arm weakness.” Petitioner’s Exhibit (“Pet. Ex.”) 17B

³ The parties did not raise the factual issue of the site of vaccination in their joint submission. However, in respondent’s Rule 4(c) Report, it is noted that petitioner’s vaccination record did not indicate in which arm he received the vaccine. Resp. Rept. at 2 n.1. Thus, for the sake of completeness, the undersigned will rule on this factual question.

at 1.⁴ The condition has been called by other names, including brachial plexus neuropathy, Parsonage-Turner syndrome (named after the physicians who described it), neuralgic amyotrophy, idiopathic brachial plexus neuropathy, brachial plexitis, and brachial plexopathy. See id.; Pet. Ex. 17D at 1;⁵ Pet. Ex. 16 at 4-5.

The brachial plexus is a network of nerves with its lymphatic system and blood vessels “originating from the anterior rami of spinal nerves C5-8 and T1. Situated partly in the neck [] and partly in the axilla,” it is subdivided into “5 anterior rami, 3 trunks [], 6 divisions [], and 3 cords.” Dorland’s Illustrated Medical Dictionary 1440 (33d ed. 2019). It has numerous branches. Id.



Pet. Ex. 17B at 2.

Signs and symptoms of brachial neuritis include “severe, acute, burning pain in the shoulder and upper arm . . . [which] may awaken the patient from sleep.” Pet. Ex. 17B at 2. In most patients, the pain may decrease over time, but weakness of the arm occurs. Id. “The usual abnormality on physical examination is one of a brachial plexus lesion, as indicated by involvement of two or more nerves.” Id. Patients may also have abnormal scapular movement and muscle atrophy. Pet. Ex. 17D at 5. Patients usually improve over time, but some patients may have “several years of muscle weakness or a slight permanent weakness.” Pet. Ex. 17B at 2.

⁴ Jimmy D. Miller et al., Acute Brachial Plexus Neuritis: An Uncommon Cause of Shoulder Pain, 62 Am. Fam. Physician 2067 (2000).

⁵ Jeroen J.J. Van Eijk et al., Neuralgic Amyotrophy: An Update on Diagnosis, Pathophysiology, and Treatment, 53 Muscle & Nerve 337 (2016).

Diagnostic evaluation includes magnetic resonance imaging (“MRI”), which may show a signal abnormality of affected muscles, and electromyography (“EMG”), which may “localize[] the lesion to the brachial plexus.” Pet. Ex. 17B at 3. Treatment includes analgesics and physical therapy. Id. Corticosteroids may also be used, but they have not shown any “proven benefit.” Id.

Brachial neuritis occurring within two to 28 days after tetanus toxoid vaccines is a covered condition by the Vaccine Act, as set forth on the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(I)(B). The condition is not a Table Injury following the flu vaccine. The aids and qualifications accompanying the Table define brachial neuritis as “dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition.” Id. at 100.3(c)(6). “The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. . . . Atrophy of the affected muscles may occur.” Id.

B. Procedural History

On April 18, 2018, petitioner filed his petition, medical records, and an affidavit. Petition; Pet. Exs. 1-9. Petitioner filed additional medical records in August 2018 and June 2019, as well as affidavits from himself and witnesses in June 2019. Pet. Exs. 10-12, 14-15.

On August 28, 2019, petitioner filed an expert report from Dr. Daniel DiCapua, followed by further medical records on October 25, 2019. Pet. Exs. 16-18. Respondent filed a responsive expert report from Dr. Brian Callaghan on March 5, 2020. Resp. Exs. A-B. This case was reassigned to the undersigned on July 30, 2020. Notice of Assignment dated July 31, 2020 (ECF No. 63).

The parties filed a joint status report on October 16, 2020, requesting a Rule 5 status conference in this case. Joint Status Rept., filed Oct. 16, 2020 (ECF No. 70). Thereafter, the undersigned held a Rule 5 conference on January 28, 2021. Rule 5 Order dated Jan. 29, 2021 (ECF No. 72). The undersigned agreed with the treating physician’s diagnosis of brachial neuritis, and preliminarily found petitioner would likely be able to satisfy all Althen prongs. Id. at 1-3.

On May 17, 2021, respondent filed a supplemental expert report from Dr. Callaghan. Resp. Ex. C. The parties then filed a joint status report on June 28, 2021, stating that the parties agreed to submission on the papers in lieu of a hearing. Joint Status Rept., filed June 28, 2021 (ECF No. 79). On September 30, 2021, petitioner filed a motion for a ruling on the record. Motion for a Ruling on the Record (“Pet. Mot.”), filed Sept. 30, 2021 (ECF No. 83). Respondent filed a responsive brief to the motion, arguing petitioner “did not present preponderant evidence of actual causation regarding flu vaccine and brachial neuritis,” and that his claim must be dismissed. Resp. Response to Pet. Mot. (“Resp. Response”), filed Dec. 2, 2021, at 25 (ECF No. 86). Petitioner replied, contending that he has “established by a preponderance of the evidence” a reliable medical theory and an acceptable timeframe of onset. Pet. Reply, filed Feb. 16, 2022, at 7 (ECF No. 95).

This matter is now ripe for adjudication.

C. Factual History

1. Medical History

Petitioner was born on March 27, 1969, and was 47 years old at the time of vaccination. Pet. Ex. 1 at 2. Petitioner's past medical history was significant for Gilbert's syndrome,⁶ a hemangioma of the liver, and on-and-off right shoulder pain, numbness, and weakness. Pet. Ex. 10 at 3; Pet. Ex. 4 at 11. At the time of the vaccination at issue, he was a bodybuilder for over 20 years. Pet. Ex. 9 at ¶ 3. Petitioner also took prescription pain medication for chronic pain syndrome dating back to 2014. Pet. Ex. 21 at 71, 73, 77; Pet. Ex. 22 at 61.

On October 6, 2016, petitioner received a flu vaccine at Walgreens. Pet. Ex. 1 at 10-11; Pet. Ex. 15. The vaccine administration records do not document the site of vaccination. *Id.* Nearly two weeks after vaccination, on October 19, 2016, Dr. William Gonte referred petitioner for an MRI of his right shoulder for "severe right shoulder pain on and off for three years with numbness and weakness." Pet. Ex. 2 at 3. The MRI revealed mild chronic tendinopathy of the supraspinatus with a small tear at the footplate, mild tendinopathy of the infraspinatus without a tear, severe atrophy or near full thickness complete tear of the biceps long head tendon with retraction to the distal groove, moderate to severe hypotrophic acromioclavicular arthropathy, chronic mild glenohumeral arthrosis with spurring, a near circumferential labral tear, and mildly dry glenohumeral capsulitis. *Id.* at 3-4.

On October 31, 2016, petitioner was referred by Dr. Gonte to Dr. Stephen Hyman of Rehabilitation Physicians, for an EMG of the neck and right upper extremity for weakness of the right shoulder and arm. Pet. Ex. 2 at 1-2, 5-8. The EMG showed weakness in the C5-6 myotomes with denervation in the deltoid, biceps, and brachioradialis. *Id.* at 1. Dr. Hyman opined this suggested upper trunk plexopathy. *Id.* at 2.

On November 2, 2016, petitioner saw Dr. Kyle Anderson, an orthopedist, for "poss[ible] injury weightlifting, having weakness in arm, [and] atrophy in [right] chest." Pet. Ex. 33 at 10. Dr. Anderson noted that petitioner had "rather long standing issues with [his right] shoulder" that had "worsened significantly" over the past few months. *Id.* at 12. On examination, petitioner had difficulty contracting his right pectoralis muscle. *Id.* Dr. Anderson recommended repeating the EMG, opining that petitioner likely had a neurological problem as the MRI showed the structure of petitioner's shoulder was "quite good." *Id.* at 12-13.

