In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1369V

* *	Chief Special Master Corcoran
RICHARD MUNOZ, *	
*	
Petitioner, *	Filed: August 12, 2024
*	
v. *	
*	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
*	
Respondent. *	
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* *	

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

Alexis Babcock, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On May 18, 2021, Richard Munoz 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 the tetanus, diphtheria, and pertussis vaccine ("Tdap") on July 2, 2019. Petition (ECF No. 1). A hearing was held in this matter on January 25, 2024.

For the reasons discussed in more detail below, I hereby deny entitlement. PMR has not generally been viewed in prior reasoned Program decisions as an injury likely caused by most

[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).

covered vaccines, including Tdap—and nothing offered *in this case* suggests a basis for departing from these prior determinations.

I. Factual Background

Petitioner was 65 when he received the vaccination at issue. He had previously obtained orthopedic treatment in 2016 for left hip pain that was deemed likely related to lower back dysfunction. Ex. 3 at 123, 139–40. Then, in the winter of 2019, he reported some arm parasthesias and syncope when sitting up. Ex. 5 at 36. An x-ray of his cervical spine showed moderate cervical spondylosis[3] with radiculopathy. *Id.* at 34. That spring, Petitioner complained of right knee joint pain and paresthesias traveling down to his right foot for the last two months, and an x-ray of the knee revealed evidence of osteoarthritis. *Id.* at 26. And he sought additional orthopedic treatment in July 2019. Ex. 3 at 11.

Vaccination and Subsequent Medical Records

On July 2, 2019, Mr. Munoz received a Tdap vaccine during his annual primary care physician ("PCP") visit. Ex. 1 at 6–7. He complained of no symptoms or concerns relevant to the claim at this time. Ex. 5 at 23. Three weeks later, however, Petitioner returned to his PCP, now reporting aching joint pain and constant fatigue that he asserted had begun approximately three days after his July 2nd visit, and which he speculated could be vaccine-related. *Id.* at 18. An exam revealed no special findings, and lab testing was also unrevealing. Petitioner's PCP diagnosed him with synovitis of the wrist, arthralgia, morning joint stiffness, myalgia, and fatigue. *Id.* at 19–20; Ex. 2 at 13–16.

Petitioner thereafter continued in August 2019 to complain of fatigue and joint pain, specifically in the larger joints (although exams revealed little more than range of motion issues). Ex. 5 at 15. By mid-August, he began to report hand swelling plus fatigue, aches, and joint pain. Ex. 13 at 15. Lab work conducted that month was now positive for an elevated biomarker for inflammation. Ex. 6 at 22–24; Ex. 7 at 1–5.

By September 2019, Mr. Munoz was still experiencing some joint swelling, and treaters began to note their suspicion of PMR. Ex. 5 at 11, 12–13. He saw a rheumatologist that month, who confirmed the possibility of PMR. Ex. 8 at 6–8. However, a neurologist Petitioner saw in September proposed instead (based on a physical exam) the possibility that vaccine-induced brachial neuritis was the issue—and to that end had Petitioner begin a course of physical therapy

[3] "Cervical Spondylosis" is defined as "degenerative joint disease affecting the cervical vertebrae, intervertebral disks, and surrounding ligaments and connective tissue, sometimes with pain or paresthesia radiating along the upper limbs as a result of pressure on the nerve roots." *Cervical Spondylosis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=107846&searchterm=cervical+spondylosis (last visited Jan. 25, 2024).

("PT"). Ex. 3 at 16, 19–20, 23. Petitioner attended PT sessions through November 2023, reporting some improvement. *Id.* at 24, 62. And electromyographic testing performed in October 2019 did not confirm the presence of polyneuropathy, radiculopathy, plexopathy, or myopathy affecting his extremities. *Id.* at 39.

PMR thereafter continued to be the prevailing assessment for Petitioner's condition, although other treaters argued for brachial neuritis. Ex. 3 at 39, 69. Petitioner received additional treatment for his symptoms into 2020 and beyond, and the PMR diagnosis was maintained. Although some subsequent records memorialize Petitioner's belief (as stated to treaters) that vaccination was the cause of his condition, overall these latter records are not particularly probative of causation, and therefore I do not include a lengthy summary of their contents.

