In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 23-655

DOUGLAS EBERLINE,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: December 1, 2025
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Amber Diane Wilson, Wilson Science Law, Washington, DC, for Petitioner.

Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On May 4, 2023, Douglas Eberline filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that he suffered polymyalgia rheumatica ("PMR") after receipt of a pneumococcal vaccine on August 19, 2020, and an influenza vaccine administered on September 12, 2020. Petition (ECF No. 1).

Petitions alleging PMR as a vaccine injury have routinely been dismissed. Therefore, and because of my reasoned skepticism that this kind of claim has any legal basis, I directed the parties to brief entitlement, and they have done so. *See* Petitioner's Brief in Support of Entitlement, dated

[1] Because this Decision contains a reasoned explanation for my actions in this case, it must be posted on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

January 10, 2025 (ECF No. 36) ("Br."); Respondent's Opposition, dated March 21, 2025 (ECF No. 39) ("Opp."); Petitioner's Rebuttal Brief, dated April 18, 2025 (ECF No. 41) ("Reply"). For the reasons set forth in more detail below, I hereby deny entitlement.

I. Factual Background

Petitioner had a past medical history significant for carpal tunnel syndrome as well as osteoarthritis ("OA") in the right knee, treated with different medications. Ex. 5 at 31–36, 41–44, 45–50, 51–56, 62–63, 66, 74–75. On August 19, 2020, Petitioner received a covered version of the pneumococcal vaccine at the office of his primary care provider ("PCP"), and on September 12, 2020, Petitioner received a flu vaccine at an Osco Pharmacy in Peoria, Arizona. Pet. at 1; Ex. 1 at 2. There is no evidence of any adverse reaction in the almost one-month interval between vaccinations.

Approximately four weeks after the second vaccination (October 9, 2020), Petitioner saw orthopedist Vimala Ramachandran, M.D., and complained of "constant numbness, tingling, and burning sensations in his bilateral hands, specifically in the middle and ring fingers." Ex. 3 at 15. Mr. Eberline noted that the pain had been present "for about a month" (which if literally true meant an onset a few days *prior* to his receipt of the flu vaccine), and he rated it a nine out of ten, adding that it increased with repetitive movements. *Id.* Following an exam, Dr. Ramachandran's assessment was bilateral carpal tunnel syndrome. He ordered an EMG,[3] provided Petitioner with wrist braces to wear at night, and advised him to apply heat and ice and to take over-the-counter analgesics for the pain. *Id.* at 16.

On October 16, 2020, Petitioner presented to his PCP, Michaela Skelly, M.D., reporting joint stiffness since his last visit, which he felt had worsened after receiving the flu and pneumococcal vaccines two months prior. Ex. 4 at 30. Petitioner further noted that his fingers were especially stiff, but that he also was experiencing tightness in his hips, knees, shoulders, wrists, and hands. *Id.*

On exam, Petitioner was slow to get up and walked stiffly. It was further noted that he was unable to make a complete handgrip with either hand. Ex. 4 at 33. Dr. Skelly's assessment was unspecified joint and hand pain, as well as carpal tunnel syndrome, for which Petitioner was prescribed Prednisone. *Id.* at 33–34. Hand x-rays and lab tests for inflammatory markers were

[3] "Electromyography" is defined as "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited on Dec. 1, 2025).

subsequently ordered, and somewhat-high levels of the erythrocyte sedimentation rate[4] ("ESR") and C-reactive protein[5] ("CRP") were observed. *Id.* at 169–72.

On November 3, 2020, Petitioner saw rheumatologist Physician's Assistant ("PA") Rachel Herrin, because of his elevated CRP level. Ex. 2 at 10. PA Herrin noted that Petitioner's pain had been gradually improving on Prednisone, and that "his body may have just been reacting to having [two] shots done within a short period of time." *Id.* at 14. Repeat lab tests were subsequently ordered. *Id.* at 13–14. Petitioner underwent an EMG/NCS[6] on November 11, 2020, and the results were consistent with mild carpal tunnel syndrome and non-localized ulnar neuropathy across the elbow on the left side. Ex. 11 at 3. His CRP levels were still high, however, so PA Herring prescribed another round of Prednisone. Ex. 2 at 15.

Petitioner returned to PA Herrin for a follow-up appointment on December 21, 2020, reporting that his "joints [were] feeling great." Ex. 2 at 16. A physical examination was mostly normal, although Petitioner did demonstrate generalized joint stiffness and muscle aches. *Id.* at 16, 19. PA Herrin noted that she was "[s]till leaning more toward PMR or reactive arthritis (given [Petitioner's] recent vaccines, shots, etc.)" as a possible cause for his pain. *Id.* at 20.

Treatment in January 2021 to May 2022

Approximately four months after receipt of the second vaccine at issue (January 12, 2021), Petitioner saw rheumatologist Vijayabhanu Mahadevan, M.D., complaining of only minimal stiffness in the morning, absent any joint swelling or pain. Ex. 2 at 21. On exam, Dr. Mahadevan noted Petitioner's lab results were now normal and his assessment was polyarthralgia. The treater note documented that Dr. Mahadevan was still "leaning more toward PMR even though symptom onset was after flu/pneumonia vaccination," and he recommended that Petitioner begin tapering his Prednisone because he was asymptomatic. *Id.* at 24.

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[4] "Erythrocyte Sedimentation Rate" is defined as "the rate at which erythrocytes precipitate out from a well-mixed specimen of venous blood, measured by the distance the top of the column of erythrocytes falls in a given time interval under specified conditions; an increase in rate is usually due to elevated levels of plasma proteins, especially fibrinogen and immunoglobulins, which decrease the zeta potential on erythrocytes by dielectric shielding and thus promote rouleau formation. It is increased in monoclonal gammopathy, hypergammaglobulinemia due to inflammatory disease, hyperfibrinogenemia, active inflammatory disease, and anemia." *Erythrocyte Sedimentation Rate*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=102146&searchterm=erythrocyte+sedimentation+rate (last visited Dec. 1, 2025).