Petitioner underwent another MRI on November 17, 2016, for "moderate dull, pinching pain in [his] shoulder for 1 month." Pet. Ex. 4 at 7-10. The MRI revealed disc protrusion at C3-

⁶ Gilbert syndrome is "an autosomal recessive disorder of bilirubin metabolism caused by mutation in the UGT1A1 gene (locus: 2q37) . . . characterized by a benign elevation of unconjugated bilirubin without liver damage or hematologic abnormalities." *Gilbert Syndrome*, Dorland's Online Med. Dictionary, <https://www.dorlandonline.com/dorland/definition?id=110655> (last accessed Apr. 25, 2022).

4, C4-5, C5-6, and C6-7, with associated mild to moderate foraminal narrowing, which was more pronounced on the right. Id. The brachial plexus MRI study showed right brachial plexus, but no other brachial plexus pathology. Id. at 7.

On December 8, 2016, on referral of Dr. Gonte, petitioner presented to Therapy Unlimited for an initial physical therapy evaluation by Samuel A. Gill. Pet. Ex. 5 at 2-3. The history taken states,

Patient is a body builder and has lifted weights for over 20 years. He was in his normal state of health until October, 2016 when he started to note some pain of the lateral neck and shoulder, and some gradual development which became quite marked in his awareness of atrophy of right triceps, right pectoral muscles, biceps and deltoid Patient is unaware of the cause of this pain and weakness, but notes that near the time of onset he had a flu shot.

Pet. Ex. 5 at 2.

Physical examination revealed “notable atrophy at right pectoral and tricep” and “weakness of right upper extremity.” Pet. Ex. 5 at 2. The evaluation was signed by Mr. Gill and Dr. Gonte. Id. at 3. A home exercise program was initiated. Id. Petitioner attended one additional physical therapy visit on December 14, 2016, and did not return. Id. at 4. He was discharged on January 17, 2017. Id.

Approximately three months later, on March 8, 2017, petitioner presented to Dr. Norman Burns at Oakland Neurology Center. Pet. Ex. 4 at 4. Petitioner reported having severe pain in his arm and shoulder region “in October shortly after receiving the flu vaccine.” Id. He also complained of ongoing pain, numbness, and tingling in his right arm. Id. Dr. Burns reviewed petitioner’s MRI results, finding evidence of “an underlying neuropathic injury with atrophy in the triceps and pectoralis.” Id. at 5. Dr. Burns suspected brachial plexopathy related to the vaccination, and scheduled a repeat EMG, noting that the only likely treatment was therapy and rehabilitation. Id.

Petitioner returned to Dr. Burns on March 29, 2017, with complaints of ongoing right shoulder pain. Pet. Ex. 4 at 1-2. After reviewing petitioner’s previous EMG, Dr. Burns noted that it showed changes consistent with either C5-6 radiculopathy or upper trunk plexopathy. Id. at 16. He diagnosed petitioner with brachial plexopathy, suspecting an inflammatory plexitis related to his October vaccination. Id. at 17. He recommended petitioner see pain specialists for injections, and to “continue aggressive exercise” and physical therapy. Id.

Approximately six months later, on September 25, 2017, petitioner saw Dr. Burns for a follow-up where he was assessed with brachial plexus disorder and neuropathic pain. Pet. Ex. 8 at 8-9. Dr. Burns noted that petitioner’s pain was “slightly better overall,” but that he still had moments where it was severe. Id. at 8. Dr. Burns encouraged petitioner to continue working out and to use hydrocodone as needed for the pain, noting that there “will likely be some permanent deficit.” Id. at 9.

Petitioner had another follow-up visit with Dr. Burns on May 2, 2018. Pet. Ex. 8 at 5-7. During that visit, Dr. Burns provided a relatively unchanged assessment of petitioner's condition, noting "only very modest improvement and recovery in the last year and a half." Id. at 6. He recommended to continue using hydrocodone as needed for the pain and encouraged petitioner to keep working out. Id.

Petitioner returned to Dr. Burns on December 3, 2018, reporting that he was doing okay and that his symptoms were stable. Pet. Ex. 19 at 8-10. He controlled his pain with Norco when needed and otherwise continued to exercise. Id. An examination revealed asymmetry and weakness on his right side compared to his left, and petitioner was instructed to follow up in another six months. Id.

On January 29, 2020, petitioner presented to Dr. Burns regarding his brachial plexopathy. Pet. Ex. 19 at 5-6. In this follow-up, petitioner showed persistent right arm/shoulder pain and significant atrophy. Id. at 6. Dr. Burns noted that petitioner remained stable, but that he had never regained much function or muscle mass since the initial injury. Id. Dr. Burns' impression was that petitioner exhibited evidence of upper trunk brachial plexopathy, likely brachial plexitis related to his immunization. Id. Dr. Burns and petitioner discussed the permanency of his condition, and petitioner was instructed to return for a follow-up appointment in one year. Id.

2. Affidavits and Other Evidence

a. Petitioner's Affidavits

Before petitioner received the flu vaccine on October 6, 2016, he had "no physical limitations or injury" to his right shoulder. Pet. Ex. 9 at ¶ 3. He was very active and could "sleep, travel, lift weights[,] and [work] out 5-6 days a week," as well as take care of household chores. Pet. Ex. 11 at ¶ 9. Petitioner had "been working out for 27 [years]" and viewed the gym as a "huge part of [his] life" and his "therapy." Pet. Ex. 9 at ¶ 3.

Petitioner recalls having pain on the evening of October 8, 2016, when he was lifting his arms to wash his hair in the shower. Pet. Ex. 11 at ¶ 5. In the days following vaccination, he was in pain and driving was "uncomfortable and miserable." Id. He had to "take off weeks at a time because the pain was unbearable" and could no longer do his usual housework, needing to instead hire people for manual labor jobs. Pet. Ex. 9 at ¶ 3. The chronic pain made it difficult to exercise and was "depressing and life changing." Id. at ¶ 4. Petitioner went to physical therapy for a short period of time, but "it was too painful" and he "had to stop." Id. The only comfortable position for him was "standing or sitting at [his] desk," and sleeping was "a struggle every night," and even two years after vaccination he could "only sleep in a certain position." Pet. Ex. 11 at ¶ 4-5.

Around the middle of October 2016, petitioner’s right arm began to atrophy and weaken.⁷ Pet. Ex. 11 at ¶ 6; Pet. Ex. 26 at ¶ 11. He “could not lift [his] arm over his head” or “lift anything that was over 20 [pounds]” in weight. Pet. Ex. 11 at ¶ 6. Petitioner saw a doctor on October 19, 2016 and remembered the pain and muscle weakness getting worse from then through December 2016. Id. at ¶ 8. The pain was so unbearable that petitioner could only do a few sessions of physical therapy. Id.

b. Jennifer Abels’ Affidavit

Jennifer Abels is the wife of petitioner. Pet. Ex. 12 at ¶ 1. Ms. Abels noted petitioner was “always happy, positive[,] and never complained.” Id. She had no memory of petitioner “experiencing any right shoulder or arm pain before his vaccination on October 6, 2016” or “complaining of being in pain.” Id. at ¶ 2. She saw “his pain, muscle weakness, and difficulty using his right arm” as “intense and debilitating” and different from typical injuries from working out. Id.

Ms. Abels stated that when petitioner first started complaining of pain, “it came on quickly and was constant.” Pet. Ex. 12 at ¶ 3. He first complained “approximately two days after” the vaccination, on October 8, 2016, and was in so much pain that he “wasn’t sure if he could make it through dinner” with their friends that day. Id. She noticed “[a] lot of muscle twitching” in his shoulder and arm area within days of the vaccination. Id. Petitioner had stopped working out and “his sleep was interrupted nightly because of the pain.” Id.