II. Trial Testimony

A. Petitioner's Expert – Petros Efthimiou, M.D., F.A.C.R.

Dr. Efthimiou, a rheumatologist, prepared two written reports and testified at hearing. *See* Efthimiou Report, dated June 27, 2022, filed as Ex. 24 (ECF No. 24-1); Efthimiou Supplemental Report, dated March 16, 2023, filed as Ex. 39 (ECF No. 30-1).

Dr. Efthimiou earned his medical degree from the University of Ioannina Medical School in Greece. Efthimiou CV at 1, filed on June 28, 2022 as Ex. 25 (ECF No. 24-2). He completed residency at Brown University's Rhode Island Hospital, and a rheumatology fellowship at New York Presbyterian. Efthimiou CV at 1–2. He maintains an active clinical practice, and teaches at NYU School of Medicine. *Id*. He has also led research on rheumatic conditions for over 20 years, and has published several journal articles. Efthimiou Report at 2. He is board-certified in rheumatology. *Id*. Dr. Efthimiou acknowledged that he does not have specific expertise in immunology, however (although much of the opinion he offered relevant to the disposition of this case involves immunologic issues). Tr. at 105–06.

Much of Dr. Efthimiou's testimony was devoted to explaining why the diagnosis of PMR was accurate for Petitioner. Tr. at 8–37. However, the case does not turn on the nature of Petitioner's injury, and I accordingly do not summarize herein Dr. Efthimiou's comments on Petitioner's medical history in association with the propriety of the diagnosis.[4]

PMR, Dr. Efthimiou maintained, could be caused by a Tdap vaccine. Tr. at 45. To explain the basis for his opinion, he made several points about PMR's nature, and possible etiology/pathogenesis. He deemed PMR to be a fairly common, immune-mediated inflammatory condition, contending that Respondent's characterization of it as an "inflammatory rheumatic disease" was essentially describing the same thing. Tr. at 38, 108. Although Dr. Efthimiou acknowledged that PMR's etiology was not fully understood, he proposed that it was likely

[4] I similarly do not reference Dr. Efthimiou's testimony regarding potential alternative causes (such as a possible interceding upper respiratory infection), or his discussion of the timing of onset.

autoimmune (and more specifically an autoinflammatory condition). *Id.* at 39–40, 110. And he maintained that the disease process would involve *both* the initial, innate response to a foreign antigen (the nonspecific, "powerful inflammatory response,") and the subsequent adaptive leg of the immune response, in which antibodies and T cells specific to the presenting foreign antigen would attack it. *Id.* at 40, 41. It would also occur due to a break in "immune tolerance"—the body's way to control damaging autoimmune self-attack, through regulatory immune cells. *Id.* at 44, 45.

In support, Dr. Efthimiou referenced evidence establishing that PMR occurs in a context of elevated cytokines (proinflammatory immune cells stimulated during the innate immune response) as well as "T helper cells," which encourage the production by B cells of antibodies specific to a foreign antigen. Tr. at 43. An article filed by Respondent, he contended, confirmed that PMR was understood to involve evidence of heightened macrophages and helper T-cells, as well as to occur in an inflammatory milieu. *Id.* at 49–51; C. Salvarani et al., *Polymyalgia Rheumatica and Giant-Cell Arteritis*, 347 N. Engl. J. Med. 261 (2002), filed on October 4, 2022 as Ex. A Tab 1 (ECF No. 26-1). He stressed that PMR was known to involve dysregulation of a large number of kinds of T cells. Tr. at 137.

Dr. Efthimiou maintained that some kind of environmental trigger could reasonably explain PMR in many cases. Tr. at 63, 69–70. For example, certain viruses had been identified as possible triggers. Savarani at 3. In Dr. Efthimiou's view, vaccinations could provoke the same kind of immune response. Tr. at 80.

In particular, Dr. Efthimiou maintained, vaccines could instigate a pathogenic process leading to PMR—first through the "classic immune response" leading to an inflammatory environment. Tr. at 42, 43. In addition, a vaccine could impact certain helper T-cells relevant to the adaptive response (since T-helper cells work to stimulate B-cell production of antibodies).[5] *Id.* at 64, 93. Exposure to vaccine antigens could also prompt a response from preexisting "autoreactive" T cells, or T memory cells, that had previously had been exposed to a particular antigen (here, the tetanus toxoid vaccine component) and would thus recognize it. *Id.* at 92–93. And vaccines might later impede immune cell regulatory processes, with the inflammation the vaccine initially instigated overwhelming those regulatory cells and encouraging disease. *Id.* at 45–46, 94.