[5] "C-reactive protein" is "a globulin that forms a precipitate with the somatic C-polysaccharide of the pneumococcus in vitro; it is the most predominant of the acute-phase proteins." *C-reactive protein*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=100489&searchterm=C-reactive+protein (last visited Dec. 1, 2025).

[6] A Nerve Conduction Study (NCS) test "measures how fast an electrical impulse moves through your nerve." During the test, a person's nerve is stimulated with electrode patches placed on their skin which is then used to identify any nerve damage. *Zacharski v. Sec'y of Health & Hum. Servs.*, No. 21-317V, 2025 WL 1235431, at n.15 (Fed. Cl. Spec. Mstr. Mar. 26, 2025).

Between March and June 2021, Petitioner saw PA Herrin on multiple occasions for follow-up appointments and reported minimal PMR symptoms as he continued to gradually decrease his Prednisone dosage. *See* Ex. 2 at 25 (documenting 3/11/2021 visit where Petitioner reported "feeling much back to his normal self and is hoping to work on getting off of prednisone"), 29 (discussing 5/5/2021 appointment and noting minimal symptoms following a decrease in Petitioner's Prednisone dosage), 35 (documenting 6/30/2021 follow-up visit at which time Petitioner reported feeling "pretty well" and denying any major joint pains or flares).

Petitioner returned to Dr. Ramachandra on July 3, 2021, and reported worsening numbness and tingling in his hands. Ex. 3 at 11–12. Approximately one month later, on August 5, 2021, Petitioner underwent a carpal tunnel release procedure on the right side. *Id.* at 46–47. Three months thereafter, on November 4, 2021, he also underwent a carpal tunnel and trigger release procedure on the left side. *Id.* He continued to see treaters through April 2022. Petitioner was off Prednisone by August 2021, and his ESR and CRP levels had improved since the last time they were tested the year prior. Ex. 7 at 11. Throughout this later treatment course, Petitioner continued to report stable conditions, exhibit a normal physical examination, and maintain normal ESR and CRP levels. *See generally* Ex. 7.

No additional medical records have been filed.

II. Expert Opinions

A. Petitioner's Expert – Petros Efthimiou, M.D. FACR

Dr. Efthimiou, a rheumatologist, offered two written reports on behalf of Petitioner. *See* Report, dated May 13, 2024 (ECF No. 16-2) ("First Efthimiou Rep."); Report, dated Oct. 31, 2024 (ECF No. 19-1) ("Second Efthimiou Rep."). Dr. Efthimiou opines that Petitioner's receipt of the flu vaccine on September 12, 2020, "more likely than not was a substantial factor contributing to the onset of clinical polymyalgia rheumatica (PMR)." First Efthimiou Rep. at 1.

Dr. Efthimiou received his medical degree from the University of Ioannina Medical School in Ioannina, Greece. Curriculum Vitae, filed as Ex. 17 (ECF No. 16-3) ("Efthimiou CV") at 1. He then completed an internship in Internal Medicine at the University of Iowa Hospital and Clinics, followed by his residency in Internal Medicine at Brown University and a fellowship in Rheumatology at the Hospital for Special Surgery and New York Presbyterian and Memorial Sloan Kettering Cancer Center Hospital. *Id.* at 1–2. Dr. Efthimiou currently serves as an Associate Professor of Medicine at St. George's University School of Medicine and Ross University Medical School. *Id.* at 2. He is board-certified by the American Board of Internal Medicine in Rheumatology and has an active clinical practice. *Id.* at 3; First Efthimiou Rep. at 1. Throughout his clinical career, Dr. Efthimiou has frequently evaluated and treated individuals with PMR, and he has spent the last twenty-one years researching inflammatory rheumatic conditions, such as PMR and other associated inflammatory disorders. First Efthimiou Rep. at 1–2.

First Report

Dr. Efthimiou began his first report with a description of Petitioner's relevant medical history. He opined that the medical records and objective testing establish that Petitioner likely suffered from PMR. First Efthimiou Rep. at 3.

PMR, explained Dr. Efthimiou, is a condition "characterized by inflammatory pain and stiffness in the shoulder and in the pelvic girdle and neck" that occurs in individuals over the age of 50. First Efthimiou Rep. at 10. It is typically associated with an acute-phase response and a rapid response to low doses of glucocorticoids with a generally favorable prognosis. *Id.* Currently, the understanding of PMR's pathogenesis is that it is an immune-mediated disease with a number of causal factors, including genetic and environmental. *Id.*; D. Camellino et al., *Pathogenesis, Diagnosis and Management of Polymyalgia Rheumatica*, 36 Drugs & Aging 1015 (2019), filed as Ex. 18 (ECF No. 16-4). Dr. Efthimiou maintained that multiple items of "peer published literature" associate the onset of PMR with immunization as a potential environmental trigger. First Efthimiou Rep. at 10; *see also* A. Soriano et al., *Giant Cell Arteritis and Polymyalgia Rheumatica after Influenza Vaccination: Report of 10 Case and Review of the Literature*, 21 Lupus 153 (2012), filed as Ex. 19 (ECF No. 16-5) ("Soriano") (identifying ten patients who developed GBS/PMR within three months of receipt of a flu vaccine). To further bulwark this position, Dr. Efthimiou noted that Soriano was "neither the first [report to confirm this association], nor the only one," and that its authors published their literature finding therein confirming additional cases. Soriano at 155, Table 2.

