In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1860V

Filed: November 26, 2025

ERIC WILLIAMS,	*
	*
Petitioner,	*
v.	*
	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
	*
Respondent.	*

Phyllis Widman, Esq., Widman Law Firm, LLC, Linwood, NJ, for petitioner.
Kimberly S. Davey, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION ON ENTITLEMENT[1]

Roth, Special Master:

On December 4, 2018, Eric Williams ("Mr. Williams") filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleges that he developed polymyalgia rheumatica ("PMR") resulting from an influenza ("flu") vaccination received on October 6, 2017. *See* Petition ("Pet."), ECF No. 1. Petitioner further alleges that during the course of this matter he developed severe hip and shoulder pain, rash, and depression. Respondent disputes petitioner's claim, arguing that no reputable scientific evidence exists to support the flu vaccine as a cause of PMR, and that petitioner's symptoms began before he received the flu vaccine. The matter was submitted for resolution on the record as filed.

Following review of all the evidence and arguments presented, I find that petitioner has failed to provide preponderant evidence that the flu vaccine he received on October 6, 2017, caused him to suffer a compensable injury.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

I. Procedural History

The petition was filed on December 4, 2018. Petition, ECF No. 1. Thereafter, petitioner filed medical records and affidavits. Petitioner's Exhibits ("Pet. Ex.") 1-9, 35, 50, 95, ECF Nos. 8, 13, 36, 54, 73.

On December 10, 2019, respondent filed his Rule 4(c) Report, advising that the matter was not appropriate for compensation. ECF No. 22. Over the next three years, the parties exchanged expert reports and supporting literature. Pet. Ex. 10-34, 36-44, 51-94, ECF Nos. 25-26, 28-29, 31, 38, 59, 61; Respondent's Exhibits ("Resp. Ex.") A-HH, ECF Nos. 34-35, 41, 64, 84.

In a joint status report filed on December 6, 2022, the parties requested a briefing schedule for the filing of a Motion for Ruling on the Record ("Motion"). ECF No. 76. Petitioner filed his Motion on March 24, 2023. ECF No. 79. Respondent filed his Response to the Motion on May 26, 2023. ECF No. 81. Petitioner filed a Reply on June 3, 2023. ECF No. 83.

I determined that the parties had a full and fair opportunity to present their cases, and it was appropriate to resolve this issue without a hearing. The parties agreed. ECF No. 76; *see* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

II. Medical Terminology

Polymyalgia rheumatica ("PMR") is considered an inflammatory rheumatic condition characterized clinically by aching and morning stiffness in the shoulders, hip girdle, and neck. Pet. Ex. 12 at 1.[3] PMR generally affects those over the age of 50. *Id*. Symptoms are usually symmetric, and onset can be abrupt. *Id*. "The cause of PMR is unknown; both environmental and genetic factors appear to play [a] role." *Id*. Case reports of PMR following vaccines have typically demonstrated onset within two weeks of infection or vaccination, with elevated inflammatory markers on routine blood work, including erythrocyte sedimentation rate ("ESR") and C-reactive protein ("CRP"), and a dramatic response to steroids. *Id*. at 2; Pet. Ex. 13.[4]

Giant cell arteritis ("GCA") is a giant cell vasculitis with a "distinct tropism for large and medium-size elastic arteries." Pet. Ex. 18 at 1.[5] GCA is commonly found in older age groups with onset in the 60s and 70s. *Id*. GCA is often associated with PMR, but PMR may develop without GCA. Both are thought to have a genetic predisposition. *Id*. Genetic linkage studies have demonstrated an association of GCA and PMR with alleles at the HLA-DRB1 locus which could predispose to the development of GCA and PMR. *Id*. at 3.

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[3] Mashal Salehi, et al., *Polymyalgia Rheumatic After Influenza Vaccine*, 8 J. Med. Cases 117 (2017), filed as "Pet. Ex. 12."

[4] Eric Liozon, et al., *Polymyalgia Rheumatica Following Influenza Vaccination*, 48 J. of the Am. Geriatrics Soc'y 1533 (2015), filed as "Pet. Ex. 13."

[5] A. Soriano, et al., *Giant Cell Arteritis and Polymyalgia Rheumatica After Influenza Vaccination: Report of 10 Cases and Review of the Literature*, 21 Lupus 153 (2012), filed as "Pet. Exs. 18 and 90."

Autoimmune, autoinflammatory, and inflammatory disorders are terms often erroneously used interchangeably, as they are interrelated but separate concepts. As such, distinguishing them from one another is necessary. Autoimmune and autoinflammatory diseases are related but distinct categories of illnesses occurring when the immune system mistakenly damages healthy cells.[6] Inflammation is the body's normal response to injury or infection, as opposed to an autoinflammatory disorder wherein the body's innate immune system mistakenly causes inflammation without a known external trigger.

III. Background

A. Petitioner's History Prior to the Subject Flu Vaccination

Petitioner established care with the Medical Center of Orting ("Orting") on March 3, 2016. Pet. Ex. 3 at 2. He had elevated blood pressure and was prescribed medication. *Id*. at 3. He presented for follow-up appointments for monitoring of his hypertension. *See generally* Pet. Ex. 3.

On October 10, 2016, petitioner presented for evaluation of pain in his right shoulder/scapular region and neck which had persisted for four months. Pet. Ex. 3 at 8. He reported that his right bicep was half the size of his left due to discomfort and disuse. Where he once could curl sixty pounds, he now could only curl forty pounds. *Id*. On examination, petitioner demonstrated neck and shoulder/scapular region pain on his right. *Id*. He was diagnosed with cervical muscle and right shoulder strain. X-rays were ordered and physical therapy prescribed. *Id*. at 9.

Petitioner returned to Orting on January 19, 2017, reporting rash and ingrown hair in his beard. Pet. Ex. 3 at 10. He was diagnosed with folliculitis[7] and prescribed cephalexin, an antibiotic. *Id*. at 11.

He returned again on June 1, 2017, for erythemic papules[8] across his back from wearing his backpack while biking in the hot sun all weekend. He was prescribed cephalexin and Zyrtec. Pet. Ex. 3 at 12-13.

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[6] *See Autoimmune*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4971 (last visited Sept. 23, 2025) (Autoimmune disorders are "characterized by a specific humoral or cell-mediated immune response against constituents of the body's own tissues (self antigens or autoantigens)."); *Autoinflammatory*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4974 (last visited Sept. 23, 2025) (Autoinflammatory disorders are "characterized by a disorder of the body's innate immunity, with inflammation that is not caused by an external irritant such as infection.").

[7] Folliculitis is an inflammation of a follicle, typically a hair follicle. *See Folliculitis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=18992 (last visited Sept. 23, 2025).

[8] Erythema is "redness of the skin produced by congestion of the capillaries." *See Erythema*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=17187 (last visited Sept. 23, 2025). A papule is a "small circumscribed, superficial, solid elevation of the skin." *Papule*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=36692 (last visited Sept. 23, 2025).

Petitioner returned again to Orting on October 6, 2017, for a rash on his thighs and a flu shot. Pet. Ex. 3 at 14. A general examination was normal/negative. Erythemic papules and scales were noted on his thighs, groin and buttock region. *Id*. The diagnoses on that day included bilateral shoulder pain, bilateral groin pain, hypertension, tinea corporis, and flu vaccine.[9] *Id*. He was to return in April with fasting labs, watch his diet, and exercise. He was given prescriptions for his rash. *Id*. at 15.

B. Petitioner's History Following the Subject Flu Vaccination

Three weeks later, on October 28, 2017, petitioner presented to the emergency room ("ER") reporting muscle spasm in his back and arthralgia.[10] Pet. Ex. 4 at 16. The record noted a 49-year-old man with back pain, right greater than left, lasting for the past ten days following off-road motorcycle riding and a long car trip exacerbated by bending forward, lifting, and twisting. Pet. Ex. 4 at 19, 22. He also started to have bilateral hip discomfort. *Id*. He was noted to be well appearing and moved fairly easily. *Id*. at 20. On examination, he was spastic and tender over his right paravertebral muscles,[11] on the right more than the left, with costovertebral angle[12] tenderness on the right but not the left. *Id*. CT scan of the abdomen and pelvis for "right flank pain" was normal but for a tiny kidney stone. *Id*. at 29-30. Urine testing and a comprehensive metabolic panel were negative. *Id*. at 31-32. The discharge diagnosis was back muscle spasm and generalized arthralgia. Naproxen was prescribed. *Id*. at 21.

Petitioner presented to his dentist on November 14, 2017, unable to open his mouth. He reported that "something happened over the weekend to his upper jaw." He was out hunting and chewing gum extensively, which he thought caused it. There was no clicking or popping but he had tenderness on the right upon palpation. Pet. Ex. 6 at 9, 16. It was recommended he wait for additional healing and to advise if not improved. *Id*. at 9.

Petitioner returned to the ER on November 19, 2017, reporting bilateral hip, right knee, and shoulder pain that started two months prior after motorcycle riding and a long car trip. Pet. Ex. 4 at 82. He had presented to the ER a month prior for back and shoulder pain. *Id*. at 65, 79, 82, 86-87. He was drinking alcohol to deal with the pain and as a sleep aid and took naproxen twice daily. *Id*. at 82. He reported a history of back surgery.[13] *Id*. On examination, he had some tenderness over

[9] The medical record from petitioner's October 6, 2017, visit is conflicting. The record notes "Vaccines: No Vaccines given today." Pet. Ex. 3 at 15. However, under "Diagnosis:" is listed "Flu vaccine," and under "Plan:" is listed "Flu vaccine given." *Id*. Nevertheless, the Court will assume that petitioner did receive the influenza vaccine on October 6, 2017, for purposes of this Decision.

[10] Arthralgia is "pain in a joint." *Arthralgia*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4230 (last visited Oct. 9, 2025).

[11] Paravertebral muscles are those muscles "beside the vertebral column," or spine. *See Paravertebral*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=37030 (last visited Oct. 9, 2025); *Columna Vertebralis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=66108 (last visited Oct. 9, 2025).

[12] The costovertebral angle is "the angle formed on either side of the vertebral column, between the last rib and the lumbar vertebrae." *Costovertebral Angle*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=56490 (last visited Oct. 9, 2025).

[13] Petitioner has not filed any medical records detailing this prior back surgery. It is therefore unclear what kind of back surgery is referred to in the Orting records, why it was ordered, or when it took place.

the left acromial clavicular joint.[14] *Id*. He displayed tenderness with abduction bilaterally, the left greater than the right, and pain with resisted abduction anteriorly and laterally on the left side and anteriorly on the right. *Id*. at 83. He had good grip strength in both hands and could flex, extend, and abduct both shoulders, with some weakness on abduction bilaterally. *Id*. Examination of the hips revealed some pain with resisted abduction on the left hip and some discomfort on the right. *Id*. There was no erythema on either side with good range of motion bilaterally. *Id*. There was no bony abnormality and only mild right hip degenerative change on imaging. *Id*. at 84. Shoulder imaging revealed mild right and mild to moderate left glenohumeral[15] degenerative change, mild bilateral AC joint degenerative change, and mild widening of the right AC joint suggesting an age-indeterminate shoulder injury. *Id*. at 84, 93-96. He was given a sling for his left shoulder. *Id*. at 85. He complained of left bicep muscle spasm, which would likely be addressed by the sling. *Id*. He was prescribed Tylenol for the hip pain and was to continue taking naproxen. *Id*. His blood pressure was slightly but notably elevated. *Id*. at 68.

Petitioner returned to Orting on November 27, 2018, 52 days post-vaccination, and reported bilateral shoulder pain, bilateral hip pain, stiffness, and resolving rash. Pet. Ex. 3 at 16-17. Blood work was ordered and a referral to rheumatology made. *Id*. at 17. The blood work results indicated elevated inflammatory markers c-reactive protein[16] ("CRP") and erythrocyte sedimentation rate[17] ("ESR"). Pet. Ex. 9 at 3.