This final aspect of pathogenesis would, Dr. Efthimiou maintained, occur even if the disease process was otherwise "autoimmune" (meaning involving a direct, if mistaken, attack by antibodies or specific T cells on self tissue instigated by a foreign antigen—here, a vaccine component). Tr. at 46–47. But in so arguing, Dr. Efthimiou denied that his theory involved the vaccine impacting "three seemingly separate immunological mechanisms," maintaining that it was the response to the vaccine-caused initial immune stimulation that was the essence of his theory. Tr. at 55. He also posited that any immune reaction would involve both arms of the response

[5] Cleveland Clinic, *Helper T Cells*, https://my.clevelandclinic.org/health/body/23193-helper-t-cells (last accessed August 9, 2024).

(innate and adaptive), and hence stimuli experienced at the outset (such as cytokines produced in reaction to a vaccine) would inherently impact the subsequent, adaptive process. *Id.* at 67–69.

Also critical to Dr. Efthimiou's theory was his argument that the disease process resulting in PMR would unfold in the context of a person's individual susceptibility to a damaging autoimmune process—and he devoted a substantial part of his testimony to explaining this. Tr. at 55-63. He proposed that PMR was likely "polygenic," meaning that several genetic mutations contributed to disease pathogenesis. *Id.* at 56. PMR, he argued, was likely associated with certain subtypes of human leukocyte antigens ("HLA")—a genetic complex that codes proteins that regulate immune system function. *Id.* at 57–58. Someone possessing a mutated HLA gene was more likely to experience an autoimmune disease, under the right circumstances (which here are posited to flow from the initial impact of vaccination). *Id.* at 59, 62–63. Merely possessing a specific form of HLA mutation did not guarantee an individual would experience PMR, Dr. Efthimiou admitted, and an environmental trigger would still be required—but he still deemed it a risk factor (although PMR could occur even in the absence of a mutated HLA gene). *Id.* at 59–60, 62, 124.

Dr. Efthimiou offered testimony about how his theory "worked" in the context of a late middle-aged individual like Mr. Munoz. He consistently proposed that immune system "senescence," which would occur as a person ages, would increase the likelihood of a break in tolerance, and therefore more autoimmune disease potentiality, due to the immune system's greater likelihood of an ineffective response to foreign pathogens. Tr. at 44. He suggested that Petitioner's age at the time of vaccination likely made him even more prone to not simply PMR (which usually afflicts older individuals), but to a vaccine-caused form of it. *Id.* at 85. On cross, however, Dr. Efthimiou acknowledged (as evidenced by the Tdap vaccine's package insert) that clinical studies pertaining to the vaccine's effect on older patient cohorts had generally found the immune response to be lower (and hence less effective), as opposed to aberrant in the manner proposed in this case. *Id.* at 131–33.

As additional support for a vaccine-PMR association, Dr. Efthimiou referenced some case reports or studies. Tr. at 71–72. One study, for example, considered data regarding 58 PMR patients, determining that six had received a vaccine prior to their onset of symptoms. Tr. at 78–81; P. Falsetti et al., *Polymyalgia Rheumatica Following Infective Triggers or Vaccinations: A Different Subset of Disease?* 58 Rheumatologia 2:76-80 (2020), filed as Ex. 58 (ECF No. 43-1) ("Falsetti"). Dr. Efthimiou also read Falsetti to establish that individuals reporting possible environmental triggers for their PMR had experienced "more of a chronic course" of disease, and displayed higher inflammation biomarker levels – consistent with Petitioner's medical history. Tr. at 81–82. And the chronicity of disease course underscored Dr. Efthimiou's prior arguments about senescence. *Id.* at 84.

On cross, however, Dr. Efthimiou acknowledged that Falsetti's authors had relied on self-reporting by existing PMR patients—not only to determine they had in fact been vaccinated before

onset, but that (in the subjective view of the surveyed patients) there might have been a relationship between the two. Tr. at 117–18. Thus, Falsetti in no way established more than a *possible* temporal association between receipt of a vaccine and PMR—and its authors did not reach a scientifically-reliable conclusion to the end, as Dr. Efthimiou admitted (although he claimed it would be "impossible" for such a small sample). *Id.* at 118.

