# In the United States Court of Federal Claims
**OFFICE OF SPECIAL MASTERS**
**No. 22-1384V**

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| MARK RADKE, | * | Chief Special Master Corcoran |
| Petitioner, | * | Filed: October 6, 2025 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

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

*Tyler King*, U.S. Department of Justice, Washington, DC, for Respondent.

## ENTITLEMENT DECISION[1]

On September 27, 2022, Mark Radke 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 conjugate vaccine on September 30, 2019. Petition (ECF No. 1) at 1.

The Vaccine Program has routinely dismissed claims alleging PMR as a vaccine injury—regardless of the vaccine involved. Because of my reasoned skepticism that this claim had any more legal basis than matters previously decided, I directed the parties to brief the claim, and they have done so. *See* Petitioner's Brief in Support of Entitlement, dated Jan. 10, 2025 (ECF No. 36) ("Br."); Respondent's Opposition, dated Mar. 21, 2025 (ECF No. 39) ("Opp."); Petitioner's

[1] "Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id."*

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

Rebuttal Brief, dated Apr. 18, 2025 (ECF No. 41) ("Reply"). For the reasons set forth in more detail below, I hereby deny entitlement.

## I. Factual Background

*Pre-Vaccination Medical History*

Petitioner had a number of treatment events in the years before the vaccination at issue that bear on his alleged injury. For example, in mid-2014, injuries to his right knee were deemed by treaters significant enough to make him a good candidate for a knee replacement procedure. Ex. 11 at 19–20. It was observed as early as 2015 that Petitioner had a history of lower limb neuropathy, featuring paresthesias and reduced reflexes, that impacted his ambulation. Ex. 19 at 268–70, 306–07. These neurologic issues lead in February 2015 to a diagnosis of peripheral neuropathy. *Id.* at 270. An EMG[3] performed that spring confirmed the presence of early axonal sensorimotor neuropathy. *Id.* at 266. These kinds of symptoms continued to plague Petitioner in 2015, although treaters did not propose any neuropathic-specific medications or comparable interventions. *Id.* at 216–17.

In 2017, Petitioner sought treatment for a worsening rash, as well as reported muscle weakness and fatigue. Ex. 19 at 271, 273. He underwent a brain MRI that August, although the findings shed no light on possible explanations for some of his complaints. Ex. 18 at 58. He was again treated for neuropathic symptoms, and now reported mild progression to his upper extremities. Ex. 20 at 3, 7. Petitioner informed some neurologists that the symptoms had existed for several years. Ex. 14 at 1, 4. Testing did not, however, aid in identifying an etiologic explanation for these symptoms. *Id.* at 6–10. In the fall of 2017, Petitioner also saw an endocrinologist, who proposed that alcohol use might explain Petitioner's condition. Ex. 15 at 33.

Petitioner continued in 2018 to explore his conditions with a variety of treaters. He sought help in January 2018 for head pain and strange sensations, although testing identified no explanation for the symptoms. Ex. 14 at 25, 29–31. He reported more neuropathic concerns that summer, coupled with weakness and fatigue, but a repeat MRI revealed nothing of concern. *Id.* at 39, 43–45. He reported tinnitus and hearing loss in October 2018. Ex. 13 at 45, 47. And in July 2019 (two months before vaccination), he again sought treatment for tinnitus and polyneuropathy concerns, although his symptoms were then deemed to be stable. Ex. 14 at 58.

*Vaccination and Purported Adverse Impact*

Mr. Radke was sixty-seven years old when he received a pneumococcal vaccine on September 30, 2019. Ex. 2 at 21. There is no medical record evidence of any immediate reaction

[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 contradictions, 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 Oct. 6, 2025).

to the vaccination. Two days later (October 2, 2019), Petitioner went to see his neurologist, Dr. Terry Wimpey, for follow-up evaluation of his preexisting neuropathy symptoms. Ex. 3 at 2. Petitioner now stated that he had been feeling increasing right leg neuropathy for the past week (which would mean prior to the vaccination), and that he was feeling "pain behind his calf associated with the neuropathy and muscle tightness" which was causing him to limp. *Id*. Examination revealed nothing inconsistent from prior treatment encounters, however, and Petitioner was referred to physical therapy ("PT") for treatment of his symptoms. *Id*. at 6.

A month later (November 1, 2019), Petitioner went to orthopedist John Manfredi for treatment of his prior, ongoing right knee pain. Ex. 11 at 16. He now stated, however, that it had worsened over the past month, and maintained that he had experienced pain and swelling the day after vaccination. *Id*. X-rays of Petitioner's right knee, however, revealed only evidence of preexisting knee concerns (severe degenerative changes in the knee and calcifications throughout the medial femoral condyle). *Id*. at 17. Petitioner was provided a lidocaine injection at this visit to treat his knee. *Id*.

That same November, Petitioner saw a different orthopedist for shoulder pain that he related to falling out of bed the prior month. Ex. 4 at 2. He fell a second time in November, resulting in an emergency room visit. Ex. 2 at 94. He claimed at this time that he had been experiencing chronic muscle aches, weakness, and headaches following his receipt of a pneumococcal vaccine. *Id*. His examination was normal, additional testing did not reveal any concerns, and he was eventually discharged home. *Id.* at 95. A post-ER visit to Dr. Wimpey resulted in the same kind of normal exam, but blood work revealed a somewhat-elevated CRP[4] and sedimentation rate—both of which are biomarkers for inflammation. Ex. 9 at 138–39. Later in November, Petitioner began PT for right shoulder and knee issues (and was later discharged from PT the following winter after reporting improvement). Ex. 16b at 1, 106.