Petitioner presented to rheumatology on January 2, 2018, reporting bilateral shoulder and pelvic girdle pain with stiffness lasting about three hours in the morning since September 2017 that was worsening.[18] Pet. Ex. 5 at 2. He was taking ibuprofen and naproxen daily, sometimes two ibuprofen before work. *Id*. His symptoms interfered with his work as a plumber. *Id*. He also reported jaw pain without association with chewing. *Id*. His inflammatory markers were recently elevated with mild elevation in platelet count. *Id*.; Pet. Ex. 9 at 3. Anti-CCP,[19] ANA,[20] and HLA-

[14] The acromion is the lateral extension of the spine of the scapula, projecting over the shoulder joint and forming the highest point of the shoulder. *See Acromion*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=708 (last visited Oct. 9, 2025). The acromial clavicular joint then is the joint where the acromion meets the clavicle.

[15] Glenohumeral refers to "the glenoid cavity . . . and the humerus." *See Glenohumeral*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=20315 (last visited Oct. 9, 2025). The glenoid cavity is "a depression in the lateral angle of the scapula for articulation with the humerus." *See Glenoid Fossa*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=77335 (last visited Oct. 9, 2025).

[16] C-reactive protein is a protein used to indicate an inflammatory illness. It is elevated in patients with a bacterial infectious disease, tissue necrosis, or an inflammatory disorder. A positive test result indicates the presence, but not the cause, of the disease. *See Mosby's Manual of Diagnostic and Laboratory Tests* 165-66 (Pagana eds., 6th ed. 2018) (hereinafter "*Mosby's*").

[17] Erythrocyte sedimentation rate is a non-specific test used to detect illnesses associated with acute and chronic infection, inflammation, and tissue necrosis or infarction. *Mosby's* at 199.

[18] The subject flu vaccination took place on October 6, 2017.

[19] Cyclic citrullinated peptide antibodies are useful in the diagnosis of patients with unexplained joint inflammation, particularly when the patient's rheumatoid factor is negative. These antibodies appear early in the course of rheumatoid arthritis and are present in the blood of most RA patients. *Mosby's* at 64-65.

[20] ANA refers to "antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis." *See Antinuclear Antibodies*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=56804 (last visited Oct. 9, 2025).

B27[21] were all negative. *Id*. Examination revealed mild erythematous papular rash on the lateral thighs, tenderness on palpation of bilateral shoulders with difficulty raising his arms above his head, tenderness on palpation on internal and external rotation of the glenohumeral joints bilaterally, and tenderness in the groin area on internal rotation of the hips. *Id*. at 3. The assessment was concern for PMR. Low dose prednisone (15mg) for diagnostic and treatment was prescribed. A rapid response within a few days would confirm the diagnosis. *Id*. at 4, 5.

Petitioner presented to rheumatology on January 18, 2018, for a follow up visit and reported a "major improvement after 12 hours of taking the first dose of prednisone," with resolution of the stiffness in his shoulder and pelvic region. Pet. Ex. 5 at 5. He could lift his arm above shoulder level and get out of bed without stiffness. He was no longer taking NSAIDs. *Id*. He reported no pain and his depression was gone. *Id*. The diagnosis was PMR. *Id*. at 5-6. The plan was to slowly taper prednisone, recheck inflammatory markers, and start calcium and vitamin D supplements. *Id*. at 6. Information on PMR and GCA was provided. Risks and benefits of long-term use of steroids were discussed. *Id*. at 6.

Petitioner returned to the rheumatologist on February 19, 2018. He was taking 7.5mg of prednisone daily and rated his shoulder and girdle pain as a 1 out of 10. Pet. Ex. 5 at 8. He reported occasional left shoulder discomfort but tremendous improvement from four months ago. He was able to dirt bike again and had no morning stiffness. *Id*. at 8. A family history of arthritis was noted. *Id*. His ESR and CRP levels were improving.[22] Petitioner was to continue 7.5mg a day of prednisone for a month, decrease to 5mg for a month, and finally 2.5mg the following month. *Id*. at 9.

At his April 23, 2018, visit with the rheumatologist, petitioner's history included bilateral shoulder and pelvic girdle pain with at least three hours of stiffness in the morning that "started **September 2017. Had a rapid response to low dose prednisone."** Pet. Ex. 5 at 10 (emphasis in original). He was taking 5mg of prednisone daily, with no worsening of symptoms, and his pain remained a 1 out of 10. *Id*. He was performing his regular activities, planned on going fishing, had no limitations, and denied associated morning stiffness. *Id*. Examination was negative/normal. The assessment remained PMR with elevated ESR and CRP improving. *Id*. at 11. No labs were ordered during this visit.

Petitioner's next visit with rheumatology was on June 20, 2018. He reported worsening of his left shoulder pain, morning stiffness that lasted less than 30 minutes, and left wrist and thumb pain. Pet. Ex. 5 at 12. Petitioner attributed the recurrence of these symptoms to discontinuation of the prednisone. *Id*. at 12. On examination, he had tenderness on palpation of the left bicep tendon and limited internal and external rotation of the left glenohumeral joint. *Id*. at 13. The assessment was a relapse of PMR. *Id*. at 14. He was assured this was not uncommon and a slow taper starting with 5mg of prednisone was prescribed, with a decrease of 1mg every 30 days. *Id*. at 14.

[21] Human leukocyte antigens ("HLA") are antigens present on the surface of white blood cells and on the surface of all nucleated cells in other tissues. *Mosby's* at 274. They are most easily detectable on the surface of lymphocytes. *Id.* HLA testing is used to assist in the diagnosis of certain diseases. *Id.* For example, the HLA-B27 antigen is commonly present in patients with Reiter syndrome, anterior uveitis, and Graves' disease. *Id.* at 274-75.

[22] The records of the testing referenced in the February 19, 2018 visit are not contained in the record.

Petitioner presented to dermatology on July 2 and August 30, 2018, for continued rash on his stomach and legs for ten months. Pet. Ex. 7 at 3-6. He was prescribed a topical steroid and warned about the risks of topical steroids. *Id*. at 6.

Petitioner's next visit with a medical provider was ten months later, on March 1, 2019, to rheumatology. Pet. Ex. 8 at 1. He reported taking 1mg of prednisone daily and lisinopril for hypertension. *Id*. He reported tenderness on the left trochanteric bursa, pain worse with movement, crepitus on movement of the left glenohumeral joint, and mild pain not associated with morning stiffness. *Id*. at 2. X-rays of the left glenohumeral joint were ordered to rule out avascular necrosis from prednisone, though this was unlikely as the steroid dose was very small. *Id*. Prednisone was to be discontinued, and meloxicam 7.5mg daily started with 50mg daily as needed. If there was no improvement, kenalog injection to the trochanteric bursa would be considered. *Id*. No record has been filed of the x-rays.

The next records filed were from petitioner's visits with his primary care physicians on January 29, 2020, December 29, 2021, January 12, 2022, and February 11, 2022. He had elevated blood pressure due to noncompliance with blood pressure medication and was going to the gym five to six days per week. Pet. Ex. 95 at 2. Other than a rash and mildly elevated blood pressure, his examinations were normal. *See generally* Pet. Ex. 95. There were no records filed with any complaints associated with PMR from these visits.

C. Affidavits

Petitioner filed two affidavits in this matter. Pet. Ex. 2; Pet. Ex. 35.

Petitioner filed an affidavit on December 18, 2018, affirming his receipt of a flu vaccine at The Medical Center of Orting on October 6, 2017. Pet. Ex. 2 at 1. He affirmed that "[i]n the beginning of October 2017, I noticed a rash on the back of my legs so I made a doctor's appointment for October 6, 2017." *Id*. He received the subject flu vaccine at that visit.

Petitioner affirmed that a week later, on October 14, 2017, he was "dirt biking" and noticed that his hips felt "awkward." Pet Ex 2 at 1. He then traveled 350 miles by truck on October 16, 2017, to his property in eastern Washington to go hunting. After about 200 miles he stopped at a rest area and could hardly walk. *Id*. He thought the difficulty walking was caused by dirt biking, but the pain in his hips persisted, and by the end of the week, his shoulders began hurting, and he could not hold his arms above his head. *Id*. at 1-2. He decided to return home early.

Petitioner affirmed that from October 21-28, 2017, his back, knees, wrists, and top of his hips and shoulders were painful. He went to the emergency room at Good Samaritan Hospital. Pet Ex. 2 at 2. He was told he was "fine" and sent home after testing. *Id*.

Petitioner had been doing an annual "Halloween dirt bike poker run" since 2003, but was unable to attend on October 29, 2017, due to pain. Pet. Ex. 2 at 2. He then made an appointment with his PCP for November 6, 2017. *Id*. Blood work was performed at that visit. *Id*.

Petitioner affirmed that, the following week, the right side of his jaw began to hurt. Pet. Ex. 2 at 2. He went to the dentist on November 14, 2017, and was told nothing was wrong. *Id*. at 2. He went to the ER on November 19, 2017, and was again sent home finding nothing wrong. *Id*.

At his November 27, 2017, visit with his PCP, he was told that his blood work results showed c-reactive protein high at 50% when the norm was 3%. *Id*. at 2. He was referred to a rheumatologist, but it took a long time to get an appointment, and he was in "immense pain." *Id*. at 3. When he saw the rheumatologist, he reported that he went to the doctor for a rash and it all went "downhill from that point." *Id*. The rheumatologist believed he had "Polymyalgia Rheumatica Arthritis" based on his symptoms. *Id*. He was prescribed prednisone and was told that if his symptoms subsided within 24-48 hours it would be "for sure" PMR. *Id*. The symptoms subsided within 48 hours, and he could lift his arms over his head. *Id*. at 3.

Petitioner affirmed being "very angry" when he learned from researching PMR that "you can get it from the flu vaccine." Pet. Ex. 2 at 3. When petitioner put the dates together "[s]ure enough, one to two weeks after receiving the vaccination, my body started falling apart."[23] *Id*. Petitioner noted being a very active person. But after the vaccine, he was unable to do any of the physical activities he would normally do, including working out, skiing, dirt biking, hunting, fishing, or hiking. *Id*. Petitioner runs a plumbing company and had his son not helped him, he "would have lost everything." *Id*.

The worst part for petitioner was the depression from being unable to do things in life he enjoyed.[24] Pet. Ex. 2 at 3. He seriously considered ending his life in December 2017 when he did not know what was wrong with him. *Id*. at 4. He will no longer receive vaccines and believes the flu vaccine was the cause of his injuries. *Id*. at 4.

Petitioner filed a second affidavit on August 25, 2020, responding to the expert reports filed by respondent. Pet. Ex. 35. Petitioner updated his medical visits and affirmed that he presented to Dr. Arthur Brawer on January 15, 2020, for a "thorough consultation and examination." *Id*. at 2. Dr. Brawer later provided a report supporting the link between his flu vaccination and his PMR. *Id*.

Petitioner then detailed his issues with the reports authored by Drs. Oddis and Romberg, claiming their reports were inaccurate and misleading. Pet. Ex. 35 at 2-4. Further, petitioner cited to two other vaccine cases in which respondent's experts were involved and which he claimed were decided favorably for petitioners.[25] *Id*. at 2-3. Petitioner further took issue with portions of the experts' reports that included medical and other personal history that did not pertain to his diagnosis of PMR, and questioned why they did not offer an alternative cause for his PMR. *Id*. at 3-4.

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[23] It is unclear what research petitioner conducted as no internet search history was filed in this matter.

[24] Petitioner did not file any records indicating that he sought treatment for depression.