Dr. Efthimiou highlighted other items of literature that also purportedly connected the Tdap vaccine specifically to PMR. *See,* e.g., A. Soriano et al., *Giant Cell Arteritis and Polymyalgia Rheumatica After Influenza Vaccination: Report of 10 Cases and Review of the Literature,* 21 Lupus 153-57 (2012), filed as Ex. 34 (ECF No. 24-11) ("Soriano").[6] Although Soriano's focus was on the flu vaccine, it referenced one other case report (never filed in this case) involving an observed temporal association between a tetanus vaccine (which would contain antigens comparable to what is found in Tdap) and PMR in a woman in her late 60s. Soriano at 155, Table 2. Although that individual (as described in Soriano) had experienced a *relapse* of PMR (not new onset as in the case of Mr. Munoz) after vaccination, Dr. Efthimiou deemed the case report relevant, in terms of potentially confirming the proposed immunologic mechanism. Tr. at 86–88.[7] But he admitted nothing was known about this individual relevant to the case (such as whether she had previously received a Tdap vaccine, what had possibly caused her PMR the first time, or anything about her treatment or disease severity) beyond what was briefly summarized in Soriano. *Id.* at 119–21.

Also connecting the Tdap vaccine to PMR, Dr. Efthimiou argued, was the capacity of the tetanus toxoid antigenic component[8] to prompt a "cellular response" from different T cells

[6] Several items of literature offered in this case discuss giant cell arteritis ("GCA"), a vascular condition, and PMR together, since PMR often develops comorbidly with GCA. Soriano at 153. However, as Dr. Efthimiou admitted, Petitioner was never diagnosed with GCA, and it is not contended in this case he might have suffered from it (Tr. at 12–13)—greatly diminishing the probative value of articles involving GCA in any regard.

[7] In referencing this case report referred to in Soriano, Dr. Efthimiou also spoke of "rechallenge" (Tr. at 88). But this usage is wholly distinguishable from circumstances of "challenge-rechallenge" as normally discussed in the Vaccine Program. That concept refers to instances where an individual (a) previously was exposed to a particular vaccine, (b) displayed some adverse reaction, then (c) experiences a second, often more acute, reaction when exposed again. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1322 (Fed. Cir. 2006). Here (and as noted on cross-examination), there is no evidence that the case study patient mentioned in Soriano had previously received a tetanus-containing vaccine, or experienced an adverse reaction to it—and in any event that set of circumstances is inapplicable to this case as well, since it is not known that Mr. Munoz did previously receive a Tdap vaccine, or experience a reaction to it. Tr. at 127–30.

[8] In addition, Dr. Efthimiou made some references to the possibility that the other vaccine Petitioner received at the relevant time—the pneumococcal vaccine—could have contributed to his injury, but he acknowledged in his testimony that he had found more evidence supporting a Tdap association, and ultimately seemed to posit only that it was "highly possible" a combination of vaccines played a contributory causal role (although he did try to outline a hypothesis for how this might have occurred). Tr. at 98, 99–101. He certainly admitted he had offered nothing specific to an association between PMR and co-administration of these two vaccines. *Id.* at 134. I ultimately find most of Petitioner's evidence goes to the Tdap vaccine's role, whereas Dr. Efthimiou admitted in passing he could offer less evidence on this topic, such as in the form of a relevant case report. *See, e.g.,* Tr. at 116. Most evidence offered in this case involved the Tdap vaccine—and since that showing alone was insufficient to meet the preponderant standard,

(autoreactive or helper T cells). Tr. at 95–96; Efthimiou Supplemental Report at 16. He deemed it likely Mr. Munoz had been exposed to the vaccine before (although he admitted he had no evidence of this, and was therefore engaging in some speculation). *Id.* at 96. But the autoreactive T cells could, he maintained, still mount a response even if they had no prior exposure to tetanus. *Id.* at 97.