On December 6, 2019, Mr. Radke saw rheumatologist Sana Makhdumi, M.D., with complaints of weight loss, fever, and night sweats, which he deemed to have begun two days after his receipt of the pneumococcal vaccine. Ex. 5 at 95. But the sole abnormality identified after examination was "some pain" upon rotation of Petitioner's hips. *Id.* at 96. Dr. Makhdumi was unable to propose an explanation for Petitioner's complaints, although she did express concern that he was experiencing some form of inflammatory arthritis—PMR or rheumatoid arthritis—that could have an infectious or neoplastic cause. *Id*. Dr. Makhdumi prescribed a steroid taper, and also tested for two viral infections (Epstein-Barr ("EBV") and cytomegalovirus ("CMV")). *Id.* Petitioner tested positive for a prior/resolved EBV infection, and also again displayed an elevated

[4] "C-reactive Protein" is defined as "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 (last visited Oct. 6, 2025).

sedimentation rate (although it was deemed within a normal limit after repeat testing from the following month). Ex. 9 at 127, 130–31.

*2020 Treatment*

On January 7, 2020, Petitioner returned to Dr. Makhdumi for follow up of his symptoms. Ex. 5 at 93. He felt the prednisone was not working, and he was experiencing side temporal headaches. *Id*. Examination revealed some limitations with movement of Petitioner's spine, knees, and hips. *Id*. at 94. Dr. Makhdumi's differential diagnosis now included giant cell arteritis versus PMR versus reactive arthritis, and she altered his steroid dose while referring him for a temporal artery biopsy and eye exam. *Id*. The eye exam yielded normal results, however, and Petitioner later decided to cancel the biopsy. Ex. 5 at 91; Ex. 12 at 10–14. Petitioner also saw Dr. Wimpey in January, and reported a cessation of headaches and improvement in how his shoulder felt. Ex. 14 at 89.

In February, Dr. Makhdumi reduced Petitioner's prednisone dose, while maintaining a differential comparable to what she had previously proposed (and keeping PMR in it). Ex. 5 at 88–89. Petitioner again visited the ER that month, complaining of left upper extremity numbness, heart flutters, mild left sided chest tightness, disequilibrium, and two days of mild urinary frequency. Ex. 2 at 170. But his exam was normal and he was again discharged. *Id*. at 173. He had a second ER visit later that month, reporting right calf pain and swelling. *Id.* at 223–24. An ultrasound showed fluid collection consistent with a ruptured Baker's cyst, and it was treated. *Id*. at 227.

On March 19, 2020, Petitioner saw rheumatologist Stephen Elmore, M.D., for a second opinion regarding his symptoms, which he felt were not being ameliorated by prednisone. Ex. 5 at 80. Examination revealed some soreness to Petitioner's shoulders with range of movement, slightly decreased strength, and tenderness to Petitioner's right wrist. *Id*. at 82. Dr. Elmore expressed concern for PMR versus seronegative rheumatoid arthritis, and proposed more blood tests plus different medications. *Id*. at 83. Petitioner continued to see Dr. Elmore in the coming months. Ex. 5 at 74 (June visit), 75, 78 (May 2020 visit). Dr. Elmore again noted difficulty in assessing the nature of Petitioner's illness (while maintaining PMR in the differential), but also observed that there was no evidence of inflammatory biomarkers, and that treatments were presuming that some kind of rheumatic condition existed. By July, however, Petitioner informed Dr. Elmore that he felt better overall, and Dr. Elmore directed a tapering of Petitioner's prednisone treatments. *Id.* at 65. A similar assessment was provided by Dr. Elmore in September. *Id*. at 24–25, 60, 63.

*Treatment Beyond 2021*

Petitioner has produced a large number of medical records reflecting treatment he received from 2021 to the fall of 2022, but they shed little to no light on the issue of vaccine causation. Petitioner continued at times to deem some of his non-orthopedic symptoms to reflect PMR, and/or to identify them as beginning close-in-time to vaccination. And while PMR remained a fair explanation for these symptoms, no treaters appear to have themselves proposed a vaccination-related etiology for it. *See, e.g.*, Ex. 5 at 5 (September 2022 visit with Dr. Elmore).

## II. Expert Opinions

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

Dr. Efthimiou, a rheumatologist, offered three written reports on behalf of Petitioner. *See* Report, dated Aug. 15, 2023 (ECF No. 25-1) ("First Efthimiou Rep."); Report, dated Apr. 19, 2024 (ECF No. 30-2) ("Second Efthimiou Rep."); Report, dated Sept. 13, 2024 (ECF No. 35-1) ("Efthimiou Third Rep."). Dr. Efthimiou opined that Petitioner's receipt of the pneumococcal vaccine "more likely than not was a substantial factor contributing to the onset of clinical polymyalgia rheumatica" herein. 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. 26 (ECF No. 25-2) ("Efthimiou CV"). 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. Efthimiou CV at 3; First Efthimiou Rep. at 1. Throughout his clinical career, Dr. Efthimiou frequently evaluates and treats 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 maintained at the outset of his first report that "[t]he current understanding of the pathogenesis of PMR is a consensus model of immune-mediated disease that includes the interaction of multiple factors, both genetic and environmental." First Efthimiou Rep. at 15; D. Camellino et al., *Pathogenesis, Diagnosis and Management of Polymyalgia Rheumatica*, 36 Drugs & Aging 1015 (2019), filed as Ex. 28 (ECF No. 25-4). Given the understood likely pathogenesis for it, Dr. Efthimiou deemed it reasonable to propose that multiple vaccine types could be associated with triggering the clinical onset of the disease—noting that PMR can be clinically expressed in predisposed individuals by an environmental stimulus, such as an infection or

vaccination. There is generally a broad spectrum for inflammatory rheumatic diseases, and that spectrum includes autoinflammatory and autoimmune diseases. First Efthimiou Rep. at 17; 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. 30 (ECF No. 25-6) ("Hysa") (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"). As a result, Dr. Efthimiou opined, it did not matter where PMR fit on that spectrum, since "the vaccines administered can reliably explain clinical onset of either subtype of immune mediated response." First Efthimiou Rep. at 17.