Dr. Efthimiou then explained that PMR can be clinically expressed in a predisposed individual by an environmental immune stimulus, such as an infection or vaccination. He noted that there is generally a broad spectrum for inflammatory rheumatic diseases, with some likely mediated by a combination of autoimmunity and inflammation. First Efthimiou Rep. at 11; E. Hysa et al., *Immune System Activation in Polymyalgia Rheumatica: Which Balance between Autoinflammation and Autoimmunity? A Systemic Review*, 21 Autoimmunity Reviews 1, 7 (2022), filed as Ex. 22 (ECF No. 16-8) (suggesting that "the balance of [PMR] between autoinflammation and autoimmunity seems to lie halfway … by considering both ends of the pathophysiological spectrum of immune-mediated rheumatic disease, PMR might be regarded as an inflammatory immune-mediated disease with mixed mechanisms"). Accordingly, Dr. Efthimiou maintained, when it comes to understanding the pathophysiology of PMR, "it could be that some diseases are characterized by being linked to being triggered by the innate immune response, whereas others are linked to being characterized by a dysregulated adaptive immune response." First Efthimiou Rep. at 11.

PMR, Dr. Efthimiou opined, likely arises as a result of disruption of self-tolerance by specific types of T cells, and the inability of T regulatory cells to prevent autoreactivity. First Efthimiou Rep. at 12. He further stated that "[t]he antigenic responses to the vaccine proteins contained in a vaccine could initiate autoreactive T cells that attack the body by providing either

specifically or nonspecifically the necessary immune signals to ultimately dysregulate (i.e., lose self-tolerance) and activate the required autoreactive immune cells necessary for clinical disease expression. *Id.*

Petitioner might have already possessed such autoreactive cells, as a result of his initial "primary antigenic-immune responses" to either previously-received vaccines or some other prior environmental exposure. First Efthimiou Rep. at 12. Because a vaccine has the potential to trigger "already present" immune cells in an individual, Dr. Efthimiou argued, the vaccine "could be" triggering a non-specific immune signal which adversely activates another immune signal and leads to disease onset. *Id.*; *see also Committee to Review Adverse Effects of Vaccines: Evidence and Causality* 82 (K. Stratton et al., eds., 2012), filed as Ex. 23 (ECF No. 16-9) (explaining that both epidemiological and mechanistic research has recognized that individuals experiencing an adverse reaction to vaccine administration have a predisposition that can exist for several reasons, including genetics, intervening illness, or prior immunological and environmental exposures).

Relevant to Dr. Efthimiou's theory was Petitioner's receipt of two vaccines within the space of one month. Petitioner was administered the pneumococcal vaccine on August 19, 2020, and then the flu vaccine on September 12, 2020. As a result, "[a]t the time of his seasonal flu vaccine, [Petitioner]'s immune response to his pneumococcal vaccine would have been anticipated to be providing a 'peak' immune response." First Efthimiou Rep. at 13 (citing Ex. 4 at 34; Ex. 1 at 2). A vaccine has the ability to provide either innate or adaptive immune response signals—sometimes both—that are necessary to demonstrate it as mechanistically causal of a subsequent adverse effect. *Id.*

Thus, the aberrant capacity of the second immunization was heightened by the one received three-plus weeks before. To support this contention, Dr. Efthimiou cited a study that analyzed vaccine-elicited responses in humans via gene profiles, emphasizing that "[w]hile the two vaccines differ in their components, mechanisms common to both vaccines were discovered, [and thus the authors] conclude[ed] that these vaccines are potent activators of the innate immune system and that innate response can be detected in the blood within hours of administration." First Efthimiou Rep. at 14; G. Obermoser et al., *Systems Scale Interactive Exploration Reveals Quantitative and Qualitative Differences in Response to Influenza and Pneumococcal Vaccines*, 38 Immunity 831 (2013), filed as Ex. 25 (ECF No. 16-11) ("Obermoser"). In addition, the pneumococcal vaccine at issue herein also contains an adjuvant, and its antigens are conjugated to a carrier diphtheria-like protein—making any reported associations with the Tdap vaccine (which includes the same diphtheria proteins) relevant when analyzing Petitioner's case. First Efthimiou Rep. at 15. Both vaccines can elicit B-cell responses in a T-cell dependent manner, making it reasonable to conclude that Petitioner's immune response post-vaccination was more susceptible to triggering cross-reactive immune memory cells, and hence causing PMR. *Id.*

Dr. Efthimiou concluded his first report with a reiteration of his overall opinion—that Petitioner's "systemic autoimmune reaction, demonstrated by the development of [PMR], was likely triggered by the influenza vaccination he received in 2020." First Efthimiou Rep. at 16. Based on the medical literature and the lack of other causal factors present that can provide a more likely explanation, Dr. Efthimiou maintained that Petitioner's clinical course most likely represents a probable case of post-vaccine PMR illness that was treated successfully with steroids. *Id.* at 17.

Second Report

Dr. Efthimiou's second report responded to comments made by Respondent's expert, Dr. Maxime Kinet. Dr. Efthimiou disagreed with Dr. Kinet's assertion that he had not provided any biological mechanistic theory detailing at a molecular level how the immune response of a flu vaccine can specifically result in clinical manifestations of PMR. Second Efthimiou Rep. at 2. He argued in response that he had performed a thorough review of the medical literature—including PMR-specific studies that discussed "how reliable immunological mechanisms support a biological mechanistic 'theory' detailing how the immune response to a flu vaccine can adversely contribute at the mechanistic level to pathologically cause clinical symptoms of PMR illness. *Id.*

Otherwise, independent literature supported "postulating a biological mechanistic (scientific) theory explaining how vaccinations can pathologically cause the clinical onset of PMR illness in the general population but medical literature, or more specifically clinical literature, is evidence the biological mechanisms being discussed, at least in theory, could have actually occurred in another patient." *Id.* at 2–3. Moreover, Dr. Efthimiou stated, the absence of biological certainty regarding the specifics of the innate immune "culprit responsible for inducing an adverse immune response" does not discredit concluding a vaccine causal theory has a medically and scientifically reliable and plausible biological basis. *Id.* at 3.