[25] Petitioner first cited to "Rodd v. SHHS, No. 13-122V," which is a claim involving polymyositis, Sjogren's syndrome, and inflammatory arthritis. *Rodd v. Sec'y of Health & Hum. Servs.*, No. 13-122V, 2015 WL 8489035 (Fed. Cl. Spec. Mstr. Nov. 13, 2015). The second case cited is "CHAD MCCLELLAN v, SHHS, No. 14-714V," a case involving a child with an SCN8A-related seizure disorder and the Prevnar vaccine, which resulted in a denial of entitlement. *L.M. v. Sec'y of Health & Hum. Servs.*, No. 14-714V, 2019 WL 4072130 (Fed. Cl. Spec. Mstr. July 23, 2019). Neither case involved a diagnosis of PMR.

D. Expert Reports

Petitioner submitted expert reports from Dr. Arthur Brawer and Dr. Omid Akbari. Pet. Ex. 10; Pet. Ex. 22; Pet. Ex. 36; Pet. Ex. 37; Pet. Ex. 51. Respondent submitted reports from Dr. Chester V. Oddis and Dr. Neil Romberg. Resp. Ex. A; Resp. Ex. F; Resp. Ex. R; Resp. Ex. Y; Resp. Ex. Z.

1. Petitioner's Expert Reports

a. Expert Reports of Dr. Arthur Brawer[26]

Dr. Brawer's initial report documented his office visit with petitioner, his review and criticisms of petitioner's medical records, the petition and the Rule 4(c) report. Pet. Ex. 10.

According to Dr. Brawer, the entire Orting medical record of petitioner's primary care provider from March 3, 2016, through November 27, 2017, was unreliable, lacked credibility, and "in all probability [was] reconstructed by the attending physician sometime after April 15, 2018." Pet. Ex. 10 at 1; Pet. Ex. 3. Dr. Brawer supports these conclusions by noting that the records listed petitioner as 50 years old on each date of service and had "multiple disjointed dates (both future and past) that have no credibility as to chronological documentation of various aspects of [petitioner's] medical conditions." Pet. Ex. 10 at 1; Pet. Ex. 3.

Dr. Brawer's summary of petitioner's medical history included a 51-year-old man with a five- or six-year history of hypertension managed by Lisinopril, a past history of heat and sweat rash when exerting himself in a hot environment, and successful surgery for a herniated disc in his lumbar spine about 20 years prior.[27] Pet. Ex. 10 at 1. Petitioner was active and engaged in a variety of physical activities. *Id*. He had both clinical and radiographic osteoarthritis in his cervical and lumbar spine, shoulders, and right hip which did not interfere with his physical activities prior to October 6, 2017.[28] *Id*. at 2. He did not take any supplements. Dr. Brawer wrote that petitioner had no history of disease or "family history of inflammatory systemic connective tissue diseases."[29] *Id*.

Dr. Brawer added that petitioner was in his usual state of health until October 6, 2017, when he received the flu vaccine. Seven to eight days later he had a spontaneous onset of pain and stiffness in both hips which became chronic. Three days thereafter he developed stiffness in both shoulders. Six days after that the pain was "very excruciating," with pain and stiffness in his wrists,

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[26] Dr. Arthur Brawer has a B.A. from Brandeis University and an M.D. from Boston University School of Medicine. He is currently the Director of Rheumatology and the Director of the Arthritis Clinic at Monmouth Medical Center. He is also an Assistant Clinical Professor of Medicine at Robert Wood Johnson Medical School and an Associate Clinical Professor of Medicine at Hahnemann/Drexel College of Medicine. He has served as both President and Vice-President of the New Jersey Rheumatology Association. He is board certified in rheumatology. He has been in the private practice of rheumatology since 1976. Pet. Ex. 11.

[27] No reference to petitioner's back surgery was contained in the records filed. It is unclear if Dr. Brawer had access to records not filed in this matter or was basing his history on what was reported to him by petitioner.

[28] This was not noted or referenced in any of the records that were filed in this matter.

[29] Petitioner reported that his father had arthritis during visits with his rheumatologist. *See* Pet. Ex. 5 at 8.

both knees, and the first MCP joints of both thumbs. Pet. Ex. 10 at 2. Stiffness was reported each morning for two to three hours. He presented to the ER on October 28, 2017. No diagnosis was rendered. He then developed temporomandibular joint pain and stiffness. He worsened and returned to the ER on November 19, 2017. *Id*.

Dr. Brawer also disagreed with the medical history documented in the ER on November 19, 2017. He claimed it was not taken by the evaluating physician and was "inherently contradictory, with one sentence reading 'two months ago he had pain after riding a motorcycle' and another sentence reading, 'he has had shoulder pain for a month.'" Pet. Ex. 10 at 2. He concluded that the medical history contained in the medical record for October 28, 2017, which included "systemic inflammatory condition" was more reliable. *Id*. at 3. He also had an issue with the x-rays taken at the November 19, 2017, ER visit of petitioner's shoulders, pelvis, and hips which revealed osteoarthritic changes, claiming that osteoarthritic changes take three to five years to develop and "have no relevance to the chronological sequence of events subsequent to October 6, 2017." *Id*. Blood tests revealed "systemic inflammation" prompting a rheumatology referral. *Id*.

Dr. Brawer also disagreed with the rheumatologist's medical record, claiming "it is obvious" the rheumatologist had the November 19, 2017, emergency room records, "because he makes the same mistake and misstatement of facts regarding the inflammatory disease onset, notably 'September 2017'" when the "precise date of [petitioner's] systemic inflammatory disorder is October 14, 2017." Pet. Ex. 10 at 3. He agreed, however, with the rheumatologist's diagnosis of PMR, and that following the prescription of prednisone there was immediate improvement. *Id*. Dr. Brawer claimed that petitioner's PMR waxed and waned over the next 12 months depending on the prednisone dosage. Petitioner was able to discontinue prednisone in January 2019 and was back to his usual state of health, with only ten minutes of morning stiffness and occasional persistent stiffness and mild discomfort in his hips, shoulders, and cervical spine which did not interfere with his activities. *Id*. According to Dr. Brawer, petitioner's residual complaints are comparable to the osteoarthritis that predated the flu vaccine. *Id*.

According to Dr. Brawer, the "confusion in this case" is a failure to appreciate the distinction between age-related osteoarthritis joint involvement and the systemic inflammatory process of PMR. Dr. Brawer claimed that this mistake is common with even experienced clinicians failing to appreciate this distinction. Pet. Ex. 10 at 4.

Dr. Brawer proffered several concepts by which PMR might be caused by flu vaccination. He began by asserting that molecular mimicry could causally connect the flu vaccine to PMR. Pet. Ex. 10 at 4-5. He asserts that it has been known for 30 years that antigens of infectious agents can cross react with self-antigens present on a variety of body cells, including immunocompetent cells, triggering systemic inflammatory reaction. *Id*. at 4. There are "numerous published reports of a variety of medical disorders treated by a variety of bacterial and viral vaccine materials."[30] Pet. Ex. 10 at 4. Dr. Brawer asserted that systemic lupus erythematosus, PMR, reactive arthritis, GBS, MS, hemolytic anemia, and thrombocytopenia purpura have been caused by vaccinations including influenza, tetanus toxoid, diphtheria, hep B, rubella, mumps, smallpox, typhoid, polio, and Gardasil. *Id*. at 4-5.

[30] Dr. Brawer's report does not contain any citations to literature, medical or otherwise, and therefore what he relied upon for any given assertion is unknown.

In addition to molecular mimicry, Dr. Brawer theorized that adverse effects on immunoregulatory cells by vaccines can alter the balance between helper and suppressor T cells. "Polyclonal B cell activation, a phenomenon routinely present in many inflammatory connective tissue diseases,[31] can also occur following vaccinations." Pet. Ex. 10 at 5. Adjuvants, modifications of surface antigens, induction of novel antigens, and exposure of sequestered antigens are also potential mechanisms of vaccine-induce autoimmune disease. As more research is conducted, "contributions of each of these mechanisms may well be unearthed." *Id*.

In his second report,[32] Dr. Brawer submitted that controversy exists regarding whether PMR is autoimmune in nature. Pet Ex. 22 at 1. He explained that anti-ferritin peptide antibodies have been described in PMR in conjunction with studies showing the presence of anti-phospholipid antibodies and anti-elastin antibodies in giant cell arteritis or GCA.[33] He agreed that the relationship between PMR and GCA is "only partially clarified" due to confusion stemming from pathologic evaluation of temporal artery biopsies in both PMR and GCA. Subsequently, not all scientists believe PMR is autoimmune. *Id*. at 1-2. The relevance of this, Dr. Brawer says, is contained in his first report where he detailed "'cross-reactive' medical mimicry theories." *Id*. at 2.

Dr. Brawer then asserted that some researchers believe PMR is autoinflammatory and arises from the activation of innate immunity cells. Pet. Ex. 22 at 2. Sodium, potassium, calcium, and other ions fluctuate in and out of cells through pores, or "channels," in cell membranes. Channelopathies are diseases caused by the disturbance of the function of ion channel components or their regulatory proteins. These diseases are either congenital or acquired. *Id*. Dr. Brawer noted that there was no evidence petitioner suffered from a genetic mutation that would cause a congenital channelopathy, but that where channel-regulating proteins are disrupted by vaccinations capable of creating multiple amplification loops of inflammatory dysregulation, PMR can occur. "[I]t has been reported that autoantibodies directed against sodium ion channels protein can precipitate repetitive and even life threatening cardiac arrhythmias." *Id*. at 2. Therefore, "[i]n the aggregate, the vaccination initiated theories producing [petitioner's] polymyalgia rheumatica are both rational and plausible." *Id*. at 2-3.

Dr. Brawer later responded to the opinions of respondent's expert, Dr. Romberg. Pet. Ex. 37. Dr. Brawer argued that the absence of large-scale epidemiologic studies is "neutral," neither supporting or disproving a causative link between the flu vaccine and PMR. *Id*. at 1. He referred to the "voluminous publications" he submitted in this matter, with another ten publications

[31] PMR is a syndrome characterized by "proximal joint and muscle pain." It is not an inflammatory disease of the connective tissue. *See Polymyalgia Arteritica*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=99324 (last visited Nov. 4, 2025).

[32] In a February 21, 2020, order, the Court stated that Dr. Brawer's first report made only generalized statements about molecular mimicry, the flu vaccine, and demyelinating diseases and failed to provide a mechanism explaining how the flu vaccine can cause PMR, in particular. ECF No. 27 at 2. The Court noted that, according to the medical literature, PMR has no known cause. *Id*. Because this report failed to address *Althen* prong one, the Court ordered petitioner to file a supplemental expert report from Dr. Brawer containing more than generalized statements explaining how the flu vaccine can cause PMR. *Id.*; *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

[33] Again, Dr. Brawer's second report contains no citations or references to literature of any kind.

accompanying this report, which he says are "directly supportive of, and adequately clarify and bolster, the theories put forth in my two prior reports." *Id*.

Dr. Brawer opined that, if not for the October 6, 2017, flu vaccine, petitioner "would not have developed" PMR eight days after vaccination. Pet. Ex. 10 at 4. "There is thus a logical sequence of cause and effect showing that the influenza vaccination" was the reason for petitioner's PMR. *Id*. Petitioner did not suffer from systemic inflammatory arthritis[34] before his flu vaccine and his PMR cannot be attributed to any "other well-defined clinical entity or infection that could have triggered" it. *Id*. Finally, there is "enough evidence in the medical records to document concordance of the correct chronological sequence of events" through the temporal relationship between the vaccination and PMR onset. *Id*.

b. Expert Report of Omid Akbari, Ph.D.[35]

Dr. Akbari issued one report. He questioned Dr. Romberg's qualifications to provide an opinion in this matter arguing that PMR is neither an allergic disease nor a disease of children. Pet. Ex. 51 at 1.

Dr. Akbari, who is not a medical doctor, then summarized petitioner's medical history concluding that petitioner had no neurological issues prior to his flu vaccination, developed PMR three weeks after receipt of a flu vaccine, responded to steroids with "some transient improvements," and then had a return of PMR-associated symptoms after the steroids were reduced. Pet. Ex. 51 at 3-4.