Despite the foregoing, Dr. Efthimiou repeatedly acknowledged the existence of a number of evidentiary holes in his theory. For example, he agreed that no autoantibody had been identified as associated with PMR. Tr. at 42, 110. He admitted that there was no evidence Petitioner possessed a genetic susceptibility that could be associated with PMR. *Id.* at 60–61, 124. He allowed that his contentions about immunologic senescence did not have scientific or medical support specific to the impacyt of vaccines in encouraging the development of PMR. *Id.* at 124–26. More broadly, Dr. Efthimiou admitted he could offer no literature generally evaluating a purported PMR-Tdap connection (other than the case reports previously mentioned). *Id.* at 110. Nor could he reference items of literature showing how the vaccine would impact helper T cells, T regulatory cells, or cytokine production. *Id.* at 111.

B. Respondent's Experts

1. *Roland Staud, M.D.* – Dr. Staud has expertise in rheumatology as well as clinical immunology, and he offered testimony at the hearing as well as one written report. Staud Report, dated September 15, 2022, filed as Ex. A (ECF No. 25-1).

Dr. Staud is a clinical rheumatologist and professor at the University of Florida. Staud CV at 1, filed on September 15, 2022, as Ex. B (ECF No. 25-2). He earned his medical degree from Freie Universitat Berlin, and completed residencies in internal medicine and a fellowship in rheumatology. *Id.* He is the director of the Center for Chronic Musculoskeletal Pain and Fatigue Research at UF, and has conducted NIH-funded research there for over 20 years. Staud Report at 1. He has authored or co-authored over 230 journal articles, as well as textbooks. *Id*. He regularly sees patients with a variety of rheumatological conditions, including PMR. *Id.*

Dr. Staud provided insights into the nature of PMR and its characteristics. *See generally* Tr. at 144–48. Most of this testimony does not bear on the claim's resolution, although he did deny that the nature or length of a patient's treatment said anything about the cause of the individual's PMR. *Id.* at 147–48, 155–56. He admitted Petitioner had been appropriately diagnosed with PMR. *Id.* at 148–49. But he maintained PMR's causes remain unknown. At most, it is speculated that PMR *may* have some association with "infection and environmental agents," although the infections that have been identified as possibly associated have no congruence with the Tdap vaccine's components. *Id.* at 150, 163. Dr. Staud at most allowed that there were case reports

then the facially less-supported contentions about the concurrent causality of the two vaccines at once have even less persuasive value.

possibly linking the flu vaccine to PMR—but far less, if anything, relevant to the Tdap vaccine. *Id.* at 165–66.

Dr. Staud flatly denied the Tdap vaccine—or any vaccine for that matter (including the pneumococcal vaccine)—could be causal of PMR. Staud Report at 9; Tr. at 151. He offered some literature in support of his opinion. *See, e.g.,* K.L. Nichol et al., *Side Effects Associated With Pneumococcal Vaccination*, 25 Am. J. Infect. Control 223 (1997), filed on October 4, 2022 as Ex. A, Tab 6 (ECF No. 26-6) ("[i]n this study we have demonstrated that pneumococcal vaccination was not associated with an increase in systemic symptoms among patients at high risk for pneumococcal disease when compared with a control period"). In fact, worldwide professional rheumatology organizations recommended vaccination to individuals experiencing likely autoimmune inflammatory conditions, like PMR. Tr. at 159–60; see V. Furer et al., *2019 Update of EULAR Recommendations for Vaccination in Adult Patients With Autoimmune Inflammatory Rheumatic Diseases*, 79 Ann. Rheum. Dis. 39 (2020) ("Tetanus toxoid and human papilloma virus vaccination should be provided to AIIRD patients as recommended for the general population"), filed on December 14, 2023 as Ex. E (ECF No. 46-1). By contrast, Dr. Staud noted that articles Dr. Efthimiou relied upon, such as Falsetti, based their findings on self-reporting as well as mere temporal associations between vaccination and PMR. Tr. at 153–55.

2. *William Hawse, Ph.D.* – Dr. Hawse is an immunologist, and he prepared a report in this case and also testified. *See* Hawse Report, dated September 22, 2022, filed as Ex. C (ECF No. 25-3).

Dr. Hawse is an Assistant Professor in the Department of Immunology at the University of Pittsburgh School of Medicine. Hawse CV at 1, filed on September 15, 2022, as Ex. D (ECF No. 25-4). He earned his Ph.D. in biophysical chemistry at Johns Hopkins. *Id*. He runs a laboratory studying CD4+ T-cell generation and immune tolerance, to inform therapeutic strategies for autoimmune diseases. Hawse Report at 1. He has published 14 peer-reviewed journal articles. *Id.* Dr. Hawse is not a medical doctor or experimental clinician, however, and thus did not offer commentary on the nature of PMR or whether Petitioner' presentation fit the diagnostic classification. Tr. at 174, 190.