Dr. Efthimiou admitted to the overall safety of vaccines, but argued that "the safety of a causal factor should not be confused with whether there is a reliable and plausible biological mechanistic theory for how the two events can, especially in theory, be causally connected." Second Efthimiou Rep. at 4. Moreover, discussing putative associations "is the point of publishing case reports in medical literature"—and here, cited case reports and case series supported his overall proposed medical theory, which was consistent with Petitioner's experience. Second Efthimiou Rep. at 6, 11.

Regarding the timing of Petitioner's onset, Dr. Efthimiou stated that his symptoms began after receipt of the flu vaccine and that his subsequent pneumococcal vaccine[7] caused a "flare" of his symptoms within the same day as administration. *Id.* at 13. Based on this clinical evidence and the cited items of literature, Dr. Efthimiou maintained that several biological mechanistic explanations could explain the triggering of an adverse response—first, Petitioner's "flu vaccine

[7] Dr. Efithimiou here switched the order of vaccination, since the record shows Petitioner *first* received the pneumococcal vaccine.

alone was [the] specific immune culprit that initiated an adverse immune response, or the flu vaccine could have adversely influenced the already circulating pneumococcal immune cells present at the time administered." *Id.* at 14. In so opining, however, Dr. Efthimiou acknowledged that it is not readily apparent at the molecular immune response level exactly which vaccine was "more likely" to trigger the adverse immune response. *Id.*; *see also* Soriano at 2, Table 1 (demonstrating that PMR relapses have been observed after receiving a flu vaccine in a temporal association of one to a few days post-administration).

B. Respondent's Expert – Maxime Kinet, M.D., Ph.D.

Dr. Kinet, a rheumatologist, offered one written report on behalf of Respondent. *See* Report, dated July 29, 2024 (ECF No. 18-1) ("Kinet Rep.").

Dr. Kinet attended Columbia University for his undergraduate degree, the Rockefeller University for his Ph.D., followed by Weill Cornell Medical College for his medical degree. Curriculum Vitae, filed as Ex. B (ECF No. 18-11) ("Kinet CV") at 1. He then completed his residency in Internal Medicine, followed by a fellowship in Rheumatology at the University of California San Francisco ("UCSF"). *Id.* Dr. Kinet currently serves as an Assistant Professor in the Division of Rheumatology and Department of Medicine at UCSF, where he has a faculty practice at the main academic center and attends on the inpatient adult Rheumatology consult service. *Id.*; Kinet Rep. at 1. He is board-certified in Internal Medicine and Rheumatology. Kinet CV at 1. Dr. Kinet has evaluated and treated approximately three dozen individuals with PMR throughout his career and has published several peer-reviewed journal articles. *Id.* at 2–3.

After providing a summary of the pertinent medical facts of Petitioner's case, Dr. Kinet discussed PMR in general, and whether there is sufficient medical and scientific literature to support a causal relationship between PMR and the flu vaccine. *See generally* Kinet Rep. at 4–6. PMR, Dr. Kinet explained, "is a systemic inflammatory disorder of unclear etiopathogenesis affecting persons over fifty years old." *Id.* at 4; *see also* A. Kermani & K. Warrington, *Polymyalgia Rheumatica*, 381 The Lancet 63 (2013), filed as Ex. A Tab 1 (ECF No. 18-2) ("Kermani"). A typical clinical presentation includes bilateral pain and stiffness in the neck, shoulders, upper arms, hips, and thighs, that can oftentimes have an acute onset. Kinet Rep. at 4; C. Salvarani et al., *Polymyalgia Rheumatica and Fiant-Cell Arteritis*, 347 New Eng. J. Med. 261, 261 (2002), filed as Ex. A Tab 3 (ECF No. 18-4) ("Salvarani I"). In the majority of PMR cases, inflammatory markers, such as ESR or CRP are elevated. Kinet Rep. at 4; C. Salvarani et al., *Acute-Phase Reactants and the Risk of Relapse/Recurrence in Polymyalgia Rheumatica: A Prospective Followup Study*, 53 Arthritis & Rheumatism 33, 35 (2005), filed as Ex. A Tab 6 (ECF No. 18-7) (finding that "ESR, CRP, and IL-6 at baseline were elevated in 91.5%, 98.9%, and 92.6% of PMR patients, respectively"). It is in most cases successfully treated with a tapering dose of glucocorticoids, although approximately half of patients with PMR will experience a relapse. Kinet First Rep. at 4; Kermani at 6–7. Dr. Kinet allowed that Petitioner's presentation was consistent with PMR, but

added that "the distal predominance of his symptoms is somewhat unusual, as is the persistence of high inflammatory markers well after resolution of symptoms." Kinet Rep. at 4.

With respect to Dr. Efthimiou's proposed theory for how the flu vaccine may have triggered Petitioner's PMR, Dr. Kinet first acknowledged that the development of PMR and receipt of the flu vaccine are both "exceedingly common occurrences." Kinet Rep. at 4. In fact, "[t]he estimated lifetime risk of PMR for men is around 2%, and the CDC estimates that over half of [the] adult population in the 2019-2020 season received [the] influenza vaccination." *Id.*; *see also* A. Schattner, *Consequence of Coincidence? The Occurrence, Pathogenesis and Significance of Autoimmune Manifestations after Viral Vaccines*, 23 Vaccine 3876 (2005), filed as Ex. A Tab 9 (ECF No. 18-10); C. Crowson et al., *The Lifetime Risk of Adult-Onset Rheumatoid Arthritis and Other Inflammatory Autoimmune Rheumatic* Diseases, 63 Arthritis & Rheumatism 633 (2011), filed as Ex. A Tab 7 (ECF No. 18-8).