Dr. Akbari asserted that infections, whether bacterial or viral, are a well-recognized cause of autoimmune diseases, with molecular mimicry the commonly implicated mechanism that can initiate immunoreactivity and lead to autoimmune disease, acute demyelination, and neuroinflammation. Pet. Ex. 51 at 4. His research led to the conclusion that the theory of molecular mimicry supports how the flu vaccine could have caused the onset of petitioner's injury. *Id*.

Dr. Akbari described molecular mimicry as a mechanism by which the host and a microbe share an immunologic epitope by either sequence or conformational homology. Pet. Ex. 51 at 4; Pet. Ex. 55 at 80.[36] For example, it has been established that autoantibodies from patients with

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[34] A systemic issue is one which "pertain[s] to or affect[s] the body as a whole." *See Systemic*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=48656 (last visited Oct. 21, 2025). Inflammatory arthritis refers to the "inflammation of a joint." *See Arthritis*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4235 (last visited Oct.21, 2025). Thus, the term "systemic inflammatory arthritis" refers to body-wide joint inflammation. Petitioner was never diagnosed with "systemic inflammatory arthritis."

[35] Dr. Omid Akbari received his undergraduate degree and his M.S. in Medical and General Microbiology at University College London. He received his Ph.D. in Cellular and Molecular Immunology from the National Institute for Medical Research in London and was a postdoctoral fellow at Stanford University. He is currently a tenured Professor of Immunology in the Department of Molecular Microbiology and Immunology and the Department of Medicine at the Keck School of Medicine at the University of Southern California, Los Angeles, an Adjunct Professor of Immunology and Medicine at the Department of Immunology at Chiba University, and an Adjunct Professor of Pediatrics-Medicine at the David Geffen School of Medicine at the University of California-Los Angeles-Harbor.

[36] Robert S, Fujinami, et al., *Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease*, 19 Clinical Microbiology Reviews 80 (2006), filed as "Pet. Ex. 55."

rheumatic fever can cross react with cardiac myosin and induce autoimmune disease in mouse models. Pet. Ex. 51 at 5. The scientific understanding of molecular mimicry has evolved, and significant sequence-specific requirements are no longer thought necessary for autoimmunity to result. Further, "molecular mimicry is accepted as a theory to explain causation of autoimmune disease and showing the direct sequence homology or cross-reactive protein involved in the process, especially *in vivo*, is the exception." *Id*. at 5; Pet. Ex. 56 at 101;[37] Pet. Ex. 57 at 318.[38]

Dr. Akbari contends that commercially available vaccines were developed "without much comprehension regarding how the vaccine activates the immune system." Pet. Ex. 51 at 5; Pet. Ex. 58 at 16.[39] He explained that receipt of a vaccine causes a local inflammatory reaction mediated by cells of the innate immune system. Nonspecific innate immune pathways recruit other immune cells to the area of the injection through cytokines. Dendritic cells that process foreign antigens display a piece of the foreign antigen on their surface to activate the adaptive immune system. Pet. Ex. 51 at 5. Once activated, the dendritic cell migrates to the lymph nodes and interacts with B and T cells that recognize the antigen. B cells, a type of white blood cell, function in the humoral immunity part of the adaptive immune system to produce antibody molecules which can directly bind to a foreign antigen for later destruction and removal from the body. *Id*. Antigens are large and complex, so antibodies can only bind to small specific areas of them.

The immune system has evolved to allow for the production of many different antibodies by many different B-cell clones against the same foreign antigen. Pet. Ex. 51 at 5. While this response increases the probability of reacting against pathogens, it also increases the chance of developing an autoimmune disease from an adverse reaction of the immune system against native self-molecules. *Id*. at 5-6. T cells are helper cells, subsets of which, Th1 and Th2, develop into effector T cells to help eliminate different types of pathogens. Th1 cells have a pathogenic role in varieties of neuropathy including multiple sclerosis. *Id*. at 6; Pet. Ex. 59 at 398.[40]

T cells mature in the thymus and are also called CD4+ cells. Peripheral self-tolerance in CD4+ T cells is maintained by several mechanisms, most importantly suppression by regulatory T lymphocytes, or "Tregs," known for their active role in maintaining tolerance to self-antigens and combating autoimmune disease. Pet. Ex. 51 at 6. If the suppression function of Tregs in humans is altered, autoimmune diseases including MS and neuroinflammatory disorders occur. *Id*.; Pet. Ex. 60 at 215;[41] Pet. Ex. 63 at 387-89.[42] "The latest scientific evidence shows that the ability of Tregs to prevent disease progression is the result of inhibiting T helper cells and the ability of Treg cells to be able to migrate to areas of inflammation and control local pathogenic

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[37] Adam P. Kohm, et al., *Mimicking the Way to Autoimmunity: An Evolving Theory of Sequence and Structural Homology*, 11 Trends in Microbiology 101 (2003), filed as "Pet. Ex. 56."
[38] Marinos C. Dalakas, *Future Perspectives in Target-Specific Immunotherapies of Myasthenia Gravis*, 8 Therapeutic Advances in Neurological Disorders 316 (2015), filed as "Pet. Ex. 57."
[39] Claire-Anne Siegrist, *Vaccine Immunology*, *in* Plotkin's Vaccines 16, 16 (7th Ed. 2018), filed as "Pet. Ex. 58."
[40] Hania Kebir, et al., *Preferential Recruitment of Interferon-γ-Expressing T_H17 Cells in Multiple Sclerosis*, 66 Annals of Neurology 390 (2009), filed at "Pet. Ex. 59."
[41] Chi-Mou Juang, et al., *Regulatory T Cells: Potential Target in Anticancer Immunotherapy*, 46 Taiwanese J. of Obstetrics and Gynecology 215 (2007), filed as "Pet. Ex. 60."
[42] Alla L. Zozulya & Heinz Wiendl, *The Role of Regulatory T Cells in Multiple Sclerosis*, 4 Nature Clinical Practice Neurology 384 (2008), filed as "Pet. Ex. 63."

cells." Pet. Ex. 51 at 7. This explains why some autoimmune diseases are acute and some chronic. *Id*.; Pet. Ex. 64 at 1.[43]

Ultimately, the immune system's ability to recognize and eliminate foreign antigens, induce immunologic memory, and develop tolerance to self-antigens results in effective homeostasis. Disruption on the other hand makes the host susceptible to autoimmunity. In both neuromyelitis and demyelination, that balance is disrupted leaving the host susceptible to an adverse autoimmune reaction upon stimulation of the immune system from infection or vaccination. Pet. Ex. 51 at 7. According to Dr. Akbari, the foregoing shows that vaccine-induced autoimmune disease pathogenesis or exacerbation, while rare, is most likely due to the failure of stringent regulatory mechanisms rather than the potential for cross reaction by immune cells. *Id*. at 9.

Dr. Akbari then described PMR as an elderly onset syndrome characterized by aching and stiffness in the shoulders and pelvic girdle with a rapid response to steroids. Pet. Ex. 51 at 9; Pet. Ex. 72 at 1700.[44] *McGonagle* explained that immune-mediated diseases are either predominantly autoinflammatory, autoimmune, or mixed based on the contribution from the innate and adaptive immune responses. *Id*.; Pet. Ex. 74 at 4.[45] Autoinflammatory diseases involve tissue inflammation due mostly to aberrant innate immune activation. Autoimmune diseases involve abnormal activation of the adaptive immune system. Pet. Ex. 51 at 9. It is currently believed that a continuum between the two leads to rare diseases of each on opposite ends of the spectrum. PMR is in the middle. *Id*. Laboratory findings in PMR lean toward innate system involvement, but some adaptive immune cells have been reported. *Id*. The highest level of IL-6 and tumor necrosis factor, or TNF-α, is found in PMR patients. *Id*.

Dysregulation of the Th1 response leads to tissue destruction and autoimmune disease. Pet. Ex. 51 at 10. Th2 dysregulation is driven by different cytokines and is more associated with allergy and asthma. *Id*. at 10. Influenza A vaccination is strongly inhibited by TNF-α. Individuals on immunosuppression or biological therapy are at increased risk from influenza A infection. *Id*.;[46] Pet. Ex. 80 at 62;[47] Pet. Ex. 81 at 23.[48]

Dr. Akbari contended that "[m]any studies, including a report by Soriano et al., reported 10 healthy individuals that received flu vaccine and developed PMR within 3 months after vaccination." Pet. Ex. 51 at 12; Pet. Ex. 90.[49] *Liozon* showed 12 individuals who reported PMR following flu vaccine. *Id*. Both studies show that activation of inflammasomes by the flu vaccine

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[43] Simon Glatigny, et al., *Integrin Alpha L Controls the Homing of Regulatory T Cells During CNS Autoimmunity in the Absence of Integrin Alpha 4*, 5 Nature Scientific Reports 1 (2015), filed as "Pet. Ex. 64."
[44] Miguel A. González-Gay, et al., *Polymyalgia Rheumatica*, 390 Lancet 1700 (2017), filed as "Pet. Ex. 72."
[45] Dennis McGonagle & Michael F. McDermott, *A Proposed Classification of the Immunological Diseases*, 3 PLoS Medicine 1242 (2006), filed as "Pet. Ex. 74."
[46] Dr. Akbari included a discussion of adjuvants and their role in inflammasome activation. Pet. Ex. 51 at 11-12. However, since the flu vaccine received by petitioner did not contain an adjuvant, this portion of his opinion will not be included.
[47] J.F. Rahier, et al., *European Evidence-Based Consensus on the Prevention, Diagnosis and Management of Opportunistic Infections in Inflammatory Bowel Disease*, 3 J. of Crohn's and Colitis 47 (2009), filed as "Pet. Ex. 80."
[48] Anthony E. Fiore, *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 Morbidity and Mortality Weekly Report 1 (2007), filed as "Pet. Ex. 81."
[49] Soriano, et al., *supra* note 5.

was to blame for the induction of immune cells that caused PMR. *Id*; Pet. Ex. 91.[50] *Falsetti* studied 58 PMR patients and noted that 15 (26%) cases were in connection to environmental agents: six reported vaccinations; four reported respiratory tract infection; and five reported seasonal flu vaccine before onset. *Id*.; Pet. Ex. 92 at 76.[51] The authors concluded that a correlation between environmental triggers in PMR and higher CRP at diagnosis, faster response to therapy, and milder shoulder synovitis suggested a more specific subtype of PMR, in which external stimuli, such as vaccination or infection, may lead to a deregulated response within the context of an impaired "senescent immuno-endocrine system." Pet. Ex. 51 at 12-13.

Dr. Akbari claimed that PMR is immune mediated, with studies showing that genetic factors are a major influence. Pet. Ex. 51 at 13. Specific human leukocyte antigen ("HLA") alleles are the strongest genetic factor, although their role in PMR's pathogenesis is unknown. It remains elusive how genetic traits cooperate with both the innate and adaptive immune mechanisms to drive disease pathology. *Id*. Dr. Akbari added that these genetic predispositions are not widespread which is why reactions to vaccines are so rare. *Id*. at 14.

Dr. Akbari concluded that "to a high degree of certainty, and by a preponderance of scientific evidence," if not for the flu vaccine, petitioner would not have developed PMR. Pet. Ex. 51 at 14. Molecular mimicry and induction of inflammasomes are the mechanisms by which an immune-stimulated response to the flu vaccine can result in PMR in a susceptible person. *Id*. The timing between vaccination and onset of PMR is consistent with what is known about PMR resulting from vaccination. *Id*.

2. Respondent's Expert Reports

a. Expert Reports of Dr. Chester Oddis[52]

Dr. Oddis summarized petitioner's medical history and Dr. Brawer's examination, findings, and conclusions. Resp. Ex. A at 2-4.