Dr. Efthimiou maintained that PMR likely clinically presents due to an environmental trigger, such as infection or vaccination, which then dysregulates an individual's T-cell response. First Efthimiou Rep. at 17. In support, he referenced government publications about how vaccine-caused adverse events can occur. *Committee to Review Adverse Effects of Vaccines: Evidence and Causality* 59–60 (K. Stratton et al., eds., 2012), filed as Ex. 33 (ECF No. 25-9) (the "IOM Rep.") (listing T-cells as an immune-medicated mechanism that likely contributes to the development of adverse events after vaccination). T-cells , he contended, contribute to an individual's maintenance of the immune system and self-tolerance. First Efthimiou Rep. at 18. But PMR is understood to mechanistically arise as a result of the disruption of one's self-tolerance by certain T-cells and their inability to prevent autoreactivity. *Id.*

Components in a particular vaccine could initiate autoreactive T-cells that in turn attack the body by providing immune signals leading to dysregulation and clinical disease onset. First Efthimiou Rep. at 18. Here, Petitioner may have already possessed these autoreactive cells due to previous vaccine exposure or some different environmental exposure. *Id.* 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.* at 18–19; IOM Rep. at 82 (explaining that both epidemiological and mechanistic research has recognized that individuals experiencing an adverse reaction to vaccine administration have a predisposition that can exists for several reasons, including genetics, intervening illness, or prior immunological and environmental exposures).

Medical literature has recognized an association between the seasonal flu vaccine and the Tdap vaccine, on the one hand, and PMR, and in Dr. Efthimiou's view such evidence bore on Mr. Radke's circumstances (although the vaccine involved in this case is different). First Efthimiou Rep. at 19. The pneumococcal vaccine covered by the Program and at issue herein contains an adjuvant, and pneumococcal proteins are conjugated to the carrier protein, Diphtheria CRM 197—thus, making any reported associations with the Tdap vaccine (which includes the same diphtheria proteins) relevant when analyzing Petitioner's case, in Dr. Efthimiou's opinion *Id.* at 20. He further explained that because these vaccines share the diphtheria toxoid component, they can both elicit

B-cell responses in a T-cell dependent manner, making it reasonable to conclude that Petitioner's immune response post-vaccination became more susceptible to triggering cross-reactive immune memory cells, and hence causing PMR. *Id.*

*Second Report*

Dr. Efthimiou's second report responded to comments made by Respondent's expert, Dr. Chester Oddis. He first addressed Dr. Oddis's opinion that Petitioner's more likely diagnosis was an "exaggerated pain response," evidenced by interactions with his surgeon following his knee replacement surgery. Second Efthimiou Rep. at 1. Dr. Efthimiou maintained in reaction that studies have reported that "peripheral arthritis has been described in up to 50% of patients with PMR with knee involvement present in the majority." *Id.* (citing M. Cimmino et al., *High Frequency of Capsular Knee Involvement in Polymyalgia Rheumatica/Giant Cell Arthritis Patients Studied by Positron Emission Tomography*, 52 Rheumatology 1865 (2013), filed as Ex. 40 (ECF No. 30-3)). Moreover, recent research on the pathophysiology of PMR has confirmed the frequency of knee involvement. *See* K. Kobayashi et al., *Ultrasound of Shoulder and Knee Improves the Accuracy of the 2012 EULAR/ACR Provisional Classification Criteria for Polymyalgia Rheumatica*, 61 Rheumatology 1185, 1180 (2022), filed as Ex. 41 (ECF No. 30-4) (finding that the data revealed not only the shoulder but also the knee [as] the joint where [ultrasound] abnormalities are frequently detected … 95% of patients with definite PMR had some [ultrasound] abnormalities in the knee, whereas 77% and 10% had tenderness and swelling, respectively.").

Here, between October and November 2019 (and hence after the September vaccination), Mr. Radke reported that his chronic right knee pain had worsened, and he noticed an acute change in pain over the past month. Second Efthimiou Rep. at 1; Ex. 24 and 139. Petitioner consistently reported a difference in his knee pain to his primary care physician, Dr. Young, and also pain that occurred suddenly. Because, Dr. Efthimiou argued, "PMR arthritis is an inflammatory arthritis that is known to occur suddenly, and joint "warmth" is a hallmark of inflammatory arthritis"—both of which were reported and documented in Petitioner's medical records—the onset of these problems was consistent with a PMR diagnosis. Second Efthimiou Rep. at 3.

Dr. Efthimiou then described atypical PMR, and how it relates to Petitioner's clinical presentation. Second Efthimiou Rep. at 3. While patients with "classic" PMR present more commonly with bilateral shoulder abnormalities (such as bursitis or bicep tenosynovitis), patients with an "atypical" clinical presentation commonly report a history of pain and swelling in the knee, symptoms of carpal tunnel syndrome, or pain localized to both knees with radiation. *Id.* at 4; M. Fitzcharles & J. Esadile, *Atypical Presentation of Polymyalgia Rheumatica*, 33 Arthritis & Rheum 403, 406 (1990), filed as Ex. 42 (ECF No. 30-5) (describing six patients that did not present with any symptoms referable to the limb girdles, and where five out of the six patients developed a more typical presentation of PMR over the course of two to twelve months). Dr. Efthimiou noted, however, that "the differential diagnosis of PMR can have overlapping symptoms" and that "[t]he most challenging mimicking disorder" is seronegative RA. Second Efthimiou Rep. at 4.