As a result, Dr. Kinet proposed that "*chance association* between these very common events is *likely*." Kinet Rep. at 4 (emphasis added). He thus considered Dr. Efthimiou's reliance on many of his cited medical literature to be misguided, noting that such "case reports and small case series of 20 patients or less, [ ] are not sufficient to establish causation in the case of two common events." *Id.* Instead, Dr. Kinet emphasized that "leading PMR experts have published in top medical journals that a viral or other infectious cause[s] to PMR *ha[ve] never been substantiated*." *Id.* (emphasis added); Salvarani I at 262 (noting that a viral cause has been suspected but not confirmed in PMR, and that other studies have been unable to find any association between infection and the onset of PMR).

In response to Dr. Efthimiou's discussion on how PMR is likely caused by an interplay between innate and adaptive arms of the immune system as well as environmental and other genetic factors, Dr. Kinet opined that while this general concept of pathogenesis has overall scientific reliability and can be applied in many disease models, "it does not provide specific evidence for how influenza and/or pneumococcal vaccination might lead to PMR." Kinet Rep. at 5. In effect, it is too general an explanation about autoimmunity writ large to have utility in the specific context of an injury deemed caused by certain vaccines. Similarly, Dr. Kinet opined that Dr. Efthimiou's proposed theory provided no mechanistic explanation for how the "antigenic response to the vaccine proteins contained in a vaccine[—specifically the flu vaccine—] could initiate autoreactive T cells that attack the body by providing either specifically or nonspecifically the necessary immune signals to ultimately dysregulate (i.e., lose self-tolerance) and activate the required autoreactive immune cells necessary for clinical disease expression." *Id.* (citing First Efthimiou Rep. at 12).

Dr. Kinet also emphasized the significance of what he viewed from Petitioner's medical history as a possible predisposition to PMR (based on evidence of prior joint pain). Kinet Rep. at 5. He argued that "[i]f one grants that any vaccine stimulus can lead to PMR in a pre-disposed individual due to non-specific immune activation, it is not clear why [Petitioner's] closely spaced

vaccinations, or any of his other recent vaccinations, did not lead to PMR." *Id.*; *see also* Ex. 6 at 1 (documenting Petitioner's receipt of the influenza and hepatitis A and B vaccines within 4 days of each other in September 2019). Moreover, Dr. Efthimiou's assertion that Petitioner's approximate one-month delay between his receipt of the flu and pneumococcal vaccines in 2019 caused a "boosting" of his immune response, and therefore increased his predisposition to PMR, was not supported by the medical literature. Obermoser—which describes an innate immune activation signature peak within hours to a few days for the influenza and 23-valent pneumococcal polysaccharide vaccines—essentially argues *against* the notion that cross-vaccine boosting of the immune response can occur in a significantly-longer timeframe. Kinet Rep. at 5; Obermoser at 5, 6, 7–8.

Finally, Dr. Kinet briefly responded to Dr. Efthimiou's contention regarding the existence of "cross-reactive immune memory cells" triggered by the receipt of the pneumococcal vaccine. Not only had Dr. Efthimiou failed to provide any record evidence or medical literature demonstrating how such cross-reactive cells might lead to autoimmunity in general, but he also failed to expand on whether "the cross-reactive cells react with [the] pneumococcal proteins and self-antigens, pneumococcal proteins and influenza antigens, or all three, and the putative antigens." Kinet Rep. at 6.

III. Procedural History

As noted above, this matter was initiated in May 2023. Respondent filed his Rule 4(c) Report contesting Petitioner's right to compensation on January 8, 2024. *See* Report, dated Jan. 8, 2024 (ECF No. 14). Thereafter, the process of obtaining expert reports began, with the final report from Dr. Efthimiou filed in October 2024. I issued a scheduling order on November 4, 2024, setting forth a briefing schedule for a ruling on the record. The parties subsequently filed their briefs, and the matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner first maintains that he suffers from PMR, a medically-recognized rheumatological illness. He notes that the "evidentiary record convincingly establishes that his clinical picture and treating rheumatologist objectively and clinically confirmed that he suffered from the diagnosis of PMR acutely after receiving a flu vaccine in connection with [the] administration of a pneumococcal vaccine just 4 weeks earlier." Br. at 1. In addition, Dr. Efthimiou cited to "highly relevant and recently published literature studies" that support his opinion that PMR patients are known to have a similar clinical set of medical facts, suffer the same clinical features, and describe a similar clinical onset (including presenting with distal symptoms and carpal tunnel syndrome) as Petitioner. *Id.* at 11.

Petitioner then addresses each *Althen* prong. Petitioner maintains that he has provided a sound and reliable medical theory causally connecting the vaccination and his injury (relying on the now-rejected concept that the theory need only be biologically plausible, rather than preponderantly established).[8] Br. at 18, 19. Relying on recently published literature, and not his medical opinion alone, Petitioner argues that Dr. Efthimiou "applied a sound and reliable causality methodology to analyze [Petitioner's] medical case; one that is founded on both supportive clinical evidence and mechanistic data scientifically explaining how the associations observed in the clinical date can, like [Petitioner's] similar sequence, support that a causal link is biologically credible even if the causal link is not scientifically certain." *Id.* at 20. Petitioner notes that the flu vaccine is the most associated vaccine reported in association with PMR, with the literature observing an onset of PMR symptoms within a few days to weeks of vaccination. Moreover, Dr. Efthimiou emphasized Petitioner's receipt of the pneumococcal vaccine four weeks prior to the onset of his symptoms—explaining that "the general understanding about [Petitioner's] immune response to [the pneumococcal] vaccine is that at the same time he received his flu vaccine, the pneumococcal immune response 'would have peaked and was also circulating in his blood.'" *Id.* at 22 (citing Ex. 26 at 12). Petitioner maintains that Dr. Efthimiou preponderantly supports his overall opinion with several items of medical literature and scientific studies. Br. at 23.