The pain, muscle weakness, and difficulty using his right arm that petitioner was experiencing not only affected his daily life, but “changed [their] married life as well.” Pet. Ex. 12 at ¶ 4. Ms. Abels and petitioner no longer slept in the same bed because petitioner could only sleep on his back, causing him to “snore all night long.” Id. For Ms. Abels, “it was very upsetting to see someone you love in so much pain and nothing would help to take it away.” Id.

c. Stephen Bushon’s Affidavit

Stephan Bushon is a health insurance advisor and friend to petitioner. Pet. Ex. 14 at ¶ 3. He has known petitioner for 20 years and would “see and talk to him regularly.” Id. at ¶ 2. Mr. Bushon joined the same gym as petitioner and would “join him at times working out if working the same muscle group.” Id. To his knowledge, petitioner “never had any issues with his right arm” prior to vaccination. Id.

Mr. Bushon remembers petitioner “complaining about his right arm after he had a vaccination shot” in mid-October 2016. Pet. Ex. 14 at ¶ 3. During one of their workouts, petitioner had to stop because of severe pain in his right arm “and went immediately home.” Id.

⁷ Petitioner confused his left and right arm in his affidavit. See Pet. Ex. 11. While he stated in his affidavit his “left arm kept getting worse and weak,” this appears to be the only place in his multiple affidavits where he makes this mistake. Id. at ¶ 6. In a subsequent affidavit, he acknowledged his error, and corrected it, saying “[m]y testimony should have been ‘my right arm started atrophying very quickly.’” Pet. Ex. 26 at ¶ 11.

Thereafter, Mr. Bushon “would attempt to schedule a workout with [petitioner] but [petitioner] often canceled shortly before complaining of his right shoulder.” Id.

Mr. Bushon spoke to petitioner on the phone a week later, petitioner told him his pain was “so severe he was unable to do anything.” Pet. Ex. 14 at ¶ 4. He did not see petitioner socially in the weeks after vaccination, which was “uncharacteristic of [petitioner]” as they would often go out to dinner “a few times a month or would go to see a movie.” Id. During that time, Mr. Bushon would only see petitioner at the steam room and restaurant in their gym. Id. at ¶ 3. When he finally saw petitioner for a social dinner in November 2016, “[petitioner’s] mood had changed and all [petitioner] could talk about was how his right arm was in pain and that he couldn’t lift it above his shoulder.” Id. at ¶ 5.

d. Letter by William Gonte, M.D.⁸

Petitioner filed a one page letter authored by Dr. Gonte, dated July 23, 2020. Pet. Ex. 31. The letterhead indicates that Dr. Gonte is a physician with First Medical Group. Id. In the letter, Dr. Gonte explains that he has had a professional, personal, and social friendship with petitioner for approximately ten years, after meeting at the health club they both attend. Id. at 1. Dr. Gonte stated,

We have had numerous conversations . . . along the years, and we have developed a friendship. He occasionally asked me my medical advice on numerous topics and issues, most of which are minor including simple colds and minor sprains and strains. Around October 12[,] 2016[,] it became apparent [] [petitioner] [was] having difficulty with his usual workout regimen including the amount of weight he could lift and his endurance and mainly affected his right side. He brought this to my attention on at least two occasions. I thought it could be his shoulder, his neck, or some type of other issue. Over the next week, it became apparent that he was developing significant atrophy and progressive weakness, at which point I advised him during one of our workouts together that it would be a good idea for him to undergo an MRI to get a more definitive diagnosis, which I did order for him, which he underwent on October 19, 2016. That prompted additional followup treatment including visits to my office and referrals for additional testing and treatment. He continues to be a patient of mine and a friend, and he continues to require treatment for the plexopathy and disability that developed in 2016. I do not believe that he was seen in my office anytime in September or October of 2016 prior to the ordering of the MRI. It was based solely on my observations and evaluations of him in the gym facility that I referred to previously.

Id.

⁸ Internet research reveals that Dr. Gonte specializes in Internal Medicine and Sports Medicine. Dr. William Gonte, MD, Zocdoc, <https://www.zocdoc.com/doctor/william-gonte-md-60286> (last accessed Apr. 26, 2022).

D. Expert Reports

1. Petitioner’s Expert, Dr. Daniel Bryant DiCapua

a. Background and Qualifications

Dr. DiCapua is an Assistant Professor of Neurology at the Yale University School of Medicine. Pet. Ex. 16 at 1. He is board certified in Neurology and Neuromuscular Medicine. Id. Dr. DiCapua received his medical degree from Temple University School of Medicine and completed his residency in neurology at the Yale-New Haven Hospital. Pet. Ex. 17A at 1. He also completed fellowships in Neuromuscular Medicine and Medical Education at Yale University School of Medicine. Id. Dr. DiCapua has an active clinical practice and treats approximately 2,000 patients annually, often for peripheral nerve conditions. Pet. Ex. 16 at 1.

Dr. DiCapua is the Director of the Neurology Clerkship and the Neuromuscular Medicine Fellowship programs at the Yale School of Medicine. Pet. Ex. 17A at 1. He is also the course director of the weekly continuing medical education (“CME”) approved Neuromuscular Educational Conference Series. Id. He has served on committees at the national level at the American Academy of Neurology, and the pharmacy and therapeutics committees at the local and national level. Pet. Ex. 16 at 1. Dr. DiCapua has received a number of honors and awards, given many presentation and lectures, and published in peer reviewed journals. Pet. Ex. 17A at 2. He is a specialist in the evaluation and treatment of patients with neuromuscular disorders. Pet. Ex. 16 at 2.

b. Opinion

Based on his training, experience, and review of petitioner’s records and affidavits, Dr. DiCapua opined that “it is more likely than not that the [flu] immunization was a substantial factor in causing [petitioner’s] right brachial plexopathy.” Pet. Ex. 16 at 5.

i. Althen Prong One

While the causal mechanism of brachial neuritis⁹ is often not known, Dr. DiCapua explained that it is thought to be an immune mediated condition. Pet. Ex. 16 at 3. “Multiple studies and case series have proposed that [it] is an immune mediated disorder.” Id. He explained that the “immune hypothesis is supported by the fact that 40-50% of [brachial neuritis] cases are preceded by an infection, typically viral, an immunization, or some other immune system trigger.” Id. at 3-4.

In support of his assertion that vaccinations have been reported as antecedent events associated with brachial neuritis, Dr. DiCapua cited several medical articles. Miller et al. stated that “[u]p to 15 percent of cases have been reported to occur following vaccinations.” Pet. Ex.

⁹ Dr. DiCapua uses several different names for brachial neuritis in his reports, including idiopathic brachial plexopathy and neuralgic amyotrophy. Pet. Ex. 16 at 3. For clarity, the undersigned will only use the phrase brachial neuritis throughout this Ruling.

17B at 1. Vriesendorp et al.¹⁰ reported that “[i]nfection, mostly viral, or immunization is a preceding event in 40% of cases.” Pet. Ex. 17E at 1. Sierra et al.¹¹ noted that “[a]ntecedents of immunization, exposure to toxic substances, or infection occur in 28-83% of patients, thus suggesting that many agents can trigger a selective immune reaction against brachial plexus nerves.” Pet. Ex. 17I at 1. Dating back to the original study published in 1948 describing the condition, Parsonage and Turner¹² reported that eleven out of 67 (16.4%) patients “had inoculations during the four weeks preceding the onset” of their symptoms. Pet. Ex. 17H at 2.