Concurring with Dr. Oddis, Dr. Efthimiou maintained that seronegative RA, along with other mimicking PMR disease, had properly been ruled out by Petitioner's treating physicians. *Id.*

Regarding Petitioner's inflammatory markers throughout his treatment course, Dr. Efthimiou noted that Mr. Radke had two documented increases—on May 5, 2020, and February 21, 2022. *Id.* Although Dr. Oddis argued that Petitioner's inflammatory markers were not consistently concordant, Dr. Efthimiou responded that "[s]ymptoms and ESR/CRP levels[5] are often not concordant"—stating that "[p]atients with PMR can present with normal ESR values and in patients with relapse, ESR levels have been observed in 68% of cases and CRP levels normal in 62% of cases." *Id.* at 5 (referencing M. Florescu et al., *Polymyalgia Rheumatica: An Update (Review)*, 26 Experimental & Therapeutic Medicine 1, 4 (2023), filed as Ex. 44 (ECF No. 30-7). Despite the medical records demonstrating multiple instances of normal labs over the course of Petitioner's treatment course, Dr. Efthimiou opined that Petitioner exhibited a "relapsing course [of PMR] that requires longer treatment." Second Efthimiou Rep. at 5 (emphasizing Dr. Oddis' citation to literature discussing slower response times to treatment with low-dose glucocorticoids).

Dr. Efthimiou concluded his second report reiterating his opinion in the matter—that Petitioner's development of PMR was likely triggered by his receipt of the pneumococcal vaccine, and that his clinical presentation and course is most representative of a probable post-vaccination cause. *Id.* at 6.

*Third Report*

In his final report, Dr. Efthimiou addressed the assertion of Respondent's other expert, Dr. Stephen Jameson, that it is essential to consider whether there is a likely link between a given vaccine and a given autoinflammatory disease in the medical literature. Third Efthimiou Rep. at 2. In response, Dr. Efthimiou instead maintained that his own analysis "focused on reliably explaining why the vaccines administered and [Petitioner's] sequence of immunological events is supported by both the clinical evidence and a biologically plausible mechanistic explanation …" *Id.* Moreover, Dr. Efthimiou reiterated that his proposed medical theory for causally linking Petitioner's receipt of the vaccine and his development of PMR was based on reliable medical and scientific information available within the field of PMR. *Id.*

Dr. Efthimiou briefly acknowledged his disagreement with Dr. Jameson's understanding of the level of support needed in the medical literature to confirm a medical theory causally connecting the pneumococcal vaccination and PMR. Third Efthimiou Rep. at 3. He explained that

[5] ESR stands for "erythrocyte sedimentation rate," and 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 (last visited Oct. 6, 2025).

both, "scientific" and "medical" literature are necessary when evaluating Petitioner's overall clinical sequence—and here, Dr. Efthimiou argued, the literature supports a finding that Petitioner's vaccination and subsequent development of PMR represents a vaccine-associated cause. *Id.* at 3–4. In his own analysis, Dr. Efthimiou stated that he examined "the totality of th[e] clinical information that supports how a biologically plausible mechanistic link connects the pneumococcal vaccination to being capable of initiating the understood adverse pathology of PMR illness." *Id.* at 4.

Dr. Efthimiou then addressed criticisms that he had generalized outcomes of other case studies involving different vaccines with triggering the onset of PMR in certain individuals. He noted, however, that such studies are "not intended, especially in isolation, to provide general conclusion," yet "if epidemiological studies observed an increased risk of PMR illness in association with receiving pneumococcal vaccines, administration of the vaccine would not be recommended." Third Efthimiou Rep. at 5 (citing T. Shimabukuro et al., *Safety Monitoring in the Vaccine Adverse Event Reporting System (VAERS)*, 33 Vaccine 4398 (2015), filed as Ex. 47) (ECF No. 35-2). Similarly, such clinical associations with different types of vaccine antigens, does not, according to Dr. Efthimiou, "equate to different adverse biological mechanisms explaining how a patient's PMR illness can reliably be pathologically caused within a few days." Third Efthimiou Rep. at 7.

Thus, relying on the timing of Petitioner's vaccination and his overall clinical presentation, plus indirect evidence such as the various cited case reports, and the VAERS data directly associating the pneumococcal vaccine with PMR, Dr. Efthimiou maintained Petitioner's PMR had likely been vaccine-caused.

B. Respondent's Experts

*1. Chester V. Oddis, M.D.*

Dr. Oddis, a rheumatologist, offered one written report on behalf of Respondent. *See* Report, dated Dec. 26, 2023 (ECF No. 29-1) ("Oddis Rep."). Based on his years of experience in the practice clinical inpatient and outpatient rheumatology, Dr. Oddis opined that Petitioner did not have PMR, and that he also did not suffer from vaccine-induced PMR. Oddis Rep. at 12.

Dr. Oddis received his undergraduate degree from the University of Pittsburgh, and his medical degree from Pennsylvania State University College of Medicine. He is board-certified in both Internal Medicine and Rheumatology. Oddis Rep. at 1. Dr. Oddis is currently Professor of Medicine in the Division of Rheumatology and Clinical Immunology and the Director of the Myositis Center in the School of Medicine at the University of Pittsburgh. *Id.* His primary area of research and clinical care is in the clinical, epidemiologic, serologic and treatment aspects of myositis and autoimmune interstitial lung disease. *Id.* Dr. Oddis has also published numerous journal articles on these subjects. *Id.* at 2. Over the course of his clinical career, Dr. Oddis has

diagnosed, treated, and managed the care of many individuals with PMR and other rheumatological disease. *Id.*

Dr. Oddis summarized the pertinent medical facts before discussing PMR in general. *See generally* Oddis Rep. at 2–8. PMR is understood as a common inflammatory rheumatic condition, oftentimes characterized by prominent morning stiffness of the shoulder, hip girdle, and neck. *Id.* at 8; C. Salvarani & F. Muratore, *Clinical Manifestations and Diagnosis of Polymyalgia Rheumatica*, UpToDate (Oct. 2023), filed as Ex. A Tab 1 (ECF No. 29-2) ("Salvarani") at 1. PMR is found in individuals almost exclusively over the age of 50, and with a peak incidence occurring between the ages of 70 and 80. Oddis Rep. at 8; Salvarani at 2. Dr. Oddis further explained that the clinical manifestations of PMR include an abrupt onset of symmetrical aching and stiffness of the shoulders, hip girdle, neck and torso, with pain being the worst in the morning. Oddis Rep. at 8; Salvarani at 4. Approximately 70–95% of patients with PMR will exhibit bilateral shoulder pain as the presenting clinical manifestation, with about 50% exhibiting lower extremity symptoms. Salvarani at 4. Patients with PMR, however, can also present with non-specific signs or symptoms, such as malaise, fatigue, depression, weight-loss or low-grade fever. *Id.* at 5; Oddis Rep. at 8.