Dr. Hawse overall disputed the immunologic mechanism proposed by Dr. Efthimiou to explain the etiology and pathogenesis of Petitioner's PMR—whether through an autoimmune cross-reaction or otherwise. Tr. at 174, 192–93. Vaccines, he noted, are intended to provoke an immune response to the specific antigens they contain. *Id.* at 174–75, 192. But that response is not precisely identical from one vaccine to another. *Id.* at 175. Although an autoimmune disease might reasonably be understood to involve *some* break in immune tolerance (such that the body would mistakenly attack self-structures), Dr. Hawse did not accept that vaccines could initiate that break. *Id.* And other evidence of a vaccine-disease relationship mostly relied on proof that vaccines are associated with increase in some immune cells found in autoimmune diseases—not that vaccination's impact on production of them *leads* to autoimmunity. *Id.* at 183–84.

Dr. Hawse further commented on Dr. Efthimiou's contentions about genetic susceptibility (and particularly the role of HLA genes might play in encouraging PMR under certain circumstances). He saw nothing in Dr. Efthimiou's reports reliably linking such genetic variants to PMR, acknowledging at most that the issue had been inconclusively explored in some studies as a hypothetical possibility. Tr. at 176–77. He denied there was any independent scientific support associating vaccination with PMR when an individual was thought to possess this genetic variant. *Id.* at 177.

Dr. Hawse similarly rejected the notion that immunologic senescence might also be a risk factor for individuals developing PMR after vaccination. Tr. at 177–82. Immune system senescence, he maintained, was characterized by the body generating "weaker responses to vaccination"—not experiencing greater aberrant reactions with aging. *Id.* at 186. Pre-market testing of the Tdap vaccine had actually observed this. *Id.* at 187, *Package Insert: Adacel*, filed on March 20, 2023, as Ex. 45 (ECF No. 30-7).

In addressing the issue of immune system senescence, Dr. Hawse specifically discussed an aspect of one of Dr. Efthimiou's written reports, in which he had proposed that a particular kind of immunosenescent T cell lymphocyte could be stimulated into a cascade, resulting in (or at least encouraging) PMR. *Id.* at 178; Efthimiou Report at 13. Dr. Hawse disputed the reliability of the view that the identified T cell was associated with autoimmunity based on existing literature—and regardless, he was aware of no evidence that the Tdap vaccine could promote the production of this T cell (or the others alleged to be involved with PMR). *Id.* at 178–79, 182. In addition, Dr. Hawse argued, literature that suggested that certain immune cells proliferated due to the presence of immunosenescent cells relied on artificial lab conditions (in vitro stimulation of certain immune cells) that could not be compared to the body's likely reaction to a vaccination, Tr. at 180; C. Dejaco et al., *NKG_2D Stimulated T-Cell Autoreactivity in Giant Cell Arteritis and Polymyalgia Rheumatica*, 72 Ann. Rheum. Dis. 1852 (2013), filed on June 28, 2022 as Ex. 27 (ECF No. 24-4).

III. Procedural History

A year after the case's initiation, Respondent filed his Rule 4(c) Report contesting Petitioner's right to compensation. ECF No. 20. The parties thereafter began obtaining and offering the aforementioned expert reports. The matter was set for hearing in January 2024, and after post-hearing briefs were filed this past spring, the case became ripe for full resolution.

IV. 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. 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,

[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).

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 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").

ANALYSIS

I. Program Treatment of PMR as Vaccine Injury

Petitioner's proposed PMR diagnosis is not contested. Tr. at 90, 144, 148. But PMR has not generally been deemed in the Program to *be* a likely vaccine-caused injury. *See generally 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, and none were appealed.