Dr. Oddis described PMR as an inflammatory disorder characterized by morning stiffness of the shoulders and hip girdle occurring almost exclusively in those over 50 with peak incidence between 70 and 80. Resp. Ex. A at 4; Resp. Ex. C at 1.[53] There is no known cause of PMR. PMR is not "uniformly considered" to be autoimmune in nature because there are no characteristic autoantibodies identified like there are in other autoimmune diseases such as rheumatoid arthritis,

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[50] Eric Liozon, et al., *Giant Cell Arteritis or Polymyalgia Rheumatica After Influenza Vaccination: A Study of 12 Patients and a Literature Review*, 20 Autoimmunity Reviews 1 (2020), filed as "Pet Ex. 91."

[51] Paolo Falsetti, et al., *Polymyalgia Rheumatica Following Infective Triggers or Vaccinations: A Different Subset of Disease?*, 58 Reumatologia 76 (2020), filed as "Pet. Ex. 92."

[52] Dr. Chester Oddis received his undergraduate degree in biochemistry from the University of Pittsburgh and his M.D. from Pennsylvania State University. He completed his residency in internal medicine at Pennsylvania State University and a fellowship in rheumatology at the University of Pittsburgh. He currently serves as the Director of the Myositis Center at the University of Pittsburgh and is a Professor of Medicine in the Division of Rheumatology and Clinical Immunology at that same university. He is specialty certified by the American Board of Internal Medicine and the American Board of Rheumatology.

[53] William P. Docken, *Clinical Manifestations and Diagnosis of Polymyalgia Rheumatica*, UpToDate (2019), filed as "Resp. Ex. C."

lupus, myositis, scleroderma, and vasculitis. Resp. Ex. A at 4; Resp. Ex. D at 1-2.[54] Evidence of a viral cause has proven inconclusive. Elevated inflammatory markers ESR and CRP are typical in PMR cases. PMR patients typically display a rapid response to glucocorticoids. Resp. Ex. A at 4.

Dr. Oddis agreed that PMR was the correct diagnosis. Resp. Ex. A at 4. He disagreed that PMR can be caused by the flu vaccine, adding that the flu vaccine is recommended for PMR patients, and he knows of no flares of PMR following flu vaccination in patients with established PMR. *Id*.

According to Dr. Oddis, petitioner suffered a mild case of PMR with minimal return of stiffness after completing prednisone with no subsequent elevation of inflammatory markers. Resp. Ex. A at 5; Pet. Ex. 5 at 12. Petitioner resumed his pre-vaccination activities, experienced no adverse sequela, and stopped taking prednisone. Resp. Ex. A at 5.

Dr. Oddis did not raise issue with Dr. Brawer's explanation of molecular mimicry but disagreed that it applied in this case because PMR is not an autoimmune disease, noting that Dr. Brawer acknowledged "controversy" as to whether PMR has autoimmune features in his second report. Resp. Ex. A at 5 (citing Pet. Ex. 22 at 1). Dr. Oddis added that it was unclear whether Dr. Brawer was opining that PMR was autoimmune or autoinflammatory based on his first two reports. *Id*. It was also unclear what channelopathies creating an amplification loop of inflammatory dysregulation had to do with this case, or with PMR generally. In any event, Dr. Oddis found this discussion wholly speculative. *Id*. at 5. Finally, the literature submitted by Dr. Brawer did not support a pathogenesis for flu vaccine leading to a rheumatic syndrome. *Id*. In summary, Dr. Oddis asserted that, in failing to distinguish whether PMR was autoimmune or autoinflammatory, Dr. Brawer ultimately failed to put forth a cognizable theory or mechanism of causation in this case. *Id*. at 6.

Dr. Oddis added that vaccinations and PMR are common in the elderly. If there was a known association between the two, the medical literature would recognize it, and medical practitioners would be hesitant to administer flu vaccines to those with known PMR. This is not the case. Resp. Ex. A at 6.

Dr. Oddis[55] addressed Dr. Akbari's[56] opinion that the *Soriano* and *Liozon* papers showed a link between flu vaccination and PMR, noting that Dr. Akbari failed to acknowledge that a majority of the individuals in the studies had either GCA or GCA/PMR and that the authors specifically stated that "post-influenza vaccine PMR generally appeared self-limited." Pet. Ex. Z at 3. Petitioner did not have GCA. *Id*. at 3-4; Pet. Ex. 18;[57] Pet. Ex. 91.[58]

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[54] Alberto Floris, et al., *Polymyalgia Rheumatica: An Autoinflammatory Disorder?*, 4 Rheumatic & Musculoskeletal Diseases Open 1 (2018), filed as "Resp. Ex. D" and "Pet. Ex. 23."

[55] Dr. Oddis also responded to petitioner's supplemental affidavit criticizing his first report. While noted, petitioner's criticisms of Dr. Oddis's report and Dr. Oddis's responses thereto have no bearing on the issues in this case. Resp. Ex. Z at 1-3; Pet. Ex. 35.

[56] Dr. Oddis also questioned whether Dr. Akbari's PhD in immunology, absent any clinical expertise, qualified him to comment on petitioner's medical history. Resp. Ex. Z at 4.

[57] Soriano, et al., *supra*, note 5.

[58] Liozon, et al., *supra*, note 50.

In Dr. Oddis's opinion, based on 39 years of experience and management of approximately 20 outpatients with PMR monthly, the flu vaccine was not the trigger of petitioner's PMR. Resp. Ex. A at 6.

b. Expert Reports of Dr. Neil Romberg[59]

i. Dr. Romberg's First Report

Dr. Romberg summarized petitioner's medical history, and included that, at petitioner's October 10, 2016, visit at Orting, petitioner followed up on chronic right-side neck and shoulder pain affecting his bicep strength, issues which predated his vaccination. Resp. Ex. F at 3; Pet. Ex. 3 at 8.

Dr. Romberg addressed Dr. Brawer's claim that the medical records were inconsistent because the record documented petitioner as 50 years old rather than 49 and noted onset of symptoms as early as October 10, 2016, making the records unreliable. Dr. Romberg explained the possibility that the computer software updated petitioner's age and problem list on the day the records were printed. He suggested that petitioner submit a certified record of all the visits he received at Orting.[60] Resp. Ex. F at 5.

Dr. Romberg agreed that petitioner's symptoms and lab work were consistent with PMR but the causes of PMR are unknown. Resp. Ex. F at 5.

According to Dr. Romberg, Dr. Brawer did not present a singular theory but rather a lengthy list of potential contributing mechanisms in his initial report. Resp. Ex. F at 6. In his second report Dr. Brawer discussed channelopathies and mitochondrial dysfunction. *Id*. Dr. Brawer submitted 18 references with his two reports, but did not cite to any of them making it difficult to ascertain how the literature or the medical records supported his causation theories. *Id*. Further, most of the references were case reports, case series, or basic science articles that only "tangentially relate[d] to" petitioner's case. *Id*.

According to Dr. Romberg, the theory of molecular mimicry is mostly unproven and unprovable in human diseases. Resp. Ex. F at 7; Resp. Ex. K at 797, 800;[61] Resp. Ex. L at 2073.[62] "Given this, leaders in the field of adaptive immunity have suggested criteria that should be met

[59] Dr. Neil Romberg received his undergraduate degree in botany from the University of Michigan and his M.D. from Pennsylvania State University. He completed his residency as Pediatric Chief Resident at New York University and completed a fellowship in Allergy and Clinical Immunology at Yale University. He is currently an Attending Physician in Immunology at the Children's Hospital of Philadelphia, an Assistant Professor of Pediatrics at the University of Pennsylvania School of Medicine, and the Jeffrey Modell Chair of Pediatric Immunology Research at the Children's Hospital of Philadelphia. He is board certified in pediatrics and allergy and immunology and is licensed in New York, Connecticut, and Pennsylvania.

[60] Petitioner ultimately did not file such a record.

[61] Christophe Benoist & Diane Mathis, *Autoimmunity Provoked by Infection: How Good Is the Case for T Cell Epitope Mimicry?*, 2 Nature Immunology 797 (2001), filed as "Resp. Ex. K."

[62] Lori J. Albert & Robert D. Inman, *Molecular Mimicry and Autoimmunity*, 341 New Eng. J. of Med. 2068 (1999), filed as "Resp. Ex. L."

before even considering molecular mimicry as a potential contributor to an autoimmune disease." *Id*.; Resp. Ex. K at 797-98;[63] Resp. Ex. M.[64] Dr. Romberg addressed each in turn.

The first criterion requires the "establishment of an epidemiologic association between the vaccine antigen and the immune-mediated disease." Resp. Ex. F at 7. Dr. Romberg submitted that Dr. Brawer relied on case reports and case series collected over a 39-year period from America, Spain, and Italy to establish an epidemiologic association between flu vaccine and PMR. Resp. Ex. F at 7; Pet. Ex. 12;[65] Pet. Ex. 13;[66] Pet. Ex. 14;[67] Pet. Ex. 16.[68] The onset in these cases ranged from one day to three months. Resp. Ex. F at 7. The case reports were epidemiologically weak as they did not compare uniformly exposed human subjects with unexposed controls, involved different types of flu vaccines from different continents, and were exposed to almost 40 years of confounding variables. *Id*.

Dr. Romberg added that PMR, like flu vaccination, is common. PMR has an incidence of 63.9 cases per 100,000 each year. Resp. Ex. F. at 8; Resp. Ex. N at 1.[69] Extrapolating the data, Dr. Romberg determined approximately 204,480 Americans over the age of 50 were diagnosed with PMR in 2015. 43.6% of Americans between the ages of 50 and 64, and 63.4% over 65, received the flu vaccine. Resp. Ex. F. at 8; Resp. Ex. Q at 5.[70] "If flu vaccination and PMR development are independent events, we would expect 43.6%-63.4% of American PMR patients (89,153-129,640 people per year) to receive a flu vaccine within twelve months of their PMR diagnosis," with a quarter of new PMR diagnoses to have occurred within three months of vaccination. Resp. Ex. F at 8. Dr. Brawer's filings show only three domestic cases between 2000 and 2017. An explanation could be that PMR and flu vaccine are common events that coincidentally co-occur independently of one another. "Either way, there is zero epidemiologic evidence to support Dr. Brawer's theory of injury by vaccine via a molecular mimicry mechanism." Resp. Ex. F at 8 (emphasis removed).

The second criterion requires "[i]dentification of autoreactive T cells or autoantibodies that recognize a human structure (target antigen) that if perturbed could explain symptomology." Resp. Ex. F at 9. Therefore, for the theory of molecular mimicry to be implicated, autoantibodies or an autoreactive T cell clone must be identified in potentially affected patients. *Id*. Dr. Brawer's literature showed no diagnostic or pathogenic autoantibody known for PMR. *Id*.; Pet. Ex. 23 at 3.[71] Further, while anti-mitochondrial, anti-ferritin, and anti-intermediate filament antibodies may

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[63] Benoist & Mathis, *supra*, note 61.
[64] C. Wim Ang, et al., *The Guillain-Barré Syndrome: A True Case of Molecular Mimicry*, 25 Trends in Immunology 61 (2004), filed as "Resp. Ex. M."
[65] Salehi, et al., *supra*, note 3.
[66] Liozon, et al., *supra*, note 4.
[67] Carlos Perez & Elias Maravi, *Polymyalgia Rheumatica Following Influenza Vaccination*, 23 Muscle & Nerve 824 (2000), filed as "Pet. Ex. 14."
[68] Juan Marti & Enrique Anton, *Polymyalgia Rheumatica Complicating Influenza Vaccination*, 52 J. of the Am. Geriatrics Soc'y 1412 (2004), filed as "Pet. Ex. 16."
[69] Shafay Raheel, et al., *Epidemiology of Polymyalgia Rheumatica 2000-2014 and Examination of Incidence and Survival Trends Over 45 Years: A Population Based Study*, 69 Arthritis Care & Res. 1282 (2017), filed as "Resp. Ex. N."
[70] Flu Vaccination Coverage: United States, 2015-16 Influenza Season, Centers for Disease Control and Prevention (Sept. 29, 2016), http://www.cdc.gov/flu/fluvaxview/coverage-1516estimates.htm.
[71] Floris, et al, *supra*, note 54.

occur in some PMR patients, the finding is disease associated not disease causing. Resp. Ex. F at 9; Pet. Ex. 23;[72] Pet. Ex. 24;[73] Pet. Ex. 26;[74] Pet. Ex. 27.[75] In this case, no autoantibodies were found in petitioner's serum. *Id*.