Dr. Oddis then discussed the common laboratory findings in PMR—emphasizing the significance of the diagnostic value of ESR and CRP. Oddis Rep. at 9. ESR, the "traditional laboratory finding in PRM," typically ranges from mildly to markedly increased, whereas CRP is "nearly always elevated." Salvarani at 5 (stating that "in two reports, an elevated ESR (greater than 30 mm/hour) was noted in 92 to 94 percent of patients at the time of diagnosis of PMR, while 99 percent of such patients had an increased serum CRP level (greater than 5mg/L)."). Here, Petitioner's inflammatory markers, specifically ESR and CRP, were not "consistently concordant with either an improvement or an exacerbation of PMR symptoms." Oddis Rep. at 10. Similarly, during a follow-up with Dr. Young on June 15, 2021, Petitioner reported "constant morning stiffness" but his inflammatory markers at that time were noted as within the normal range. Ex. 5 at 46, 49. Dr. Oddis stated that this instance, among others noted in the medical records, indicates an inconsistency between Petitioner's symptoms and lab results and proposed diagnosis. Oddis Rep. at 10.

The initial treatment course for PMR typically involves the use of low-dose glucocorticoids (i.e., Prednisone) and the therapeutic response is understood to be brisk and complete. Oddis Rep. at 9. Patients oftentimes start with a suggested dose of 15mg/day; however, lower dosages may be more appropriate for certain individuals. *Id.* On the other hand, chronic management of PMR involves the gradually tapering of the Prednisone dosage, of which the duration of treatment can vary among individuals (i.e., some patents can wean off treatment in 1 to 2 years, while others require longer). *Id.* Dr. Oddis emphasized not only how unusual it was that Petitioner's Prednisone dosage fluctuated greatly throughout his treatment course, but that the dosage often exceeded 20mg/day—a level that generally aids in alleviating symptoms of PMR quickly and completely. *Id.* at 11; C. Salvarani & F. Muratore, *Treatment of Polymyalgia Rheumatica*, UpToDate (Oct. 2023), filed as Ex. A Tab 2 (ECF No. 29-3) at 1–2.

Based on the medical records and literature, Dr. Oddis opined that Petitioner more than likely did not have PMR. Oddis Rep. at 11. Petitioner's symptoms did not feature the classical presentation of bilateral shoulder pain and hip stiffness that improves throughout the day and responds well steroid treatment. *Id.* at 10. Moreover, Petitioner's treating physicians were not confident that his overall signs and symptoms were consistent for a diagnosis of PMR—and Dr. Oddis referenced a note from an April 2, 2020, visit with Dr. Young that stated "[w]e discussed that [Petitioner's] presentation has not been classic for PMR … the doses of prednisone which have relieved [Petitioner's] symptoms are higher than which would normally be used in PMR." *Id.* at 11 (citing Ex. 24 at 186). In addition, Petitioner's treating physicians ruled out other inflammatory and non-inflammatory diseases that can sometimes mimic PMR, such as elderly onset Rheumatoid Arthritis, late-onset Spondyloarthropathy, Inflammatory Myopathy, Lupus, various forms of Vasculitis, Calcium pyrophosphate Deposition Disease, or infection. Oddis Rep. at 9.

*2. Stephen C. Jameson, Ph.D.*

Dr. Jameson, an immunologist, offered one written report on behalf of Respondent. *See* Report, dated June 25, 2024 (ECF No. 34-1) ("Jameson Rep."). Dr. Jameson opined that it is more likely than not Petitioner's receipt of the pneumococcal vaccine on September 20, 2019, did not cause his development of PMR. Jameson Rep. at 5.

Dr. Jameson attended the University of Bristol, England for his undergraduate degree in Cellular Pathology, and the University of Cambridge, England for his Ph.D. in Physiology and Genetics Research. Curriculum Vitae, filed as Ex. C (ECF No. 34-4) ("Jameson CV") at 1. He then completed a post-doctoral fellowship in Immunology at the Scripps Research Institute, La Jolla, California, and the University of Washington, Seattle, before establishing his own laboratory at the University of Minnesota in 1995. *Id.*; Jameson Rep. at 1. Dr. Jameson is currently a Professor in the Center for Immunology, Masonic Cancer Center and Department of Laboratory Medicine and Pathology, at the University of Minnesota Medical School. Jameson Rep. at 1–2. He has published over 130 primary research papers, as well as over 50 review articles—nearly all focusing on various topics in immunology and on the immune response to pathogens. *Id.* at 2. Dr. Jameson's primary research focus is the study of cellular immune response against pathogens and vaccines via animal models, and the impact the studied immune responses have on protective immunity, immunopathology, and autoimmunity. *Id.*