As described above, brachial neuritis is thought to be an immune mediated condition. Pet. Ex. 16 at 3. Dr. DiCapua cited a paper by Eijk et al., who reviewed existing studies and concluded that brachial neuritis was “an organ-specific immune-mediated disorder. The immune hypothesis is supported by the fact that half of affected patients report antecedent events that trigger the immune system, mostly infections” Pet. Ex. 17D at 3-4. In addition, they reported that biopsies of brachial plexus nerve bundle fibers revealed findings consistent with an immune mediated etiology. *Id.* at 4. These findings included T-cell infiltration, axonal degeneration, lymphocytes associated with autoimmune diseases, and increased levels of certain complement.¹³ *Id.*

Although the exact mechanism of causation of brachial neuritis is not known, several theories have been proposed. Pet. Ex. 16 at 4. As explained by Dr. DiCapua, these include both innate and adaptive immune system mechanisms. *Id.* He explained that the “innate immune system is a rather primitive and nonspecific defense which is activated within minutes to hours after exposure to an antigen. The adaptive immune response which is [] more specific and deliberate[,] [] requires time for the specific response to generated.” *Id.*

Specific to the innate system, Dr. DiCapua suggested that the complement system of the innate immune system may play a role in the cause of brachial neuritis. Pet. Ex. 16 at 4. Dr.

¹⁰ Francine J. Vriesendorp et al., Anti-Peripheral Nerve Myelin Antibodies and Terminal Activation Products of Complement in Serum of Patients with Acute Brachial Plexus Neuropathy, 50 Archives Neurology 1301 (1993).

¹¹ A. Sierra et al., Blood Lymphocytes Are Sensitized to Brachial Plexus Nerves in Patients with Neuralgic Amyotrophy, 83 Acta Neurologica Scandinavica 183 (1991).

¹² M.J. Parsonage & J.W. Aldren Turner, Neuralgic Amyotrophy the Shoulder-Girdle Syndrome, 1 Lancet 973 (1948).

¹³ The complement system refers “to the entire functionally related system comprising at least 20 distinct serum proteins, their cellular receptors, and related regulatory proteins that is the effector not only of immune cytotoxicity but also of other biological functions, including anaphylaxis, phagocytosis, opsonization, and hemolysis.” Complement, Dorland’s Online Med. Dictionary, <https://www.dorlandonline.com/dorland/definition?id=10705> (last accessed Apr. 26, 2022).

DiCapua stated that the alternative pathway of the complement system¹⁴ “can be activated by . . . the presence of foreign materials and damaged tissue.” *Id.* He opined that the flu vaccine was “the nidus for the activation of the alternate complement pathway” and subsequent brachial neuritis. *Id.* “While the complement pathway is normally tightly regulated, once activated an amplification loop can be set into motion” and if not controlled it can lead to autoimmune disease. *Id.* While the “alternate pathway of complement activation serves as a major mechanism of recognition and elimination of foreign or dangerous pathogens, unfortunately, it . . . [has] the same capacity to destroy self-tissues.” *Id.* Once activated, the complement system may lead to demyelination, causing brachial neuritis. *Id.*

The Vriesendorp et al. paper cited by Dr. DiCapua reported the findings of a study on the alternative pathway of the complement system¹⁵ and its potential role in the cause of brachial neuritis. Pet. Ex. 17E. The authors studied three patients with acute brachial neuritis and found that complement-fixing antibodies to peripheral nerve myelin and terminal complement activation products were increased in the serum of patients with brachial plexus as compared to normal controls. *Id.* at 2. Notably, the levels of complemental fixing antibodies were “markedly increased” as compared to the controls. *Id.* The authors concluded that “complement dependent, antibody mediated demyelination” may play a role in causing nerve damage in brachial neuritis. *Id.* at 3.

Regarding the role of the adaptive immune system, Dr. DiCapua explained that studies have demonstrated the presence of “anti-ganglioside antibodies,” suggesting a mechanism similar to that implicated in the etiology of Guillain-Barré Syndrome (“GBS”). Pet. Ex. 16 at 4. He cited a study by Moriguchi et al.¹⁶ in support of this mechanistic theory. *Id.* (citing Pet. Ex. 17G). Moriguchi et al. reported four patients with brachial neuritis “who presented with increased levels of anti-ganglioside antibodies . . . [and] who had a good response to intravenous immunoglobulin infusion therapy.” Pet. Ex. 17G at 1. Three of the patients had antecedent infections. *Id.* at 3. All four patients were positive for the anti-ganglioside antibodies, specifically anti-GalNAc-GD1a antibody, a “minor component of the ganglioside in the nervous system,” and a “target antigen for the acute-phase serum antibody in GBS.” *Id.* at 3. The “findings might indicate that autoimmune mechanisms similar to GBS [are] involved in the pathogenesis of some cases of [brachial neuritis].” *Id.* The role of the antibodies is not clear, but the authors suggested that they may bind to the “nodes of Ranvier, the paranodal regions, and []

¹⁴ For an explanation of the three pathways of the complement system, classical, lectin, and alternative pathway, see Pet. Ex. 17L (Nehemiah Zewde et al., Quantitative Modeling of the Alternative Pathway of the Complement System, 11 PlosOne e0152337 (2016)).

¹⁵ In addition to the Zewde et al. paper, a thorough explanation of the complement system is described by Thurman and Holers, also cited by Dr. DiCapua. See Pet. Ex. 17J (Joshua M. Thurman & V. Michael Holers, The Central Role of the Alternative Complement Pathway in Human Disease, 176 J. Immunology 1305 (2019)).

¹⁶ Kota Moriguchi et al., Four Cases of Anti-Ganglioside Antibody-Positive Neuralgic Amyotrophy with Good Response to Intravenous Immunoglobulin Infusion Therapy, 238 J. Neuroimmunology 107 (2011).

the small-diameter dorsal root fibers” of peripheral nerves causing “atrophy, weakness, and severe pain.” Id.

Dr. DiCapua concluded that “the innate immune system, which has been implicated in [brachial neuritis], was activated by either the [flu] vaccine either directly or by the local intramuscular tissue damage that [] was induced by administration of the [flu] vaccine.” Pet. Ex. 16 at 4. “Additionally, once the complement cascade is activated[,] other components of the immune system are triggered. Complement dependent antibody mediated demyelination has been proposed as the pathophysiologic mechanism of [brachial neuritis]. This likely accounts for the diffuse proposed immune mediated mechanisms which have been implicated in [brachial neuritis].” Id.

ii. Althen Prong Two

Citing petitioner’s affidavits, Dr. DiCapua opined that prior to receipt of the flu vaccine on October 6, 2016, petitioner “had no physical limitations or injuries to his right shoulder.” Pet. Ex. 16 at 2 (citing Pet. Ex. 9 at ¶ 3). Petitioner was “extremely physically active, exercising 5-6 days per week for 28 years.” Id. However, on October 8, 2016, Dr. DiCapua noted that petitioner had severe and unbearable pain that limited his daily activities and interfered with his sleep. Id. at 4. Petitioner’s wife observed muscle twitches. Id. at 3. Dr. DiCapua explained that muscle twitching indicated denervation in the right deltoid, biceps, and brachioradialis muscles, consistent with the petitioner’s EMG findings. Id. “The fact that [petitioner’s] symptoms evolved over the subsequent days is consistent with an immune mediated process,” as Dr. DiCapua described, related to how the flu vaccination can cause brachial neuritis. Id. at 4.

Dr. DiCapua attributed petitioner’s “history of on and off right shoulder pain, weakness, and numbness,” to “chronic musculoskeletal shoulder changes.” Pet. Ex. 16 at 3. Petitioner’s chronic musculoskeletal condition was evidenced by his MRI findings of “chronic tendinopathy and moderate to severe hypertrophic acromioclavicular joint arthropathy[,] with mild chronic glenohumeral arthrosis with spurring.” Id. According to Dr. DiCapua, these chronic abnormalities would not be “unexpected in a body builder who was extremely physically active” and who exercised to the extent that petitioner did. Id. In contrast, brachial neuritis has an acute presentation, and the pain is “severe, excruciating, debilitating[,] and incapacitating.” Id.