In support of his showing under *Althen* prong two, Petitioner argues that Dr. Efthimiou reviewed all the relevant medical records and concluded that there was no evidence to suggest that Petitioner was suffering from PMR prior to receipt of the vaccines at issue. Br. at 13. Petitioner's clinical presentation of pain, morning stiffness, generalized aches in the hips, shoulders, and joints were "suggestive to an experienced practitioner that he was suffering from most likely an inflammatory condition that affected multiple joints consistent with the diagnosis of PMR." *Id.* at 14. Petitioner's symptoms prompted him to seek medical care and undergo the appropriate treatment for PMR (i.e., steroid treatment) to which his symptoms subsequently resolved and resumed when he stopped therapy. Moreover, his objective labs and overall clinical course confirmed the diagnosis of PMR, and thus, Petitioner contends that Dr. Efthimiou preponderantly established a logical sequence of cause and effect showing the vaccine is the reason for the PMR injury in Petitioner's case. *Id.* at 13.

Lastly, Petitioner maintains that he has demonstrated a medically acceptable, proximate temporal relationship between vaccination and his subsequent injury. Br. at 34. Based on the clinical studies discussing the timing of flu vaccine innate immune responses in human studies, as well as in clinical reports that observe similar PMR symptom onset temporally associated with the receipt of the flu vaccine, Petitioner argues that his clinical presentation of symptoms onset and progression demonstrates a medically appropriate temporal relationship. *Id.* In addition, Petitioner

[8] *See Cerrone v. Sec'y of Health & Hum. Servs.*, 146 F.4th 1113, 1121 (Fed. Cir. 2025) ((the contention that *Althen* prong one requires only a showing of plausibility "understates the burden [a petitioner] bears under the first factor in the *Althen* formulation").

relied upon several items of literature documenting symptoms onset within several days of vaccination, as seen here. *Id*. at 35, 36.

In his reply, Petitioner reiterated the argument that the evidentiary record preponderantly establishes that he did suffer from PMR, a medically recognized injury—arguing that "when viewed under the totality standard, Mr. Eberline's records, his treating physicians, and the medical literature all preponderantly establish that he suffered from PMR illness that started acutely after receiving a flu vaccine." Reply at 2. Specifically, Petitioner maintains that his reported distal symptoms of carpal tunnel, which Respondent argues is "atypical," are known associated symptoms in the rheumatology community. *Id.* at 5. Moreover, the cited medical literature "confirms that [Petitioner's] medical picture of PMR is fully acknowledged by other researchers in the field of rheumatology." *Id.* at 8. Medical literature supports the notion that PMR patients can suffer from associated carpal tunnel symptoms, as well as other hand pain symptoms, as Petitioner did. *Id.* In addition, the literature confirms that "patients with PMR symptoms can suffer from fluctuating abnormal inflammatory markers throughout their clinical course, which *do not* correlate with the presence of relapse symptoms", according to Petitioner. *Id.* (emphasis in original); *see also* Reply at 8–11 (referencing several items of literature cited by Respondent which Petitioner argues support Dr. Efthimiou's medical testimony and Petitioner's overall clinical course of PMR).

Petitioner also takes issue with Dr. Kinet's opinion, maintaining that it required "specification of an exact biological mechanism and confirmation of studies proving vaccine causation exists in the medical community and literature studies," even though such an evidentiary standard did not apply in Vaccine Act cases. *Id.* at 13. He argues that Dr. Efthimiou's opinion relies directly on vaccine studies that specifically observe the innate immune response to the flu vaccine occurring within one to seven days of vaccination, and that such studies apply to Petitioner's medical facts and clinical course—hence allowing the conclusion that his receipt of the flu vaccine can cause PMR. *Id.* Relying on the filed expert reports, the detailed medical records, and the studies from the peer-reviewed literature, Petitioner strongly maintains that he has met his legal burden under *Althen* and all of the other statutorily required element for the requirement of establishing a prima facie case under the Act *Id.* at 35.

Respondent

Respondent argues that Petitioner has failed to provide a reliable scientific or medical theory establishing that the flu and/or pneumococcal vaccines can cause PMR. Opp. at 10. He notes that Dr. Efthimiou did not provide "*any* specific, scientific evidence demonstrating how the influenza and/ and/or pneumococcal vaccinations might lead to PMR." *Id.* Rather, Petitioner through his expert, has offered "high-level, general, scientific principles" about the function of the immune system. *Id.* And this occurred in the context of an oft-dismissed causation theory involving PMR as a purported vaccine injury. *Id.* at 12–13.

As for *Althen* prong two, Respondent maintains that Petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect between his receipt of the vaccines at issue and his injury. Opp. at 13. He acknowledges Petitioner's treating physicians entertained multiple likely diagnoses, including carpal tunnel syndrome, polyarthralgia, *and* PMR, but Dr. Kinet had noted reasons the diagnosis might not be applicable under the circumstances. *Id.* at 14. Moreover, Respondent notes that Petitioner reported suffering from similar symptoms in 2010–2011, and "[i]f these symptoms represented a predisposition to PMR, it follows that [P]etitioner would have suffered a relapse of his symptoms given the number of closely spaced vaccinations he received in subsequent years"; however, he did not. *Id.* Accordingly *Althen* prong two has not been satisfied.