Dr. Jameson primarily focused his brief report on responding to Dr. Efthimiou's proposition that Petitioner's immune response to his receipt of the pneumococcal vaccine subsequently led to his development of PMR. The innate immune response, explained Dr. Jameson, can be considered as "the acute response to infection, vaccination or tissue damage" that typically leads to the subsequent induction of inflammatory responses. Jameson Rep. at 3. This response involves several different cell types—predominantly myeloid cells, such as macrophages. *Id.* When an individual has an immune response to a trigger such as an infection or vaccination,

however, it is the secondary, adaptive immune response (involving primarily T- and B-cells) that takes over. *Id.* This is because macrophages are usually insufficient in containing an individual's immune response to infection or vaccination. *Id.* Specifically, T-helper cells promote the activation of B-cells which then lead to the production of "potent high-affinity antibodies, capable of neutralizing the pathogen or its toxins." *Id.* And when a cooperative response exists between T-cells and B-cells, their populations of cells can persist long-term, thus, creating immunological memory. *Id.* Therefore, any future exposure to the same or related pathogens will essentially trigger faster and more effective control via the adaptive immune response, Dr. Jameson opined. Jameson Rep. at 3. However, because vaccines (like the pneumococcal vaccine) are attenuated, "effective immune memory is typically generated without excessive or prolonged inflammation." *Id.*

Dr. Jameson briefly responded to Dr. Efthimiou's assertion that aspects of the innate and adaptive immune response have been observed in immunopathological responses, such as autoimmunity and autoinflammatory diseases—relied upon by Dr. Efthimiou for his contention that PMR may involves both autoimmunity and autoinflammatory characteristics. Jameson Rep. at 3. Dr. Jameson, however, argued that simply because the same types of pathways are involved in protective immune responses and those that lead to autoimmune and/or autoinflammatory disease, does not on its own, lead to the conclusion that one type of pathway will likely lead to illness. *Id.* If this were true, every infection or vaccination would lead to "damaging autoinflammatory diseases and multiorgan autoimmunity", even though that is not the case. *Id.* Instead, Dr. Jameson maintained that the similarity between the types of pathways involved in protective and damaging inflammatory/immune responses can exist without being causally related. *Id.*

When considering whether a causal link exists between a given infection or vaccination and a specific autoimmune/autoinflammatory disease, Dr. Jameson maintained, the scientific community looks for reliable evidence such as epidemiological and mechanistic studies (although he admitted that establishing sound bases for concluding causality under such circumstances was difficult). Jameson Rep. at 3, 4. But here, there was very little in the way of medical literature suggesting the existence of a causal link between infections and/or vaccination and PMR. *Id.* at 4. At most, Dr. Efthimiou had offered articles that discuss a possible connection between PMR and the flu or Tdap vaccines— neither of which were relevant to Mr. Radke's case. Indeed, one such article ultimately concluded that "a causal association between [influenza vaccination] and GCA or PMR is not supported by adequate evidence." *Id.*; E. Liozon et al., *Giant Cell Arteritis or Polymyalgia Rheumatica after Influenza Vaccination: A Study of 12 Patients and a Literature Review*, 20 Autoimmunity Rev. 1 (2021), filed as Ex. 32 (ECF No. 25-8) ("Liozon") at 5.

Dr. Efthimiou also proposed "a somewhat tortuous link" for a causal association, Dr. Jameson argued. Jameson Rep. at 5. Dr. Efthimiou had attempted to demonstrate an association between pneumococcal vaccine and PMR based upon the fact that the Tdap and pneumococcal vaccines share the same conjugate CRM197 component, and therefore, the pneumococcal vaccine

could also provoke the onset of PMR. *Id.*; *see also* P. Falsetti et al., *Polymyalgia Rheumatica following Infective Triggers or Vaccinations: A Different Subset of Disease?*, 58 Rheumatologia 76 (2020), filed as Ex. 29 (ECF No. 25-5) ("Falsetti") at 3 (finding that two out of six patients received a Tdap vaccination prior to the onset of PMR). Dr. Jameson, however, took issue with Dr. Efthimiou's reliance on Falsetti—arguing that "all [one] can glean from [the] report is that those patients received tetanus toxoid vaccines—and since tetanus toxoid is *not* a component of the Prevnar 13 pneumococcal conjugate vaccine received by [Petitioner], this undercuts Dr. Efthimiou's argument that the presence of diphtheria toxin in Prevnar 13 provides a mechanistic basis by which it could induce PMR, based on the literature." Jameson Rep. at 5.

Dr. Jameson maintained that Dr. Efthimiou's generalization that the "elements of the immune system that are involved in the response to vaccines are also involved in autoimmune response" is "not pertinent" when analyzing whether Petitioner's receipt of the pneumococcal vaccine on September 13, 2019, most likely led to his development of PMR. Jameson Rep. at 5. He opined instead that based on Petitioner's clinical presentation and course, as well as the medical literature, it is more likely than not that Petitioner's receipt of the vaccine at issue did not cause his alleged injury. *Id.*

## III. Procedural History

As noted above, this matter was initiated in September 2022. Respondent filed a status report on April 12, 2023, indicating his intent to defend the matter, but acknowledging the lack of filed medical records at that time. *See* Status Report, dated Apr. 12, 2023 (ECF No. 19). Petitioner completed the filing of all pertinent medical records on August 15, 2023. Thereafter, the process of obtaining expert reports began, with the final report from Dr. Efthimiou filed in September 2024. I issued a scheduling order on October 2, 2024, setting forth a briefing scheduling 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 maintains that the evidentiary record preponderantly establishes that PMR is his proper diagnosis. Br. at 1–2. As support, Petitioner emphasizes that following the receipt of the vaccine he reported symptoms of chills, muscle aches, and joint aches, and that he continued to report such clinical symptoms of PMR in the weeks after. *Id.* at 2, 3. In addition, several of Petitioner's treating physicians involved in his care "opined that [Petitioner] diagnostically suffered from a clinical picture that included the diagnosis of PMR, even though his clinical picture represents a refractory subtype of PMR illness. *Id.* at 2 (referencing Ex. 5 at 93–95; Ex. 2 at 53; Ex. 5 at 36). Moreover, Petitioner's current treating rheumatologist opined in a filed stated that he would "lean more towards a diagnosis of PMR" and that Petitioner's "largest areas of symptom

involvement included his shoulders with some lower extremity and hand involvement. *Id.* at 6 (citing Dr. Elmore Treater Letter, dated July 22, 2024 (ECF No. 35-3) at 1, 2). And through highly relevant and recently published items of literature, Petitioner argues that Dr. Efthimiou provided "reputable support for his opinion that PMR patients are known to have a similar clinical of medical facts as [Petitioner]." Br. at 8.