Although he agreed that petitioner had pre-existing and chronic musculoskeletal shoulder issues prior to the flu vaccine, Dr. DiCapua opined that “the brachial [neuritis] was something completely different than he had ever experienced. The records indicated that [petitioner’s] musculoskeletal shoulder issues had never been severe enough for him to discontinue his exercise regimen, perform physical chores, sleep[,] or seek medical care.” Pet. Ex. 16 at 4. “The MRI of petitioner’s shoulder, though obtained after the [flu] vaccine, demonstrate[d] some chronic joint and tendon changes which were likely present, as least to some extent, before October 6, 2016.” Id.

Further, Dr. DiCapua did not believe that petitioner’s pre-existing musculoskeletal shoulder problems caused or “precipitated his subsequent development of brachial [neuritis].”

Pet. Ex. 16 at 4. He conducted a medical literature review and “did not find a single case of musculoskeletal shoulder issues precipitating brachial [neuritis].” Id.

iii. Althen Prong Three

Petitioner received the flu vaccine on October 6, 2016. Pet. Ex. 16 at 2. On October 8, 2016, lifting his arm caused significant shoulder pain. Id. Two weeks after vaccination, petitioner had muscle weakness. Id. On October 31, 2016, petitioner’s EMG was abnormal, and Dr. Hyman opined that petitioner had upper trunk plexopathy. Id.

Dr. DiCapua opined that petitioner’s onset of symptoms was on October 8, two days after vaccination, which is rapid but consistent with his causal theory. Pet. Ex. 16 at 4. Due to this “rapid onset of symptoms [and] progression of weakness,” Dr. DiCapua opined that there was “activation of the innate immune system . . . by either the [flu] vaccine either directly or by the local intramuscular tissue damage . . . induced by . . . the vaccine.” Id. This clinical course is consistent with the proposed theory of “[c]omplement dependent antibody mediated demyelination.” Id.

Additionally, Dr. DiCapua explained that an onset of two days is consistent with the case reported by Taras and Donohue.¹⁷ Pet. Ex. 16 at 4 (citing Pet. Ex. 17M). In that report, the authors describe the clinical course of a 26-year-old male who developed denervation of the radial nerve after receiving the flu vaccine. Pet. Ex. 17M at 1. The patient had a “motor palsy [that] began as clumsiness while typing on a keyboard and progressed to a complete wrist drop . . . over 3 to 4 hours.” Id. at 1-2. The authors explained that brachial neuritis “has been shown to manifest as an isolated radial nerve palsy in several studies.” Id. at 1. The patient in the report had “features of both [brachial neuritis] and direct nerve injury.” Id.

Another case report cited by Dr. DiCapua also referenced a similar clinical presentation to that of petitioner. Pet. Ex. 16 at 4 (citing Pet. Ex. 17C). Shaikh et al.¹⁸ presented a case of a 46-year-old who had an acute onset of pain in her left shoulder a “few days after [flu] vaccination.” Pet. Ex. 17C at 1. “Within a week of the onset of pain, she developed left-upper-limb weakness with difficulty in performing her usual activities.” Id. The authors stated, “[t]ypically, there is a sudden onset of severe burning pain around the affected shoulder or upper arm.” Id. at 2. After days or weeks, the pain is “followed by weakness.” Id.

2. Respondent’s Expert, Dr. Brian C. Callaghan

a. Background and Qualifications

¹⁷ John S. Taras & Kenneth W. Donohue, Radial Nerve Motor Palsy Following Seasonal Influenza Vaccination: A Case Report, 23 J. Surgical Orthopaedic Advances 42 (2014).

¹⁸ Maliha Farhana Shaikh et al., Acute Brachial Neuritis Following Influenza Vaccination, 28 BMJ Case Reps. 1 (2012).

Dr. Callaghan is Associate Professor of Neurology at the University of Michigan. Resp. Ex. A at 1. He has board certifications in Neurology and Electrodiagnostic Medicine. Resp. Ex. B at 1. Dr. Callaghan received his medical degree at the University of Pennsylvania Medical Center, and his master's degree in clinical research design and statistical analysis at the University of Michigan. Id. Dr. Callaghan completed his residency in neurology at the University of Pennsylvania Medical Center, and a neuromuscular fellowship as well as a fellowship at the Center for Healthcare Research and Transformation Policy at the University of Michigan Health System and University of Michigan. Id.

Dr. Callaghan is the past Director of the Amyotrophic Lateral Sclerosis (“ALS”) Clinic at the University of Michigan Health System and is currently the Director of the ALS Clinic and a staff physician at the Department of Neurology at the Veterans Administration Ann Arbor Health System. Resp. Ex. B at 1. He has received numerous honors and awards, and holds memberships in a number of professional societies. Id. at 3-4. Dr. Callaghan has lectured and presented many times, has been on numerous committees, and has published many articles in peer reviewed journals and publications. Id. at 4-15.

b. Opinion

Dr. Callaghan agreed that brachial neuritis is “the correct diagnosis.” Resp. Ex. A at 2.

i. Althen Prong One

Dr. Callaghan agreed that an “autoimmune mechanism may play a role” in some cases of brachial neuritis. Resp. Ex. A at 2. However, he suggested that there is insufficient evidence of causation because petitioner’s expert “provide[d] only 3 case reports and 1 of the 3 available case series as evidence supporting an association between the [flu] vaccine and brachial neuritis.” Id. Further, Dr. Callaghan noted that “there are currently no case/control or cohort studies to look at the association of any vaccine with brachial neuritis.” Id. “Given the lack of epidemiologic evidence other than 3 large case series, the causal relationship between vaccines and/or exercise with brachial neuritis is unclear.” Id.

The three case series cited by Dr. Callaghan include the first and oldest case series (also cited by Dr. DiCapua) authored by Parsonage and Turner, and published in 1948. Pet. Ex. 17H. The authors studied 136 cases during the “war years 1941-1945.” Id. at 1. A vaccination history was only obtained in 67 of the patients, and of these, 11 (16.4%) had vaccinations in the four weeks prior to onset. Id. at 2. The vaccines included typhoid, anti-tetanus toxoid, diphtheria antitoxin, and anti-typhus. Id.

The second case series was undertaken by Tsairis et al.¹⁹ in 1972 on 99 patients with brachial neuritis. Resp. Ex. A, Tab 1 at 1. Of the 99 patients, all but nine were asked about prior vaccination history. Id. at 2. Of these, 14 had received a vaccination within one month prior to

¹⁹ Peter Tsairis et al., Natural History of Brachial Plexus Neuropathy: Report on 99 Patients, 27 Archives Neurology 109 (1972).

onset. Id. at 3. Four patients received tetanus toxoid, four received flu, and one received both tetanus toxoid and flu. Id.

The last case series cited by Dr. Callaghan was authored by van Alfen and van Engelen,²⁰ and published in 2006. Resp. Ex. A, Tab 2. They studied brachial neuritis as well as a hereditary form of the condition (hereditary neuralgic amyotrophy), which results in a predisposition to “recurrent attacks of peripheral nerve damage.” Id. at 1. The authors noted that brachial neuritis was “assumed to be autoimmune in origin, but the precise mechanism is unknown.” Id. A total of 246 patients were identified from a large national database in the Netherlands. Id. at 2. Vaccination was identified as an antecedent event in 4.3% (5 cases) out of those who reported an antecedent attack (53.2% or 115 patients). Id. at 6. The authors did not report the specific vaccines administered.

Regarding the fact that the “tetanus vaccine is listed as a cause of brachial neuritis in the vaccine table,” Dr. Callaghan stated that “this was based on numerous cases of brachial neuritis following [the tetanus] vaccination.” Resp. Ex. A at 2. He identified four medical articles²¹ that support the Vaccine Table Injury of brachial neuritis following the tetanus vaccine, and noted that for the flu vaccination, there are only three published case reports.²² Id. Therefore, Dr. Callaghan concluded that “there is insufficient evidence to support a causal relationship between the [flu] vaccination and brachial neuritis.” Id.