The two most on-point determinations are *Van Dycke* and *Suliman,* since both involve the Tdap vaccine. In *Suliman,* a petitioner alleged onset of PMR within two weeks of receipt of the Tdap vaccine. *Suliman*, 2018 WL 6803697, at *5, *20. *Suliman* admittedly turned in part on the special master's rejection of a theory that the vaccine's adjuvant triggered PMR (something not contended in this case). *Id.* at *25–26. However, the special master also found fault in the proposed causation theory, since (a) nothing was established showing how any antigenic component of the Tdap vaccine could spark PMR, (b) nothing was offered to link the vaccine to PMR more generally, (c) no known causes of PMR were established that could be deemed analogous to the Tdap vaccine, and (d) no secondary kinds of proof, such as case reports, had been offered. *Id.* at *26–28. Although *Suliman* is over five years old, it highlights the baseline issues with the theory that the Tdap vaccine could cause PMR.

Van Dycke, by contrast, was decided a year ago, and its analysis of the persuasiveness of the theory more closely tracks what has been advanced here. In that matter, the relevant expert failed to identify a specific causal antigen—and even assumed a vaccine-instigated process without proposing molecular mimicry as the mechanism. *Van Dycke,* 2023 WL 43120701, at *22. As here, that expert also proposed a T cell-driven pathogenic process, but failed to link the vaccine to the initiation of that process. *Id.* The expert similarly maintained that an immunosenescent context (involving an aged petitioner) played a role, but had not shown that an aberrant immune process sufficient to trigger pathogenesis *due* to immune system senescence was likely. *Id.* at *23. Articles offered in this case, like Falsetti, were also cited by the *Van Dycke* petitioner's expert. *Id.* at *24. And the *Van Dycke* expert relied on a theory that involved both

the innate and immune responses—"casting a broad net," but without ultimately providing sufficient preponderant proof that the Tdap vaccine could likely initiate such a complex, interconnected disease process. *Id.*

These cases do not control the outcome of this matter. But they all provide reasoned grounds to be skeptical of claims that many covered vaccines—including the Tdap vaccine—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.

Dr. Efthimiou's causation opinion largely repeats the kinds of arguments that other special masters have routinely rejected as unpersuasive. Like experts in past cases, he fails to identify a specific antigen associated with the development of PMR, or demonstrate that Petitioner himself possessed the proposed genetic susceptibility. Further, 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 even admitted during testimony that there were not even case reports documenting PMR after receipt of the Tdap vaccine (other than the unfiled report involving a tetanus vaccine that was referenced in Soriano). Tr. at 116.

By contrast, Respondent's experts (especially Dr. Hawse) effectively and persuasively rebutted Petitioner's causation contentions. Dr. Hawse not only highlighted an absence of direct evidence associating the vaccine with PMR, but also the degree to which the proposed theory relied on the vaccine doing multiple things as the disease process progressed—but without ever showing how the impact of the *initial receipt* of either vaccine would be significant enough to affect the immune process at so many different inflection points.

This is, in the end, another matter in which a claimant wants to transmute 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 susceptibilities—

due to age, or some individual genetic propensity to autoimmunity—that are not bulwarked with enough evidence to show that vaccination likely poses risks in these contexts.

This is not a matter in which *no* probative evidence was offered. Petitioner has identified a handful of case reports, and although case reports stand as weak evidence to support causation (especially when they involve a different vaccine), they should not be disregarded categorically. *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011) ("'[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value,' even if they should receive some weight"). Dr. Efthimiou has also provided insights into the pathogenic mechanisms of PMR, showing how the immune response's different stages might play a role in disease progression—somewhat allowing for a *faint possibility* that a vaccine could impact that process (although at what point, and where most importantly, remains unknown). And he has offered some evidence explaining how individual susceptibility might also encourage PMR (although the aspects of Dr. Efthimiou's theory relying on immune system senescence were ultimately not well constructed or substantiated—especially since the very concept of immune response senescence involves *reduced* immune system effectiveness, rather than greater aberrance due to age).

But what is ultimately missing is sufficient probative evidence allowing for the conclusion that it is more likely than not that a Tdap vaccine's components can trigger PMR. Instead, there are too many speculative assumptions about the roles prior exposure to the vaccine, or the Petitioner's unspecified genetic susceptibilities (assumed, in circular fashion, to have existed merely because Petitioner developed PMR), would play in setting up a disease process. And large leaps are made from evidence that PMR *involves* 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 that they would drive pathogenesis.

The Program has now repeatedly observed the lack of persuasive scientific/medical evidence linking most covered vaccines to PMR. Until a claimant is able to muster 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 this causation theory.

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.