Lastly, Respondent contends that Petitioner has failed to establish a medically appropriate temporal relationship between his vaccines and the onset of his PMR. Op. at 14. Petitioner received the pneumococcal vaccine on August 19, 2020, followed by the flu vaccine over three weeks later, with no reported symptoms until October 9, 2020 (twenty-seven days post-flu vaccine and fifty-one days post-pneumococcal vaccine). *Id.* at 15 (citing Ex. 3 at 15). Respondent states that "there is no data available that present a reliable timeline from vaccination to [the] development of PMR" and thus, Petitioner has not satisfied his burden under *Althen* prong three. *Id.*

V. Applicable Law

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

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9] There is no Table claim for PMR as an injury associated with *any* covered vaccine, so Petitioner can only advance a causation-in-fact claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct.

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

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

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

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

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

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Cerrone v. Sec'y of Health & Hum. Servs.*, 146 F.4th 1113, 1121 (Fed. Cir. 2025); *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019);

see also Howard v. Sec'y of Health & Hum. Servs., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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

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

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical

understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

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

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

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

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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

C. *Analysis of Expert Testimony*

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

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

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

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review*

den'd, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

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

E. *Disposition of Case Without Hearing*

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

ANALYSIS

I. Program Treatment of PMR as Vaccine Injury

It is not all that clear from the medical record whether Petitioner did likely experience PMR. While Dr. Efthimiou clearly favors the diagnosis, Dr. Kinet is more equivocal in embracing it, and cited some aspects of Petitioner's presentation inconsistent with PMR. *See, e.g.*, Kinet Rep. at 4. Certainly many of Petitioner's treaters do seem to have accepted the diagnosis.

But in the end, resolution of the claim does not turn on diagnosis—for even if PMR is assumed to be Petitioner's injury, it has not generally been deemed in the Program *to be* vaccine-caused. *See generally Munoz v. Sec'y of Health & Hum. Servs.*, No. 21-1369V, 2024 WL 4113486 (Fed. Cl. Spec. Mstr. Aug. 12, 2024) (Tdap vaccine not causal of PMR), *mot. for review den'd,* 174 Fed. Cl. 276 (2024), *appeal docketed*, No. 25-1409 (Fed. Cir. Feb. 4, 2025); *Sciortino v. Sec'y of Health & Hum. Servs.*, No. 22-99V, 2024 WL 4579389 (Fed. Cl. Spec. Mstr. July 24, 2024) (flu vaccine not shown causal of PMR); *Thompson v. Sec'y of Health & Hum. Servs.,* No. 18-1217V, 2023 WL 9053982 (Fed. Cl. Spec. Mstr. Dec. 5, 2023) (SM Oler) (pneumococcal vaccine not found causal of claimant's PMR); *Van Dycke v. Sec'y of Health & Hum. Servs.,* No. 18-106V, 2023 WL 4310701 (Fed. Cl. Spec. Mstr. June 7, 2023) (SM Dorsey) (Tdap vaccine not found causal of claimant's PMR); *Giesbrecht v. Sec'y of Health & Hum. Servs.,* No. 16-1338V, 2023 WL 2721578 (Fed. Cl. Spec. Mstr. March 30, 2023) (SM Moran) (flu vaccine not found causal of claimant's PMR); *Kelly v. Sec'y of Health & Hum. Servs.,* No. 17-1475V, 2022 WL 1781957 (Fed. Cl. Spec. Mstr. Oct. 12, 2022) (SM Horner) (flu vaccine not found causal of claimant's PMR); *Suliman v. Sec'y of Health & Hum. Servs.,* No. 13-993V, 2018 WL 6803697 (Fed. Cl. Spec. Mstr. Nov. 27, 2023) (SM Roth) (Tdap vaccine not found causal of claimant's PMR). All of these decisions provide persuasive, useful guidance for resolving this matter.

One on-point determination is *Thompson,* since it also involves the pneumococcal vaccine. There was no dispute as to the accuracy of the PMR diagnosis in that case. *Thompson,* 2023 WL 9053982, at *2. That petitioner's causal theory was that the vaccine promoted (as part of the innate immune response) upregulation of cytokines, leading to immune dysregulation followed by an autoimmune condition. *Id.* at *13. The special master found, however, that theory proposed over-relied of aberrant cytokine upregulation (an oft-rejected concept) and literature involving different vaccines. *Id.* at *14–16. She also emphasized how many times other special masters had rejected theories of vaccine causation of PMR. *Id.* at *16 (citing five prior decisions, including *Suliman, Kelly, Giesbrecht,* and *Van Dyke*).

Several other decisions (including opinions I have authored) have found the flu vaccine was not causal of PMR. *See, e.g.*, *Sciortino*, 2024 WL 4579389, at *12. In so finding in *Sciortino*, I noted that the petitioner's theory largely mirrored what has been unsuccessful in prior cases

involving PMR—one that "relies heavily on a cytokine-driven process that conflates innate and immune phases, but largely focuses on the vaccine's initial stimulation of cytokine production" but absent a persuasive or reliable showing that that such upregulation of cytokines is likely to trigger a disease process that involves several other aspects of the immune response. *Sciortino*, 2024 WL 4579389 at *13. *Giesbrecht* turned in part on a special master's finding that petitioner's PMR diagnosis had not been substantiated. 2023 WL 2721578, at *5–7. However, the special master also found that *Althen* prong one had not been met. *Id.* at *7–8. The special master rejected an opinion offered by the same expert in *Sciortino* as suggesting an autoimmune theory of causation for a disease that is not likely to have an autoimmune mechanism, as well as relying on an innate, cytokine driven response which has been repeatedly rejected in numerous prior matters. *Id.*

In *Kelly*, a petitioner's PMR diagnosis was not in dispute, but the special master found that none of the three *Althen* prongs were established. *Kelly,* 2022 WL 1781957, at *8–12. Specifically, the special master criticized the theory's failure to identify target antigens for autoimmune attack, and the lack of evidence suggesting that PMR was autoimmune, that it could be initiated by a specific kind of autoantibody, or that it had any known external trigger. *Id.* at *9. The special master also found comparisons to giant cell arteritis unpersuasive, as well as reliance on case reports weak proof. *Id.* at *10–11.