Additionally, Dr. Romberg submitted that PMR is not an autoantibody-mediated disease. The therapies often used to treat autoantibody-mediated diseases, such as plasmapheresis to remove autoantibodies, B-cell depletion with rituximab, and plasma-cell proteasome modulation with bortezomib, are not recommended by the European League Against Rheumatism or the American College of Rheumatology to treat PMR. Resp. Ex. F at 9; Resp. Ex. P.[76] Mainstream treatment for PMR recommends immunosuppression with glucocorticoids with or without methotrexate. Resp. Ex. F at 9. Dr. Brawer provided no support for the role of autoantibodies in PMR.[77] *Id*. at 10. Dr. Romberg concluded that Dr. Brawer provided no evidence that autoantibodies play a role in PMR in general or in petitioner's case. Therefore, his opinion that molecular mimicry caused petitioner's PMR remains unfounded in the literature and in petitioner's medical records. *Id*.

The third criterion requires "[i]dentification of a vaccine antigen that is molecularly similar to the target antigen." Pet. Ex. F at 10. Dr. Romberg submitted that the 2017-18 flu vaccine contained four antigens, two from flu A strains and two from flu B strains. Dr. Brawer failed to identify which of the four antigens was suspected of generating an autoantibody or autoreactive T cell receptor that also binds to a self-protein. *Id*. Without this, he has not presented a clear theory of causation in this case. *Id*.

The fourth criterion requires "[r]eproduction of the disease in an animal model." Dr. Romberg posited that there are none. Resp. Ex. F at 11.

According to Dr. Romberg, Dr. Brawer failed to provide any evidence supporting any of the four criteria required for molecular mimicry to be considered a potential mechanism linking the flu vaccine to a PMR-related antigen. Further, there is little evidence to support PMR being an autoimmune disease and less to suggest that it should be managed as one. Additionally, Dr. Romberg notes that much of the literature filed by Dr. Brawer is wholly inapposite to this case,

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[72] *Id.*

[73] M.A. Sattar, et al., *Polymyalgia Rheumatica and Antimitochondrial Antibodies*, 43 Annals of the Rheumatic Diseases 264 (1984), filed as "Pet. Ex. 24."

[74] N.T. Baerlecken, et al., *Association of Ferritin Autoantibodies with Giant Cell Arteritis/Polymyalgia Rheumatica*, 71 Annals of the Rheumatic Diseases 943 (2012), filed as "Pet. Ex. 26."

[75] I. Monteagudo, *Antibodies to Intermediate Filaments in Polymyalgia Rheumatica/Giant Cell Arteritis: Do They Reflect the Underlying Disease Activity Rather Than the Acute Phase Response?*, 53 Annals of the Rheumatic Diseases 150 (1994), filed as "Pet. Ex. 27."

[76] Christian Dejaco, et al., *2015 Recommendations for the Management of Polymyalgia Rheumatica*, 67 Arthritis & Rheumatology 2569 (2015), filed as "Resp. Ex. P."

[77] Dr. Brawer submitted a study for which he was the sole author, in which 70 PMR patients were treated with hydroxychloroquine and/or NSAIDs, but not the recommended glucocorticoids. These treatments do not target autoantibodies or B cells. Dr. Romberg had many criticisms of the study, including that standard treatment was not followed and indeed withheld from PMR patients. Resp. Ex. F at 9-10. Resp. Ex. P; *see* Arthur E. Brawer, *Polymyalgia Rheumatica: Observations of Disease Evolution Without Corticosteroid Treatment*, 8 Open Access Rheumatology: Res. and Revs. 45 (2016), filed as "Pet. Ex. 21."

either because the subjects of the literature had a different malady than petitioner or because the subjects received a different or no vaccine preceding their PMR. Resp. Ex. F at 11-12.

ii. Dr. Romberg's Second Report.

In his supplemental report, Dr. Romberg responded to the literature filed with Dr. Brawer's August 11, 2020, report. Resp. Ex. R at 1; Pet. Ex. 37; Pet. Exs. 38-44.

Dr. Romberg described the hierarchy and reliability of medical studies with case reports and case series being the lowest of evidential value. Resp. Ex. R at 2-3; Resp. Ex. S.[78] Dr. Brawer relied on case studies and case series to suggest that the seasonal flu vaccine can cause PMR. Resp. Ex. R at 2-3. Dr. Romberg provided *Demicheli*, issued by the Cochrane Library, which conducts systematic reviews and is the gold standard for meta-analysis. *Demicheli* selected 52 trials and compared the safety and efficacy of the seasonal flu vaccine with a placebo or no vaccination in over 80,000 healthy individuals aged 16 to 65. Resp. Ex. R at 3; Resp. Ex. T.[79] The meta-analysis found no evidence connecting the seasonal flu vaccine to serious adverse events, including neurologic, hematologic, or rheumatologic disorders. Resp. Ex. R at 3.

Dr. Romberg added that although Dr. Brawer included additional literature with his second report, he opted to disregard the medicine contained therein in favor of relying on his own personal clinical instincts and experiences to make patient care decisions. This practice has historically proven harmful. Resp. Ex. R at 4-5. Dr. Brawer also included literature discussing the practice of excluding overly complex patients with pre-existing conditions from randomized control trials, which has no bearing on this case since petitioner was not a complex patient. Resp. Ex. R at 4; Pet. Exs. 38-44. Petitioner's medical records and demographics fit within *Demicheli*'s healthy individuals between the ages of 16-65 for the meta-analysis. Resp. Ex. R at 4.

Dr. Romberg concluded that Dr. Brawer's theory of injury lacks supporting evidence or a basis in science maintaining his opinion that petitioner's flu vaccine was not the cause of his PMR. Resp. Ex. R at 7.

iii. Dr. Romberg's Third Report

In his third report, Dr. Romberg responded to Dr. Akbari's opinions.[80] Resp. Ex. Y.

Dr. Romberg noted that Dr. Akbari rejected Dr. Brawer's claim that petitioner's PMR was caused by antigen-specific molecular mimicry but chose instead to describe PMR broadly as an autoinflammatory disease associated with elevated inflammatory cytokines. Resp. Ex. Y at 4. However, the cause of PMR is currently unknown and its pathogenesis poorly understood. *Id.*; Resp. Ex. AA at 2.[81]

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[78] M. Hassan Murad, et al., *New Evidence Pyramid*, 21 Evidence Based Med. 125 (2016), filed as "Resp. Ex. S."

[79] V. Demicheli, et al., *Vaccines for Preventing Influenza in Healthy Adults (Review)*, 2 Cochrane Database of Systematic Revs. 1 (2018), filed as "Resp. Ex. T."

[80] He also responded to Dr. Akbari's accusations that he was not qualified to render opinions in this matter detailing his professional history, clinical practice, and specialties. Resp. Ex. Y at 1-3.

[81] Carlo Salvarani & Francesco Muratore, *Clinical Manifestations and Diagnosis of Polymyalgia Rheumatica*, UpToDate (2021), filed as "Resp. Ex. AA."

Dr. Romberg agreed that patients with PMR often demonstrate high circulating Th17 cell frequencies and elevated IL-6 concentration in serum but "if and how these immune perturbations relate to myopathy remains uncertain." Resp. Ex. Y at 4; Resp. Ex. BB.[82] "Unlike other autoimmune/autoinflammatory diseases that directly cause end-organ damage, muscular tissues in PMR patients are by definition histopathologically normal." Resp. Ex. Y at 4; Resp. Ex. AA.[83] Further, while genetic factors including HLA alleles have been associated with PMR, no robust disease-specific autoantigen has been identified. Resp. Ex. Y at 4.

Addressing the relevance of Dr. Akbari's discussion of NLRP3 inflammasomes leading to IL-1 production, Dr. Romberg pointed out that the flu vaccine received by petitioner in 2017 did not contain the NLRP3 ligand alum; it was either unadjuvanted or less likely Squalene adjuvanted, which is NLRP3 inflammasome independent. Resp. Ex. Y at 5. Even if the vaccine had contained an alum adjuvant, petitioner did not describe a large local reaction at the injection site or fever in the hours or days post-vaccination, suggesting no excessive IL1-B production. *Id*.; Resp. Ex. CC at 2.[84]

Dr. Romberg disagreed with Dr. Akbari that it is clear the flu vaccine can cause PMR in some individuals. Dr. Romberg discussed each study, submitting first that *Soriano* involved 10 vaccinated Italian geriatric patients presenting over six years who suffered from GCA, PMR, or both with onset between one week and three months. Resp. Ex. Y at 6; Pet. Ex. 18.[85] The authors provided no controls or statistical analysis but concluded that data supported the possibility that the flu vaccine triggered GCA/PMR and speculated that the "pseudo-scientific autoimmune/inflammatory syndrome induced by adjuvants (ASIA) theory was mechanistically responsible." Resp. Ex. Y at 6. The lead author in *Soriano* would go on to publish with Yehuda Shoenfeld, whose ASIA theory was thoroughly debunked.

Dr. Romberg continued that *Liozon* was a French study which identified 10 geriatric patients out of 358 over 20 years who developed GCA after the flu vaccine with onset ranging from 8 to 145 days. Resp. Ex. Y at 6; Pet. Ex. 91.[86] Two patients in an unspecified sized cohort group developed PMR. No controls or statistical analysis were included, but the conclusion was that the flu vaccine triggered GCA via an ASIA mechanism. The authors concluded that "'unlike PMR, GCA can be a serious complication of IV' (influenza vaccine)." Resp. Ex. Y at 6 (quoting Pet. Ex. 91[87] (emphasis removed)). No statistical evidence was provided to support causal relationships between flu vaccine and GCA or PMR. Resp. Ex. Y at 6-7.

Finally, Dr. Romberg discussed *Falsetti*, an "unblinded, uncontrolled study" of 15 new-onset PMR cases in Italy, which were self-reported. Resp. Ex. Y at 7; Pet. Ex. 92.[88] The enrollment

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[82] Christian Dejaco, et al., *Giant Cell Arteritis and Polymyalgia Rheumatica: Current Challenges and Opportunities*, 13 Nature Revs. Rheumatology 578 (2017), filed as "Resp. Ex. BB."
[83] Salvarani & Muratore, *supra*, note 81.
[84] Vaccine Excipient Summary: Excipients Included in U.S. Vaccines, By Vaccine, Food & Drug Administration (Feb 2020), http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.
[85] Soriano, et al., *supra*, note 5.
[86] Liozon, et al., *supra*, note 50.
[87] *Id*.
[88] Falsetti, et al., *supra*, note 51.

was retrospective by chart review rather than validated survey instrument. Resp. Ex. Y at 7. Of the 15 cases of PMR reported, four received an unspecified type flu vaccine, two received a tetanus vaccine, five had flu infections, and four had non-flu respiratory infections including pneumonia. *Id*. at 8. Those with reported triggers had a higher CRP inflammatory marker that took longer to normalize than those without triggers. *Id*. "CRP is well known to rise during infections, including influenza, and to slowly downtrend after." *Id*.; Resp. Ex. GG.[89] The authors did not separate out the highest CRP values or the interval between infections and first elevated CRP. Resp. Ex. Y at 8. The CRP values for those receiving the flu and tetanus vaccinations were not listed. *Id*.