The first of the three case reports of brachial neuritis following the flu vaccine cited by Dr. Callaghan was Miller et al., published in 2000. Pet. Ex. 17B. It described a 66-year-old who reported left-sided neck pain that radiated into his left shoulder after the flu vaccine. Id. at 1. Subsequently, the patient had muscle weakness. Id. EMG was consistent with brachial neuritis. Id. The next case was from Shaikh et al., who presented the case of a 46-year-old woman who reported severe shoulder pain a “few days after a[] [flu] vaccination.” Pet. Ex. 17 C at 1. “Within a week of the onset of pain, she developed left-upper-limb weakness with difficulty in performing her usual activities.” Id. EMG showed “axonal denervation” of left shoulder muscles. Id. The third case was by Taras and Donohue, published in 2014, of a 26-year-old who developed symptoms 12 to 16 hours after receipt of the flu vaccination. Pet. Ex. 17M at 1. He was diagnosed with radial nerve palsy. Id.

²⁰ Nens van Alfen & Baziél G.M. van Engelen, The Clinical Spectrum of Neuralgic Amyotrophy in 246 Cases, 129 *Brain* 438 (2006).

²¹ See Resp. Ex. A, Tab 1; Resp. Ex. A, Tab 3 (Ettore Beghi et al., Brachial Plexus Neuropathy in the Population of Rochester, Minnesota, 1970-1981, 18 *Annals Neurology* 320 (1985)); Resp. Ex. A, Tab 4 (William A. Martin & George H. Kraft, Shoulder Girdle Neuritis: A Clinical and Electrophysiological Evaluation, 139 *Military Med.* 21 (1974)); Resp. Ex. A, Tab 5 (Kenneth R. Wooling & Joseph G. Rushton, Serum Neuritis: Report of Two Cases and Brief Review of the Syndrome, 64 *Archives Neurology Psychiatry* 568 (1950)).

²² See Pet. Exs. 17B, 17C, 17M.

Another paper cited by Dr. Callaghan was published in 1974 by Martin and Kraft, describing 20 patients, seven of whom had a vaccination prior to onset. Resp. Ex. A, Tab 4 at 1. The vaccinations administered included the flu vaccine. Id.

ii. Althen Prong Two

Regarding Prong Two, the focus of Dr. Callaghan's opinion was that petitioner's history of bodybuilding provided evidence of an alternative cause for his brachial neuritis. Resp. Ex. A at 2. Dr. Callaghan stated that petitioner "was a bodybuilder who frequently performed strenuous upper extremity exercise." Id. In his first expert report, Dr. Callaghan opined that the "current evidence only supported a proximate temporal relationship for both vaccination and strenuous upper extremity exercise (bodybuilding) with brachial neuritis. . . . Given the lack of epidemiologic evidence other than 3 large case series, the causal relationship between vaccines and/or exercise with brachial neuritis is unclear." Id. He opined, however, that a proximate temporal relationship alone was insufficient to show causation. Id.

In support of his opinion that petitioner's strenuous exercise may have been an alternative cause for his brachial neuritis, Dr. Callaghan referenced a paper by Eijk et al., in which the authors identified "unusual and/or strenuous upper extremity exercise" as a "speculative" hypothesis that "may contribute to nerve inflammation." Pet. Ex. 17D at 4. They stated, "[a]lthough still speculative, we hypothesize that the predilection of [brachial neuritis] for the brachial plexus . . . is caused by mechanical stretching and compression of the nerves that follows from the wide range of motion of shoulder joints." Id. The authors discuss several different theories for why exercise may play a role in causing brachial neuritis. Of particular interest, however, is their explanation of how biomechanical factors (exercise) "in addition to an immune trigger, such as infection, add to an individual's susceptibility" to develop brachial neuritis. Id.

Eijk et al. provide two examples of "Biomechanical-Immune Interplay" in the pathophysiology of brachial neuritis. Pet. Ex. 17D at 4. The first example occurred in a village in Czechoslovakia after residents "were infected with Coxsackie A2 virus" due to "contaminated water." Id. There was a knitting factory in the village where employees were required to "bend and stretch their right arms for 8 hours/day." Id. There was an "epidemic" of brachial neuritis. Id. The combination of infection and biomechanical factors were thought to play a causal role. Id. "The epidemic ended . . . when the main water supply was replaced." Id. The second example was two surfers who developed brachial neuritis after they were infected with hepatitis E virus caused by sewage runoff on the beach where they swam and surfed. Id. The authors explained that in both events, not all who were exposed developed brachial neuritis. Id. at 4-5. Thus, they suggested that in addition to the immune trigger and biomechanical stress, there was an unknown genetic factor also at play. Id. at 5.

Dr. Callaghan stated that while "vaccines are antecedent events in 16.4%, 13.1%, and 4.3% of cases (Parsonage et al, [] Tsairis et al [], and van Alfen et al[])," exercise is "an

antecedent event in 8.1% and 17.4% of cases from the two articles that present this data.”²³ Resp. Ex. A at 2.

In his second expert report, Dr. Callaghan maintained “that [petitioner’s] frequent strenuous upper extremity exercises led to the development of brachial neuritis that was documented to be occurring before receipt of the [flu] vaccine.” Resp. Ex. C at 2. For this reason, Dr. Callaghan did not believe there was a “logical sequence of events between the receipt of the [flu] vaccination and [petitioner’s] brachial neuritis.” Id.

After reviewing additional records, in his second expert report, Dr. Callaghan changed his opinion as to onset, as discussed below, which in turn, changed his opinion as to a logical sequence of cause and effect, finding that since onset occurred prior to vaccination, there was no logical sequence of cause and effect. Resp. Ex. C at 2.

However, in his second report, Dr. Callaghan again repeated a statement from his first report. He opined that “while the current medical evidence only supports a proximate temporal relationship for both vaccination and strenuous upper extremity exercise (bodybuilding) with brachial neuritis, importantly, a proximate temporal relationship alone is insufficient to show causation. Therefore, the causal relationship between vaccine and/or exercise with brachial neuritis is unclear.” Resp. Ex. C at 2.

iii. Althen Prong Three

In his first expert report, Dr. Callaghan opined that petitioner “developed brachial neuritis shortly after the [flu] vaccine.” Resp. Ex. A at 2. He agreed that the evidence supported a “proximately temporal relationship” between vaccination and brachial neuritis.²⁴ Id.

However, in his second expert report, Dr. Callaghan retracted his opinion that there was a temporal association between vaccination and the onset of petitioner’s brachial neuritis.²⁵ Resp. Ex. C at 2. After reviewing the records of Dr. Anderson (Pet. Ex. 33), Dr. Callaghan opined that the “onset and worsening of [petitioner’s] brachial neuritis symptoms was a few months before

²³ Dr. Callaghan does not provide cites for the two articles he references here, but presumably he is referencing the Eijk et al. article, which cites the van Alfen et al. paper stating that 10% of brachial neuritis cases are “preceded by unusual and/or strenuous upper extremity exercise.” Pet. Ex. 17D at 4. It is not clear where Dr. Callaghan obtains his references to 8.1%. See id.; see also Resp. Ex. A, Tab 2 at 6 (finding antecedent events occurred in 17.4% of their cases).

²⁴ Dr. Callaghan’s first expert report was based on his review of Exhibits 1-18 and the petition.