I also note that I am specifically familiar with the form of causation theory articulated by Dr. Efthimiou in this case, since he has previously proposed a comparable theory in a different case I decided. *See, e.g.*, *Munoz,* 2024 WL 4113486. Although *Munoz* involved the Tdap vaccine, it also featured Dr. Efthimiou—and the opinion he prepared therein (*and* which he verbally offered at a live entitlement hearing) was strikingly comparable to what was filed in this case. Thus, the first report prepared by Dr. Efthimiou in *Munoz* was not only consistent with what was offered in this case, but it features eight of the same citations. *Compare* First Efthimiou Rep. at 18–19 *with* Report, dated June 27, 2022 (ECF No 24-1), filed in *Munoz*. There is effectively little, if anything, new about the argument offered in this case that I did not previously consider in *Munoz*.[10]

II. Petitioner Has Not Carried His Burden of Proof

As is well understood in the Program, the failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient basis for a claim's dismissal. *Dobrydnev v. Sec'y of Health & Hum. Servs.,* 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). This case

[10] Admittedly, *Munoz* is on appeal to the Federal Circuit. But it arrived there only after my dismissal was affirmed by the Court of Federal Claims—and it has plenty of company in finding PMR not likely to be a vaccine-caused adverse event, regardless of the vaccine. It is thus reasonable to reference it as a trustworthy finding, and the holding reflects my own experience directly in evaluating Dr. Efthimiou's opinion.

wholly turns on the first, "can cause" prong—and because I find it has not been preponderantly established, no discussion of Petitioner's success with respect to the other prongs is necessary.

Dr. Efthimiou's causation opinion largely repeats the kinds of arguments that other special masters—including me—have routinely rejected as unpersuasive. *See generally Munoz,* 2024 WL 4113486, at *13. Further, and like experts in past cases, he fails to (a) show a relationship between the flu or pneumococcal vaccine's wild infectious analogs and PMR (evidence that is not required for causation, but would if it existed help bulwark the conclusion that the vaccine could also be causal) (b) identify a specific antigen associated with the development of PMR, (c) persuasively explain (other than by generalities about the immune process) how the specific vaccines in question would cause immune harm resulting in PMR symptoms simply due to innate immune stimulation, and/or (d) demonstrate that Petitioner himself possessed any genetic susceptibility making an adverse reaction resulting in PMR more likely. Petitioner has not otherwise offered any more recently-published scientific or medical studies or articles that would suggest a likely PMR-vaccine association. And he did not persuasively show that the pneumococcal vaccine can be for present purposes deemed interchangeable with the Tdap vaccine (such that any causal association with the latter applies to the former).[11] The pneumococcal vaccine does not include the tetanus toxoid component, and pneumococcal conjugate is not wholly equivalent to the diphtheria component of Tdap, even if pneumococcal vaccine is conjugated to a *diphtheria-like* compound. By contrast, Dr. Kinet effectively and persuasively rebutted Petitioner's causation contentions, showing that PMR is a common malady, and has little in the way of known triggers or mechanistic explanations.

This is, in the end, another matter in which a claimant wants to convert the intended effect of vaccination, and/or a vaccine's understood capacity to provoke some immune response, into something pathogenic, but without sufficient probative evidence to connect all the dots. *Palattao v. Sec'y of Health & Hum. Servs.*, No. 13-591V, 2019 WL 989380, at *36 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) ("claimants cannot transmute scientific evidence exploring how vaccines normally function in the immune system into a reliable and persuasive causation theory that any vaccine can be pathogenic without a more specific showing that applies to the circumstances at hand"). The fact that vaccines provoke an innate response does not mean that response causes injury.

What is ultimately missing is sufficient probative evidence allowing for the conclusion that it is more likely than not that flu and/or pneumococcal vaccine components can trigger PMR, alone or in combination (here an especially attenuated relationship, since one vaccine was administered over three weeks after the second, with no evidence of intervening symptoms or concerns). Instead, there are too many speculative assumptions about the roles prior exposure to the vaccine would play in setting up a disease process. And large leaps are made from evidence that PMR *involves*

[11] I note that in *Munoz* I rejected the contention that the Tdap vaccine can cause PMR, and therefore it is not a given that there is any association at all between Tdap and PMR that can be borrowed in this case, involving two different vaccines.

the presence of certain immune cells (T helper cells, or cytokines) to the conclusion that vaccines not only provoke the production of these cells, but would drive pathogenesis.

The Program has now repeatedly observed a lack of sufficient persuasive scientific/medical evidence preponderantly linking any covered vaccines to PMR. While there are many causation theories involving different kinds of injuries upon which the special masters reasonably disagree, PMR has been routinely rejected as a likely vaccine injury. Accordingly, it is fair to be highly skeptical of petitions involving PMR. Absent some newly-published research on the topic more specific to PMR and/or its studied association with a vaccine, petitioners (and their counsel) would be advised not to continue to pursue claims involving this injury. And now, having again rejected such a claim, it is my reasoned view that *this case* lacks reasonable basis going forward. While I will permit Petitioner to recover fees and costs associated with the case's adjudication to date, I will not compensate counsel for any appeals taken from this decision.

CONCLUSION

Preponderant evidence does not support Petitioner's causation theory. He is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[12]

IT IS SO ORDERED.

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

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