Dr. Romberg ultimately opined that Dr. Akbari undermined Dr. Brawer's theory of molecular mimicry as the mechanism by which the flu vaccine caused petitioner's PMR. Resp. Ex. Y at 9. Dr. Romberg maintained that there is no factual or scientific basis for a claim of injury by vaccine in this case. *Id*.

IV. Standard for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. § 13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before they may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted) (cleaned up). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. *See Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); *see also Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357 (Fed. Cir. 2000); *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

A. Legal Standard

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii); *see also Wright v. Sec'y of Health & Hum. Servs*., 22 F.4th 999, 1006 (Fed. Cir. 2022) (defining the term "residual effects" in the Act, as "detrimental conditions within the patient, such as lingering or recurring signs and symptoms" of the alleged vaccine injury, which

[89] Hasse Melbye, et al., *The Course of C-Reactive Protein Response in Untreated Upper Respiratory Tract Infection*, 54 British J. of Gen. Prac. 653 (2004), filed as "Resp. Ex. GG."

are compensable). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Hum. Servs*., 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioners are not required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Hum. Servs*., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Hum. Servs*., 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes"). Once a petitioner has proven causation by preponderant evidence, "the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs*., 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing § 13(a)(1)(B)).

To prove causation, a petitioner must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that a petitioner show by preponderant evidence that a vaccination they received caused their injury "by providing: (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." *Id*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Hum. Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each *Althen* prong requires a different showing. Under the first prong, a petitioner 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 (citation omitted). To satisfy this prong, a petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id*. at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde*, 746 F.3d at 1341.

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, a petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Hum. Servs*., 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or

scientific explanation must support this logical sequence of cause and effect," *id*. at 961 (citation omitted), and "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," *Paluck v. Sec'y of Health & Hum. Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

The third *Althen* prong requires that a petitioner establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id*. However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id*.; *see also Locane v. Sec'y of Health & Hum. Servs*., 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Finally, although this decision discusses some but not all the literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

B. Law Regarding Diagnosis

In *Broekelschen v. Sec'y of Health and Human Servs.,* 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test." This principle also means that a petitioner must establish that the vaccinee suffers the injury allegedly linked to the vaccination. *Lombardi v. Sec'y of Health & Hum. Servs.,* 656 F.3d 1343, 1353-54 (Fed. Cir. 2011).

V. Discussion

As a preliminary matter, there is no dispute that petitioner suffered from PMR based on clinical presentation, elevated inflammatory markers, and response to prednisone.

Because petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, for petitioner to prevail on an "off-Table" claim, he must show by preponderant evidence that his claimed injury resulted from the vaccination at issue.

Capizzano, 440 F.3d at 1320. Doing so shifts the burden to respondent to show that the injury was caused by factors unrelated to the vaccination. *Deribeaux*, 717 F.3d at 1367.

Presenting a sound and reliable theory is essential to petitioner's case. A theory causally connecting the vaccine to the injury is the first *Althen* prong. When petitioner fails to establish this element, compensation is denied. *See Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1360-62 (Fed. Cir. 2019). Moreover, the theory advanced for *Althen* prong one influences the remaining two *Althen* prongs. For the second *Althen* prong, which addresses whether a logical sequence connects the vaccine to the injury, special masters may consider whether the vaccinee responded in a way consistent with the theory being offered. *Hibbard v. Sec'y of Health & Hum. Servs*., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012); *Miller v. Sec'y of Health & Hum. Servs.*, 172 Fed. Cl. 762, 784 (2024) (finding special master did not err in denying entitlement when petitioner did not establish that she had immune complexes after asserting a theory involving immune complexes); *Dodd v. Sec'y of Health & Hum. Servs*., 114 Fed. Cl. 43, 52-57 (2013); *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 205 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). Similarly, the third *Althen* prong, which concerns timing, depends at least in part upon the theory being offered. *Langland v. Sec'y of Health & Hum. Servs*., 109 Fed. Cl. 421, 443 (2013); *see also Koehn v. Sec'y of Health & Hum. Servs*., 773 F.3d 1239, 1244-45 (Fed. Cir. 2014) (holding that special master was not arbitrary in finding an onset of injury seven months after vaccination incompatible with a theory based upon cytokines). Without a defined theory, attempting to determine whether preponderant evidence supports the logical sequence or timing is difficult if not impossible.

A. *Althen* Prong One: Petitioner Has Not Provided a Sound and Reliable Medical Theory

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). This standard was clarified by the Federal Circuit. *See Boatmon*, 941 F.3d at 1359-60 (stating that the correct standard for *Althen* prong one is "reputable," and "sound and reliable" not a "lower reasonable standard" (internal quotations omitted)). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. *See Depena v. Sec'y of Health & Hum. Servs.*, No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), *mot. for rev. denied*, 133 Fed. Cl. 535, 547-48 (2017), *aff'd without op.,* 730 Fed. App'x 938 (Fed. Cir. 2018); *Copenhaver v. Sec'y of Health & Hum. Servs.,* No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), *mot. for rev. denied*, 129 Fed. Cl. 176 (2016). Indeed, "special masters are expected to carefully scrutinize the reliability of each expert report submitted." *Herms v. Sec'y of Health & Hum. Servs.*, No. 19-70V, 2024 WL 1340669, at *19 (Fed. Cl. Spec. Mstr. Mar. 4, 2024).

The experts agreed that petitioner had PMR. They agreed that PMR is a disease of unknown etiology. Drs. Brawer and Akbari opined that flu vaccine and vaccines in general can cause and/or trigger PMR. Drs. Oddis and Romberg disagreed arguing that there is no scientific evidence to support that PMR is associated with either the influenza virus or vaccine, or any virus or vaccine, or that PMR is considered an autoimmune or autoinflammatory disease. Having considered the parties' submissions, I find that Drs. Oddis and Romberg were more persuasive in their opinions and reasoning than Dr. Brawer. Dr. Brawer presented underdeveloped, conclusory and/or generalized statements and criticized the accuracy of the medical records and the opinions of the other experts without citing to any authority in support of his statements or opinions. Dr. Brawer's reports have been criticized in the past for being similarly unhelpful and antagonistic and his opinions have been given little weight in prior decisions by other special masters. [90]

PMR is a common inflammatory syndrome typically affecting those over the age of 50 with onset typically in the fall and winter. Flu vaccine is a commonly received vaccine in the fall and winter. A temporal relationship between the two is more likely a coincidence. *See* Resp. Ex. F at 8. PMR has no known cause, no known autoantibody associated with it, and is therefore not considered an autoimmune disease. *See* Resp. Ex. A at 4 ("The cause of PMR remains unknown and it is not uniformly considered as an autoimmune disease as there are no characteristic autoantibodies identified."); Pet. Ex. 22 at 1 ("[T]here continues to be controversy as to whether polymyalgia rheumatica has any autoimmune features."). *But see* Pet. Ex. 22 at 2 ("[I]mmunologists are not technically nor plausibly correct when they state that polymyalgia rheumatica does not have features of autoimmunity."). The experts agree that PMR is inflammatory in nature, that blood work will show elevated inflammatory markers—ESR and/or CRP—and that it is characterized clinically by aching and morning stiffness in the shoulder and/or pelvic girdle that disappears with movement. There are no specific diagnostic tests or pathological findings determinative of PMR, and diagnosis is made by clinical presentation and after other diseases have been ruled out. The experts further agree that use of low dose prednisone generally shows rapid response. Pet. Ex. 10 at 3; Pet. Ex. 51 at 3, 11; Resp. Ex. F at 9. Finally, the experts agree that PMR can be isolated or related to GCA. The experts agreed that petitioner did not have GCA. Pet. Ex. 22 at 1-2; Resp. Ex. Z at 3.

The foregoing forms the basis for the prong one analysis. Both Drs. Brawer and Akbari detailed how the immune system works and the processes or mechanisms by which autoimmune or autoinflammatory diseases may result following some viruses or vaccinations. However, they each failed to provide any credible evidence to support how those processes can result in PMR, specifically. Neither did Drs. Brawer or Akbari identify a component in the influenza vaccine that shares homology with or mimics anything in the body that could even plausibly cause or trigger PMR.

[90] *See, e.g., Herms*, 2024 WL 1340669, at *19 n. 68; *McDonald v. Sec'y of Health & Hum. Servs.*, No. 15-612V, 2023 WL 2387844, at *5-8, *23 (Fed. Cl. Spec. Mstr. Mar. 7, 2023); *Hughes v. Sec'y of Health & Hum. Servs.*, No. 20-1548V, 2023 WL 8432849, at *3-4, *12-13 (Fed. Cl. Spec. Mstr. Nov. 7, 2023); *Whelan v. Sec'y of Health & Hum. Servs.*, No. 16-1174V, 2019 WL 1061473, at *3-4, *13-15 (Fed. Cl. Spec. Mstr. Jan. 28, 2019); *Clark v. Sec'y of Health & Hum. Servs.*, No. 17-1553V, 2023 WL 4897284, *27, *29 (Fed. Cl. Spec. Mstr. June 16, 2023); *J.S. v. Sec'y of Health & Hum. Servs.*, 164 Fed. Cl. 314, 332 (2023).

Dr. Brawer compared PMR to GCA, opining that both are inflammatory or triggered by a combination of genetic and environmental factors. *See* Pet. Ex. 22. He discussed molecular mimicry as the cause of PMR along with inflammatory processes that occur following receipt of a vaccination. He also considered the role of adjuvants modifying, inducing, or exposing antigens. Pet. Ex. 10 at 4-5. He later discussed how a vaccine can cause an autoinflammatory syndrome through sodium, potassium, calcium, and other ion channels, suggesting that regulatory proteins are disrupted by vaccinations causing amplification of inflammatory loops. Pet. Ex. 22 at 2. He agreed that PMR was an inflammatory syndrome. Pet. Ex. 10 at 3 (describing petitioner's injury as an "inflammatory disease" and a "systemic inflammatory disorder"). However, he also discussed PMR as either autoimmune or autoinflammatory depending on which point he was making. *Compare* Pet. Ex. 10 at 5 (referring to "a variety of autoimmune diseases such as polymyalgia rheumatica"), *with* Pet. Ex. 22 at 2 (referring to "autoinflammatory syndromes such as polymyalgia rheumatica"). In any instance, Dr. Brawer provided no credible evidence to show that PMR is either or that it can be caused by either vaccination or viral infection. He did not cite any of the 28 articles he filed in support of his opinions and in fact showed only that PMR is an inflammatory syndrome with no known cause.

Dr. Akbari also described in detail the immune system and autoimmunity and the processes by which a vaccine can induce or exacerbate those diseases, including molecular mimicry. Pet. Ex. 51 at 4-9. He also discussed autoinflammatory diseases and claimed that PMR falls in the middle of a spectrum of autoimmune and autoinflammatory diseases. *Id*. at 9. He included the role of adjuvants and inflammasome activation. *Id*. at 11-12. He relied on case reports and case series including *Soriano, Liozon*, and *Falsetti* to show individuals who had onset of PMR following vaccinations. *Id*. at 12; Pet. Ex. 18;[91] Pet. Ex. 91;[92] Pet. Ex. 92.[93] However, *Soriano* was a study conducted in Italy, where the content of the vaccine involved is unknown, and it involved the debunked ASIA theory. *Falsetti* was also conducted in Italy and was based on patient self-reporting and on patients' subjective view of the relationship between receipt of a vaccination and onset of symptoms. Both *Soriano* and *Liozon* studied GCA or GCA with PMR. Petitioner did not have GCA. Dr. Akbari also discussed the role of HLA alleles and HLA-B27 positivity making those individuals genetically predisposed to PMR and/or GCA. However, petitioner tested negative for HLA-B27 alleles. Pet. Ex. 5 at 3.