²⁵ Prior to submitting his second expert report, Dr. Callaghan reviewed additional Exhibits 19-34.

an office visit on 11/12/2016 (Exhibit 33, page 12).²⁶ This would place the onset of [petitioner's] brachial neuritis well before his [flu] vaccination on 10/6/2016." Id. Dr. Callaghan concluded that "if [petitioner] had developed symptoms of brachial neuritis prior to the vaccination, then it is not possible that the vaccine caused his brachial neuritis." Id. at 3.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, petitioner must prove 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)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-

²⁶ Dr. Callaghan cited a portion of petitioner's office visit with Dr. Anderson dated November 12, 2016, which states that petitioner reported "rather long standing issues" with pain in his right shoulder, "but over the past few months it had worsened significantly." Resp. Ex. C at 2 (citing Pet. Ex. 33 at 12).

63 (2014); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief.”); Pafford, 451 F.3d at 1358-59 (“[T]he presence of multiple potential causative agents makes it difficult to attribute ‘but for’ causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.”).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is “consistent, clear, cogent, and compelling.” Sanchez v. Sec’y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec’y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony 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) (“[L]ike 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 v. Sec’y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting 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))). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports,

diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that he suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Because petitioner does not allege he suffered a Table Injury, he must prove a vaccine he received caused his injury. To do so, petitioner must establish, by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in petitioner’s favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”); Althen, 418 F.3d at 1280 (noting that “close calls” are resolved in petitioner’s favor).

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner’s theory of causation need not be medically or scientifically certain, but it must be informed by a “sound and reliable” medical or scientific explanation. Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec’y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (“The special master’s decision

often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); Perreira v. Sec’y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an “expert opinion is no better than the soundness of the reasons supporting it” (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds that petitioner has provided preponderant evidence of a sound and reliable medical theory explaining how the flu vaccine can cause brachial neuritis. This finding is supported by expert opinion and medical literature.

Dr. DiCapua’s expert report provides a cogent and thorough description of the petitioner’s proposed causal mechanisms. He explains that brachial neuritis is thought to be an immune mediated condition based on “the fact that 40-50% of [] cases are preceded by an infection, typically viral, and immunization, or some other immune system trigger.” Pet. Ex. 16 at 3-4. The medical literature supports this general proposition.

Dr. DiCapua opined that both the innate and adaptive immune systems may be at play, and explained the reasons for that belief. The principal mechanism of causation is thought to be complement dependent antibody mediated demyelination. In support of this assertion, he cited several papers. Shaikh et al. described the causal theory, an immune-mediated inflammatory reaction against brachial plexus nerve fibers involving complement, anti-peripheral nerve myelin antibodies, and T cells. Vriesendorp et al. discussed the same theory—“[d]etection of anti-PNM antibodies and complement activation products in the serum of three patients with acute brachial plexus neuropathy supports the hypothesis that complement-dependent, antibody-mediated demyelination may participate in initial peripheral nerve damage.” Pet. Ex. 17E at 3. Petitioner provides a number of on point articles that present an uncontroversial and accepted theory of causation.

Respondent’s expert does not take issue with the mechanism described by Dr. DiCapua, or offer any medical literature, or other evidence, to show that petitioner’s proposed mechanisms are not sound or reliable. Instead, Dr. Callaghan opines that there is a “lack of epidemiologic evidence other than 3 large case series.” Resp. Ex. A at 2. As compared with the paucity of epidemiological studies and/or medical literature regarding many alleged post-vaccination adverse conditions, here there is an abundance of data, including case series studies and case reports showing an association between vaccinations and brachial neuritis. Further, there is a presumption of a causal association between tetanus toxoid vaccines and brachial neuritis, and that association is reflected in the Vaccine Injury Table. The presumption of causation for brachial neuritis following the tetanus toxoid vaccine has not been extended to other vaccines. The evidence filed in this case, however, supports vaccine causation as to the flu vaccine administered here.

Moreover, a petitioner may satisfy Althen Prong One without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a theory that has general acceptance in the medical or scientific community. Andreu, 569 F.3d at 1378-79 (citing Capizzano, 440 F.3d at 1325-26); see also Harmon v. Sec’y of Health & Hum. Servs., No. 12-298V, 2017 WL 2872293, at *24 (Fed. Cl. Spec. Mstr. June 6, 2017).

Therefore, the undersigned finds that petitioner has proven by preponderant evidence a sound and reliable theory of causation.

B. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical 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 trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

Before turning to an analysis of logical sequence of cause and effect, the undersigned first finds that there is preponderant evidence that petitioner received the flu vaccine at issue in his right shoulder. While his vaccine administration records are silent as to the location of vaccination, there is ample other evidence. In his affidavit, he avers that he received the flu vaccine in his right arm on October 6, 2016. Pet. Ex. 26 at 2. Afterward, his right arm became weak and began to atrophy. Id. at 11. Approximately October 12, 2016, Dr. Gonte noted that petitioner was having difficulty with his usual workout routine on the right side. Pet. Ex. 31 at 1. Dr. Gonte ordered an MRI and an EMG of petitioner’s right shoulder. Pet. Ex. 2 at 3. On November 2, petitioner saw Dr. Anderson, complaining of pain and weakness of his right shoulder. Pet. Ex. 33 at 10. On December 8, petitioner saw a physical therapist, and had weakness of his right triceps, pectoral, biceps and deltoid muscles. Pet. Ex. 5 at 2. The physical therapist also observed atrophy of these right sided muscles. When he presented to Dr. Burns, petitioner complained of severe pain in his right arm that began shortly after receiving the flu vaccine. Pet. Ex. 4 at 4. This evidence preponderantly establishes that the flu vaccination was administered in petitioner’s right shoulder.

Next, the undersigned finds that petitioner has provided preponderant evidence of a logical sequence of cause and effect. This finding is based on expert opinion, petitioner’s clinical course, evidence provided by petitioner’s physician friend Dr. Gonte, treating physician opinions, and lack of evidence to support an alternative cause.

The first reason for the undersigned's finding on Althen Prong Two is based on Dr. DiCapua's explanation and opinions about petitioner's clinical course. Specifically, Dr. DiCapua opined that petitioner's clinical course was consistent with post-vaccination brachial neuritis. Dr. DiCapua noted that prior to receiving the flu vaccination, petitioner did not have any "physical limitations or injuries to his right shoulder" and "he was extremely physically active, exercising 5-6 days per week for 28 years." Pet. Ex. 16 at 2. After vaccination, however, petitioner had severe pain, was unable to maintain his workout schedule, had difficulty sleeping, and had muscle twitching. Dr. DiCapua explained that petitioner's medical records evidenced "mild tenderness" of the shoulder at the insertion sites of his right biceps and supraspinatus tendons, consistent with the pathology seen on his MRI. Id. at 3. Additionally, petitioner's history of "on and off right shoulder pain, weakness, and numbness [was] not indicative of . . . a developing brachial plexopathy. A brachial plexopathy presentation is acute[,] . . . [and] the pain is described as severe, excruciating, [and] debilitating . . . and drives one to seek medical care." Id. Dr. DiCapua concludes that the records "are only consistent with a brachial plexopathy that developed after the vaccination. There is no indication that [petitioner] was developing a brachial plexopathy before the vaccination." Id. Dr. DiCapua's explanation provides strong support for why petitioner's clinical course was consistent with the development of brachial neuritis after vaccination.

Further, petitioner's clinical course was consistent with that of patients who experienced post-vaccination brachial neuritis, as described in the case series and case reports. For example, Shaikh et al. described a "fit and well 46-year-old" woman who had acute shoulder pain "a few days" after receiving a flu vaccination. Pet. Ex. 17C at 1. EMG showed severe axonal denervation of the shoulder muscles. She was diagnosed with post vaccination acute brachial neuritis. The authors state that the pattern of "pain followed by weakness, is classic of brachial neuritis." Id. at 2. As explained by Taras et al., brachial neuritis "typically presents with intense pain in the shoulder girdle followed by the rapid development of motor weakness after a variable period of time." Pet. Ex. 17M at 1.