Petitioner next asserts that he has provided a logical sequence of cause and effect showing that the pneumococcal vaccine is the reason for his PMR injury. Br. at 15. Based on the objective medical records and the cited medical literature, Dr. Efthimiou preponderantly explained how Petitioner's clinical presentation of pain, the morning stiffness, the generalized aches and pains, the weight loss, and symptoms of fatigue were all indicative, according to Dr. Efthimiou, that Petitioner was more likely than not suffering from an inflammatory condition consistent with the diagnosis of PMR. *Id.* at 16. Because Petitioner's symptoms started "abruptly" within several days post-vaccination, and there being no record evidence to suggest Petitioner suffered similar symptoms prior to receipt of the vaccine, a logical sequence of cause and effect has been shown. *Id.* at 17. Furthermore, Dr. Efthimiou found no other cause factors present in Petitioner's medical history, clinical presentation, or alleged by Respondent's experts, that would provide a better causal explanation for Petitioner's development of PMR. *Id.*

Petitioner also maintains that he has established a medically and scientifically reliable theory causally connecting vaccination and the alleged injury. Br. at 21. Relying on clinical evidence and mechanistic data, Dr. Efthimiou preponderantly explained how associations examined in the various cited clinical studies support a causal link that is biologically credible. *Id.* at 22. Petitioner notes that Dr. Efthimiou provided several items of literature demonstrating that more than one vaccine, including pneumococcal, is associated with triggering an onset of PMR. *Id.* at 23. Specifically, Petitioner finds significant that the "most studied and associated" vaccine and an onset of PMR is the flu vaccine—which, Petitioner emphasizes that he "factually received just four weeks prior to [his] receipt of [the] Prevnar 13 vaccine."[6] *Id.* Moreover, because of the identified innate immune mechanism responses common to both the flu and pneumococcal vaccines, Dr. Efthimiou has preponderantly established "how an innate immune response from the Prevnar 13 vaccination can cause the dysregulation of immune cells already present [an] individual." *Id.* at 26. Thus, Petitioner argues that, via multiple types of evidence, Dr. Efthimiou has provided a sound a reliable medical theory.

Lastly, Petitioner briefly maintains that he has established a preponderant showing of a proximate temporal relationship between vaccination and the alleged injury. Br. at 34. Dr.

[6] In his opposition, Respondent "contends that [P]etitioner has not plead this in his petition, nor in the [Motion for Ruling on Record], that the flu vaccine caused in any way his PMR." Opp. at 32. Moreover, Respondent argues that in this regard, Petitioner has failed to demonstrate how the two vaccines working in conjunction could cause PMR. *Id.* at 33. I find that this stray reference is not Petitioner's actual proposed theory in this case (and in any event it would not render the claim more successful, since PMR claims uniformly fail—regardless of the vaccine at issue).

Efthimiou provided items of medical literature—involving the flu vaccine and a subsequent develop of PMR—that adequately supports his assertion that such clinical symptoms can occur within a day of vaccination via the innate immune response. *Id.* at 35. When considering the totality of the evidence (i.e., Petitioner's medical records and the medical and scientific literature), Petitioner maintains that Dr. Efthimiou preponderantly established a medically acceptable timeframe that involves the vaccine initiating a fast and non-specific immune response resulting in the development of PMR. Br. at 35.

*Respondent*

Respondent maintains that Petitioner has the burden of showing a defined and recognized injury by preponderant evidence—and thus must establish PMR was the likely diagnostic explanation for his injury. Opp. at 23. But Petitioner's initial presenting symptoms were not considered the more "classical" onset of proximal shoulder and hip stiffness. *Id.* at 24. Instead, his first symptomatic complaints included weight loss, fatigue, and night sweats, with any report of shoulder pain not occurring until approximately *one-month* post-vaccination. *Id.* Similarly, Petitioner's inflammatory markers, specifically his ESR/CRP levels, were not consistently associated with either his improvement and/or exacerbation of his alleged symptoms. *Id.* at 25. Moreover, his multiple reports of crippling pain and his lack of a complete response to prednisone treatment, is again, unusual with a diagnosis of PMR. *Id.* Accordingly, Respondent contends that Petitioner has failed to prove, by a preponderance of the evidence, that he more than likely suffered from PMR. *Id.*

Respondent further argues that Petitioner has failed to submit preponderant evidence establishing a reliable and persuasive medical theory. Opp. at 27. Respondent first notes that "existing case law overwhelmingly favors a finding that PMR is not caused by vaccines," and that the case adds nothing new to Dr. Efthimiou's previously relied-upon theories of causation in similarly situated vaccine injury claims. *Id.* at 2, 729; *Munoz v. Sec'y of Health & Hum. Servs.*, No. 21-11369V, 2024 WL 4113486 (Fed. Cl. Spec. Mstr. Aug. 12, 2024), *mot. for review den'd*, 174 Fed. Cl. 276 (2024), *appeal docketed*, No. 2025-1409 (Fed. Cir. Feb. 4, 2025). In addition, Dr. Efthimiou's theory is relatively "unclear." Opp. at 29. The cited medical literature is not only "scant," but even Dr. Efthimiou's reliance on several items of literature regarding the flu vaccine and PMR explicitly state the inadequacy of finding a causal association. *Id.* at 31 (referencing Liozon at 5). And while Dr. Efthimiou did present a study that supported the contention that some overlap exists between the pneumococcal and flu vaccines (i.e., specific gene profiles), he failed to identify which of the overlapping genes, if any, is relevant in how vaccines activate the immune response. *Id.* at 33.