Drs. Brawer and Akbari summarily discussed the concepts of autoimmunity, molecular mimicry, autoinflammatory diseases, and genetic predisposition. Both relied on literature that discussed symptomatology, diagnosis, and immunological processes. But each failed to provide any literature that identified any known causes or triggers for PMR or how the processes they described could cause PMR. Neither proposed an autoantibody or antigen identified in PMR or a sequence of amino acid that compares to those in the influenza vaccine. At best, the literature showed a temporal relationship between vaccination and onset of symptoms.

Drs. Oddis and Romberg maintained that PMR has no known cause with no autoantibody or antigen identified and is not credibly believed to be autoimmune or autoinflammatory. With no

[91] Soriano, et al., *supra*, note 5.
[92] Liozon, et al., *supra*, note 50.
[93] Falsetti, et al., *supra*, note 51.

immune-mediated process known, no causal link between the flu vaccine and PMR can be established. Resp. Exs. A, F, R, Y, and Z.

Dr. Romberg addressed Dr. Akbari's opinions that PMR is an autoinflammatory disease associated with elevated inflammatory cytokines, like IL-6, that favor Th17 cell differentiation, and which implicated NLRP3 inflammasome's response to alum, Treg deficiency, elevated TNF-α and HLA-alleles in PMR pathogenesis. Resp. Ex. Y at 4. Dr. Romberg agreed that PMR patients often demonstrate high circulating Th17 cell frequencies and elevated IL-6 concentration in serum but if or how this relates to myopathy[94] is uncertain. *Id*.; Resp. Ex. BB.[95] Further "[u]nlike other autoimmune/autoinflammatory diseases that directly cause end-organ damage, muscular tissues in PMR patients are by definition histopathologically normal." *Id*.; Resp. Ex. AA.[96] Genetic factors including HLA alleles have been associated with PMR, but no disease-specific autoantigen has been identified. *Id*. Finally, the subject flu vaccine did not contain an adjuvant. Resp. Ex. Y at 5. Therefore, there is no factual or scientific basis for the subject flu vaccine to have caused PMR. *Id*. at 9.

A special master's obligation to examine the evidence under the preponderance standard requires her to "inquir[e] into the soundness of scientific evidence" presented. *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing Vaccine Rules of the Court of Federal Claims Rule 8(b)(1)). Special masters are responsible for "[w]eighing the persuasiveness of particular evidence" by "assess[ing] the reliability of testimony." *Moberly*, 592 F.3d at 1325. "The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories," and "[a]s such, the special master's credibility findings 'are virtually unchallengeable on appeal.'" *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1361).

The law does not merely require that scientific theories be possible; rather, petitioner must preponderantly establish that the vaccine at issue more likely than not can cause the alleged disease. *Cerrone*, 146 F.4th at 1122. Therefore, the question is whether petitioner presented preponderant evidence supporting a sound and reliable theory that a flu vaccine can cause PMR. The answer is that he did not.

Petitioner's experts' conclusory statements do not constitute a sound and reliable theory for how flu vaccine can cause PMR, a condition that has no known cause or autoantibody associated with it. Further, petitioner's experts failed to provide any credible corroborating evidence or reliable scientific studies to support how the flu vaccine could even theoretically cause PMR. This conclusion—that petitioner has not established that a vaccine can cause polymyalgia rheumatica—is consistent with the results in other cases on this issue. I have issued two prior reasoned decisions determining that petitioner had failed to meet their burden of proof on this issue.[97] Other special masters have also concluded that petitioners have failed to provide a sound

[94] Myopathy refers to "any disease of a muscle," including muscle weakness and dysfunction. *See Myopathy*, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4971 (last visited Nov. 10, 2025).
[95] Dejaco, et al., *supra*, note 82.
[96] Salvarani & Muratore, *supra*, note 81.
[97] *See Suliman v. Sec'y of Health & Hum. Servs.*, No. 13-993V, 2018 WL 6803697, at *25-28 (Fed. Cl. Spec. Mstr. Nov. 27, 2018) (Tdap vaccine); *C.P. v. Sec'y of Health & Hum. Servs.*, No. 14-917V, 2019 WL 5483621, at *22-28

and reliable theory of how a vaccine can cause PMR.[98] On other occasions, petitioners have sought dismissal of their cases as a result of being unable to present minimally persuasive evidence.[99]

Althen requires that petitioner "prove by a preponderance of the evidence" that a vaccine caused the alleged injury with a "persuasive medical theory." *Althen*, 418 F. 3d at 1278. While prior decisions lend support, they do not dictate the outcome of this case because the evidence in each case is different. However, petitioner's experts provided no new scientific evidence in the time since those prior decisions were issued. The etiology of PMR remains unknown, there is no known autoantibody or antigen that causes it, and it is uncertain whether PMR is autoimmune, autoinflammatory, or neither. Therefore, based on the medical literature, case studies, expert reports, and medical records, petitioner has failed to put forth a sound and reliable medical theory of causation that would implicate the flu vaccine as a cause of PMR.

Petitioner has failed to satisfy his burden of proof under prong one.

B. *Althen* Prong Two: Petitioner Has Not Demonstrated a Logical Sequence of Cause and Effect

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccination could cause the injury, petitioner must show "that it did in [this] particular case." *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "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," *Paluck v. Sec'y of Health & Hum. Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375). Petitioner is not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Hum. Servs.*,

(Fed. Cl. Spec. Mstr. Aug. 21, 2019) (flu vaccine).

[98] *See Munoz v. Sec'y of Health and Hum. Servs.*, 174 Fed. Cl. 276 (2024) (special master's decision that neither the Tdap or pneumococcal vaccines caused petitioners PMR was sustained); *Giesbrecht v. Sec'y of Health and Hum. Servs.*, No. 16-1338V, 2023 WL 2721578 (Fed. Cl. Spec. Mstr. Mar 30, 2023) (flu vaccine); *Sciortino v. Sec'y of Health & Hum. Servs.*, No. 22-99V, 2024 WL 4579389 (Fed. Cl. Spec. Mstr. July 24, 2024) (flu vaccine); *Wilkinson v. Sec'y of Health & Hum. Servs.*, No. 18-1829V, 2024 WL 3857696 (Fed. Cl. Spec. Mstr. July 22, 2024) (flu vaccine); *Thompson v. Sec'y of Health & Hum. Servs.*, No. 18-1217V, 2023 WL 9053982 (Fed. Cl. Spec. Mstr. Dec. 5, 2023) (pneumococcal vaccine); *Van Dycke v. Sec'y of Health & Hum. Servs.*, 18-106V, 2023 WL 4310701 (Fed. Cl. Spec. Mstr. June 7, 2023) (Tdap vaccine); *Kelly v. Sec'y of Health & Hum. Servs.*, No. 17-1475V, 2022 WL 17819157 (Fed. Cl. Spec. Mstr. Oct. 12, 2022) (flu vaccine); *C.P. v. Sec'y of Health & Hum. Servs.*, No. 14-917V, 2019 WL 5483621 (Fed. Cl. Spec. Mstr. Aug. 21, 2019) (flu vaccine); *Suliman v. Sec'y of Health & Hum. Servs.*, No. 13-993V, 2018 WL 6803697 (Fed. Cl. Spec. Mstr. Nov. 27, 2018) (Tdap vaccine).

[99] *See Gauthier v. Sec'y of Health & Hum. Servs.*, No. 18-753V, 2021 WL 5754976 (Fed. Cl. Spec. Mstr. Oct. 5, 2021) (flu vaccine); *Godek v. Sec'y of Health & Hum. Servs.*, No. 19-106V, 2021 WL 1851389 (Fed. Cl. Spec. Mstr. Apr. 15, 2021) (Tdap vaccine); *Discher v. Sec'y of Health & Hum. Servs.,* No. 18-777V, 2019 WL 6701681 (Fed. Cl. Spec. Mstr. Nov. 12, 2019) (flu vaccine); *Johnson v. Sec'y of Health & Hum. Servs.,* No. 14-931V, 2019 WL 1992631 (Fed. Cl. Spec. Mstr. Apr. 11, 2019) (flu vaccine).

485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

The failure to satisfy prong one in the context of a causation in fact claim is sufficient for dismissal. *Dobrydnev v. Sec'y of Health & Hum. Servs.*, 566 Fed. App'x 976, 980 (Fed. Cir. 2014) ("Because petitioners must meet their burden under all three *Althen* factors to prevail, a failure to do so on any one of these factors is dispositive."). Having failed to sustain his burden under prong one, petitioner cannot sustain his burden under prongs two and three.

It bears repeating that the cause of PMR is unknown and neither Dr. Brawer nor Dr. Akbari could show otherwise. It is therefore axiomatic that if there is no known cause for PMR, there cannot be a logical sequence of cause and effect, other than a mere temporal link, between vaccination and the onset of symptoms. Indeed, none of petitioner's treating physicians explicitly opined that the flu vaccine caused petitioner's PMR.

There is no question that petitioner was diagnosed with, suffered from, and was treated for PMR. Based on the contemporaneous medical records, petitioner's PMR had an onset of about 12 days, at the earliest, after receipt of his flu vaccine. Pet. Ex. 4 at 16. However, the law states that evidence of the development of a disease and/or injury temporally following a vaccination is insufficient on its own to establish causation. *See Grant v. Sec'y of Health & Hum. Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Merely identifying the vaccine as causal because of its existence as a known, pre-onset occurrence is insufficient to establish causation without corroborative record proof demonstrating the "logical sequence of cause and effect" required. *Id*. Petitioner's experts, having failed to establish a sound and reliable theory for how a flu vaccine can cause PMR, have therefore failed to establish a logical sequence of cause and effect. Opining that there is a temporal association between the vaccine and petitioner's development of PMR is insufficient to satisfy prong two.

Petitioner has failed to sustain his burden under prong two.

C. *Althen* Prong Three: Petitioner Has Not Demonstrated a Proximate Temporal Relationship

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Petitioner is being given the benefit that the onset of his PMR followed receipt of the October 6, 2017 flu vaccine and not in September as he reported on numerous occasions to various unrelated providers. *See* Pet. Ex. 5 at 2 ("Symptoms started in September 2017."). Petitioner consistently equated his initial presentation for back pain and hip discomfort with five hours of dirt biking and a long drive which took place 12 days after receipt of the flu vaccine. Pet. Ex. 4 at 19-20 (On October 28, 2017, petitioner reported his pain began "when he went motorcycle riding off-road" and "then the next day, he sat on a long car trip for about 7 hours.); Pet. Ex. 4 at 82 (On November 19, 2017, petitioner reported "he had pain after riding a motorcycle" and "after sitting in his car for 200 miles.); Pet. Ex. 2 at 1; Pet. Ex. 35. Petitioner had also presented four months prior to his vaccination with complaints of "right shoulder/scapular region and neck pain". Pet. Ex. 3 at 8.

"[T]o satisfy the 'proximate temporal relationship' prong of the *Althen* test, petitioners must demonstrate, by a preponderance of the evidence, that the onset of symptoms occurred within a time frame for which it is medically acceptable to infer causation-in-fact. With no reputable theory as to how the vaccination could cause the injury, this exercise is not possible." *Langland v. Sec'y of Health & Hum. Servs.*, 109 Fed. Cl. 421, 443 (2013) (citations omitted). Further, although petitioner's experts discussed in depth the immune system, how it works and reacts, and their respective theories about how the flu vaccine can cause PMR, where there is no known cause for a particular disease or syndrome, it follows that there can be no known medically acceptable timeframe for onset. Other than a temporal relationship, there is no evidence of any association between the flu vaccine and PMR.

Petitioner has failed to sustain his burden under prong three.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter—including the medical records, expert reports, medical literature, and arguments of the parties—I must conclude that, where the scientific evidence is lacking and the cause of a disease or syndrome unknown, petitioner cannot show by preponderant evidence that he is entitled to compensation under the Vaccine Act. Such is the case here. **The Clerk shall enter judgment accordingly.**[100]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[100] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.