Petitioner's clinical course is perhaps best described by his physician friend, Dr. Gonte, who had observed petitioner's workout routine for a number of years before the petitioner's vaccination in October 2016. Dr. Gonte directly observed the change in petitioner's condition post-vaccination. On October 12, 2016, approximately six days after vaccination, Dr. Gonte stated that "it became apparent [that petitioner was] having difficulty with his usual workout regimen including the amount of weight he could lift and his endurance . . . [on the] right side." Pet. Ex. 31 at 1. Dr. Gonte observed that "[o]ver the next week, it became apparent that he was developing significant atrophy and progressive weakness." Id. The description by Dr. Gonte is consistent with the course described in the medical literature and case reports of post-vaccination brachial neuritis.

The clinical course described by Dr. Gonte is also consistent with that set forth in Dr. Anderson's records. Dr. Anderson saw petitioner on November 2, 2016. Dr. Anderson's history of present illness noted "poss[ible] injury weightlifting, having weakness is arm, atrophy in [right] chest . . . main prob[lem] is no strength." Pet. Ex. 33 at 10. This history suggests that petitioner or Dr. Anderson questioned whether petitioner's weightlifting caused him to sustain an injury. Dr. Anderson's history also noted that petitioner reported "long standing issue with the

shoulder, but over the past few months it has worsened significantly.” *Id.* When seen by Dr. Anderson, the petitioner could no longer “contract his pectoralis muscle.” *Id.* However, after a thorough evaluation, Dr. Anderson did not diagnose a musculoskeletal problem but instead, he opined that petitioner had a neurological problem.

Subsequently, petitioner was referred to a neurologist, Dr. Burns, who reviewed petitioner’s MRI of the cervical spine, shoulder and brachial plexus, and EMG. Dr. Burns opined that “there was certainly evidence suggestive of brachial plexus injury. Given the association with receiving the vaccine last October, suspect an inflammatory plexitis.” Pet. Ex. 8 at 12.

Thus, petitioner was evaluated by an orthopedist, Dr. Anderson, who did not find a structural or musculoskeletal problem to account for petitioner’s symptoms. While weightlifting is referenced, it is characterized as a possibility.²⁷ And after evaluation, Dr. Anderson opines that the problem is neurological. Subsequently, petitioner sees a neurologist, Dr. Burns, who notes the association between petitioner’s vaccination and his brachial neuritis. Neither Dr. Anderson nor Dr. Burns attribute petitioner’s brachial neuritis to exercise or weightlifting.

Dr. Callaghan raises the question of whether petitioner’s body building workout regime caused his brachial neuritis and he cited literature showing that brachial neuritis can be associated with weightlifting.²⁸ However, petitioner had adhered to his workout regime for number of years, and there is no evidence that he changed his workout routine prior to the development of symptoms. On approximately October 12, 2016, Dr. Gonte observed that petitioner had “difficulty with his usually workout regimen including the amount of weight he could lift and his endurance and mainly affected his right side.” Pet. Ex. 31 at 1. Weightlifting was a constant, with vaccination as the new variable. Additionally, the petitioner’s treating physicians did not recommend that he modify or stop exercising due to his condition. If petitioner’s physicians had attributed his brachial neuritis to his workout routine, one would have expected that they would have advised him to reduce or stop his workout routine. In fact, the records show that Dr. Burns recommended that petitioner continue his aggressive exercise.

Moreover, there is a disconnect in Dr. Callaghan’s opinions as they relate to exercise and causation. In his second report, Dr. Callaghan states that “strenuous upper extremity exercise is

²⁷ The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. *Moberly*, 592 F.3d at 1322 (finding “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); *Waterman v. Sec’y of Health & Hum. Servs.*, 123 Fed. Cl. 564 (2015) (denying petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a plausible or possible mechanism does not rise to the level of preponderance. *Id.*; see also *de Bazan*, 539 F.3d at 1351; *Capizzano*, 440 F.3d at 1323.

²⁸ See Resp. Ex. A, Tab 1; Resp. Ex. A, Tab 2.

an alternative explanation.” Resp. Ex. C at 3. However, in both of his expert reports, he states that “the causal relationship between vaccines and/or exercise with brachial neuritis is unclear.” Id. at 2; Resp. Ex. A at 2. While he opines that exercise is an alternative explanation, at the same time, he opines that the evidence of causation as to both vaccines and exercise is unclear. Thus, Dr. Callaghan’s opinion as to the role played by exercise is internally inconsistent. This inconsistency renders it less persuasive. The undersigned finds that Dr. Callaghan’s opinion that exercise was an alternative cause for petitioner’s brachial neuritis does not meet the standard of more likely than not.

For all of these reasons, the undersigned finds that petitioner has provided preponderant evidence of a logical sequence of cause and effect.

C. Althen Prong Three

Althen Prong Three requires petitioner to establish a “proximate temporal relationship” between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a “medically acceptable temporal relationship.” Id. The petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease’s etiology, it is medically acceptable to infer causation-in-fact.” de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec’y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. denied after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013).

Prior to vaccination on October 6, 2016, petitioner had no physical limitations or injuries to his right shoulder. He had pain on October 8, and by October 12, 2016, Dr. Gonte observed that petitioner had difficulty with his usual workout routine. Over the next week, Dr. Gonte noted that petitioner’s condition progressed. On November 12, 2016, physical examination by Dr. Anderson revealed that petitioner had difficulty contracting his right pectoralis muscle. Physical examination by the physical therapist on December 8, 2016, showed notable atrophy of pectoral and triceps muscles. Petitioner saw Dr. Burns on March 8, 2017, who suspected brachial neuritis. After further workup, Dr. Burns diagnosed brachial neuritis, and associated the condition with petitioner’s flu vaccination.

Additionally, onset of pain, the first manifestation of brachial neuritis, is corroborated by the affidavits submitted by petitioner, his wife, and Dr. Gonte. Perhaps the most persuasive evidence of onset is the letter by Dr. Gonte, who did not observe any problems prior to vaccination, but noted that on approximately October 12, 2016, the petitioner was having difficulty with his usual workout routine. Dr. Gonte noted that petitioner developed significant atrophy and progressive weakness.

Dr. DiCapua opined that petitioner would not have been able to exercise and maintain his consistent exercise routine prior to his vaccination on October 6, 2016 if he had been developing a brachial plexopathy. Dr. DiCapua opined that the timeline from petitioner's vaccination to progression of pain and weakness was consistent with an immune mediated process. The activation of the innate immune system and the complement system increases complement-fixing antibodies to peripheral nerve myelin and may lead to demyelination. While Dr. DiCapua acknowledges that the onset of brachial neuritis symptoms two days after vaccination is rapid, he cites medical literature which shows that this time frame has been reported. In Taras et al., the vaccinee reported symptoms within 16 hours after vaccination. And in Shaikh et al., the vaccinee had onset several days after flu vaccination.

Further, three different health providers place onset of petitioner's pain and/or weakness, the initial manifestations of brachial neuritis, in October 2016, after vaccination. As described above, Dr. Gonte observed a change in petitioner's condition on October 12. Physical therapist, Samuel Gill, documented onset in October 2016, and lastly, Dr. Burns documented that petitioner had severe pain in October, shortly after receiving the flu vaccine. These three independent reports provide consistent and persuasive evidence of onset.

The undersigned finds that the onset of pain, the first manifestation of petitioner's brachial neuritis, was October 8, two days after vaccination, and that he began having weakness attributable to brachial neuritis, as observed by Dr. Gonte on approximately October 12, 2016. Therefore, petitioner has provided preponderant evidence of an appropriate temporal association between vaccination and onset of his brachial neuritis.

VI. CONCLUSION

For the reasons discussed above, the undersigned finds that petitioner has established by preponderant evidence that his flu vaccine caused his brachial neuritis. Therefore, petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master