Next, Respondent contends that Petitioner has failed to submit preponderant evidence of a logical sequence of cause and effect showing that the vaccination was the reason for his alleged

injury. Opp. at 34. A majority of Petitioner's alleged symptoms either pre-dated the vaccine at issue, were not commonly recognized symptoms of PMR, or were caused by other injuries altogether. *Id.* at 35. For example, his hip pain was consistently attributed to his osteoarthritis by treating physicians and his initial complained of symptoms including fatigue, muscle weakness, and loss of stamina. *Id.* (citing Ex. 5 at 41; Ex. 6 at 2). Moreover, Respondent argues that Petitioner reportedly developed symptoms of PMR approximately twenty-four hours post-vaccination, and relying on Petitioner's own cited medical literature, such a timeframe is far too quick for such a disease onset. Opp. at 35.

Respondent concludes his argument by stating that Petitioner did not present any reliable evidence, that is consistent with his proposed theory, and in range with a medically acceptable timeframe to infer causation. *Id.* at 36.

## 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).[7] 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. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y, Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed.

[7] 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).

Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & 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.*, No. 17-1158V, 2023 WL 3816718 (Fed. Cl. Spec. Mstr. June 1, 2023), *mot. for rev. denied,* 168 Fed. Cl. 745 (2023), *aff'd*, 146 F.4th 1113 (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

PMR has not generally been deemed in the Program to *be* a likely vaccine-caused injury. *See generally Munoz*, 2024 WL 4113486; *Sciortino v. Sec'y of Health & Hum. Servs.*, No. 22-99V, 2024 WL 4579389 (Fed. Cl. Spec. Mstr. July 24, 2024); *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.

The most 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. The 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*).

I also note that I am familiar with the causation theory offered by Dr. Efthimiou in this case, since he has previously proposed essentially the same theory. In *Munoz* (which was decided after hearing—not on the papers, as here), Dr. Efthimiou offered a medical theory in which a claimant's receipt of a Tdap vaccine initiated a heightened immune response which resulted in a loss of immunologic tolerance and led to his symptoms onset of PMR. *Munoz,* 2024 WL 4113486, at *2–3. Not only were several items of literature relied upon in *Munoz* also cited herein (and for the same proposition), but Dr. Efthimiou also appears to have essentially copied and pasted several sections of his of previously-filed experts reports to his reports addressing the case at hand.[8]

[8] *See Munoz*, 2024 WL 4113486, at *4 (discussing the Falsetti, Salvarani , and Soriano articles).

These cases do not control the outcome of this matter. But they all provide reasoned grounds to be highly skeptical of claims that *any* covered vaccines can cause PMR.

## 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 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. For even if Petitioner had experienced PMR, as alleged,[9] he has not preponderantly established that the pneumococcal vaccine could be causal of it.

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. Indeed, the report offered in this case is exceedingly similar to what I reviewed in *Munoz,* even if the vaccines are not the same. Further, and like experts in past cases, he fails to identify a specific antigen associated with the development of PMR, or demonstrate that Petitioner himself possessed any genetic susceptibility. Petitioner has not otherwise offered any more recent scientific or medical studies or articles that would suggest a PMR-vaccine association is now thought to be more likely. And he did not persuasively show that the pneumococcal vaccine can be for present purposes deemed interchangeable with the Tdap vaccine—the former does not include the tetanus toxoid component, and pneumococcal conjugate is not wholly equivalent to the diphtheria component of Tdap. By contrast, Respondent's experts effectively and persuasively rebutted Petitioner's causation contentions—Dr. Jameson in particular, who succinctly demonstrated the clear failings in Petitioner's causation theory.

This is, in the end, another matter in which a claimant wants to treat 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"). And to reverse-engineer a causation theory, Petitioner assumes different autoimmune susceptibilities that

[9] Respondent vigorously disputes the PMR diagnosis—and his arguments raise reasonable questions about the nature of the injury. As a result, even if Petitioner were to prevail in appealing this decision, I would still need to resolve the diagnosis issue. In addition, Petitioner's many preexisting related conditions somewhat undermine the conclusion that the pneumococcal vaccine did cause his PMR—and his onset either predated vaccination or occurred too close in time to have been medically acceptable. Thus, the remaining two *Althen* prongs are also unlikely to have been satisfied—but I need not reach these matters, given Petitioner's prong one failure.

are not bulwarked with enough evidence to show that vaccination likely poses risks in these contexts.

My analysis herein is admittedly truncated. I could certainly write 50 or more pages spelling out in detail all the ways in which the proposed causal theory is preponderantly deficient. But special masters *should not be compelled* to do so when they are familiar with a theory that they understand has almost never succeeded—as is the case here. The Vaccine Program has too many cases before it to engage in lengthy analysis in each and every case, picking through each item of literature filed and addressing every argument made by an expert, no matter how many times that expert has said the same thing. Special masters must streamline their review of matters so that Program resources can be devoted to reasonably disputed issues and/or novel causation theories.

Admittedly, as scientific knowledge progresses, new discoveries could call into question the reasoning that has so often led special masters to reject theories that vaccines cause PMR. But I have provided Petitioner the opportunity, through the filing of expert reports and briefs, to substantiate what about the pneumococcal vaccine and PMR is now known that is *different* from the past—and that challenge was not met. Nothing filed in this case suggests to me that this vaccine, or any other, is more likely to be causal of PMR than before.

## 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.[10]

**IT IS SO ORDERED.**

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

[10] 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.