In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-993V

(Filed: November 27, 2018)

JULIE SULIMAN,	*	To Be Published
Petitioner,	*	Tetanus-diphtheria-acellular pertussis ("Tdap") Vaccine; Polymyalgia Rheumatica ("PMR"); Myositis; Dismissal
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Franklin John Caldwell, Esq., Maglio, Christopher, & Toale, Sarasota, FL, for petitioner.
Lisa Watts, Esq., U. S. Department of Justice, Washington, D.C., for respondent.

DECISION[1]

Roth, Special Master:

On December 16, 2013, Julie Suliman ("Ms. Suliman," or "petitioner") timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, et seq.[2] (the "Vaccine Act" or "Program"), alleging that the tetanus-diphtheria-acellular pertussis ("Tdap") vaccination that petitioner received on April 1, 2011 caused her to develop polymyalgia rheumatica ("PMR") and/or myositis. Petition at 1-2.

[1] This Decision has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will be available to anyone with access to the internet.** 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] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

An entitlement hearing was held on January 29 and 30, 2018, in Washington, D.C. For the reasons stated herein, I find that petitioner's evidence is insufficient to demonstrate that the Tdap vaccine she received on April 1, 2011 more likely than not caused her development of PMR and/or myositis. Accordingly, I find that petitioner is not entitled to compensation.

I. Issues to be Determined

The parties agree that petitioner has PMR. Joint Sub. at 1. The parties disagree on the timing of onset of petitioner's PMR, and on whether petitioner also developed myositis. *Id*. They further disagree on whether Tdap vaccine can cause PMR and/or myositis, and, if it can, if it did so in this case. *Id*. at 1-2. Petitioner did not advance a claim that Tdap vaccine significantly aggravated a preexisting PMR or myositis. *Id*. at 1.

II. Background

A. Procedural History

Petitioner filed her petition on December 16, 2013 and medical records on December 17, 2013. Petitioner's Exhibits ("Pet. Ex.") 1-7, ECF No. 5. On February 28, 2014, respondent filed a Rule 4(c) Report ("Rule 4") stating that compensation was not appropriate. ECF No. 7.

On July 3, 2014, petitioner filed additional medical records. Pet. Ex. 8-10, ECF No. 10. Respondent filed a status report on October 21, 2014, stating that settlement was not feasible. ECF No. 19.

On February 23, 2015, petitioner filed the report of Dr. Raji Grewal, petitioner's treating physician, along with supporting literature. Pet. Ex. 11-18, ECF No. 23.

On April 24, 2015, respondent filed an expert report from Dr. Mehrdad Matloubian along with supporting literature. Resp. Ex. A-F, ECF No. 26.

Following a status conference on May 20, 2015, petitioner was ordered to file a supplemental expert report by July 22, 2015. ECF No. 28. After requesting and receiving six extensions of time, petitioner filed a supplemental expert report from Dr. Grewal on February 5, 2016, along with supporting medical literature. Pet. Ex. 21-37, ECF Nos. 42, 43.

This case was reassigned to me on January 14, 2016. ECF No. 37.

A Rule 5 conference was held on April 21, 2016. Settlement discussions were encouraged. Scheduling Order, ECF No. 45. Petitioner filed a status report on July 20, 2016, stating that the parties were not able to resolve this matter, and requested an entitlement hearing. ECF No. 47. A status conference was held on August 10, 2016; petitioner was ordered to file a supplemental expert report which addressed specific questions about petitioner's theory of causation, specifically her aluminum adjuvant, or "ASIA-like," theory of causation. Scheduling Order, ECF No. 48.

A prehearing order was issued on October 13, 2016, setting this matter for an entitlement hearing on January 29 and 30, 2018 in Washington, D.C. Prehearing Order, ECF No. 51. Petitioner filed a second supplemental expert report from Dr. Grewal on December 29, 2016. Pet. Ex. 38, ECF No. 53. Petitioner filed updated medical records on March 28, 2017 and January 4, 2018. Pet. Ex. 39-40, ECF No. 54; Pet. Ex. 41-42, ECF No. 61.

Petitioner filed her pre-hearing brief on December 7, 2017. ECF No. 58. Respondent filed his pre-hearing brief on January 4, 2018. ECF No. 59.

An entitlement hearing was held in Washington, D.C. on January 29 and 30, 2018.

At the conclusion of Dr. Grewal's testimony, the courtroom was cleared and Dr. Grewal's testimony was discussed with counsel as follows:

> The Court: Counsel would you like to tell me how you are going to sustain your burden of causation in this case?
>
> Mr. Caldwell: This is a bit surprising, actually. As I sit here, I can't. But that doesn't mean – what I would like to do is continue with the case since we are here, through Dr. Matloubian's testimony and cross-examination, look at the transcripts and see where we go.
>
> I think that what I watched in this testimony was somebody who was not a typical expert witness in these cases. I think a lot of the questions confused him and I think he answered them in a way to sort of follow along with what you were both saying to him. I think he didn't have that sort of – the academic backbone to talk about what was happening. Because I think when I—what I want to do is go through the transcript and compare what he's talking about with what he's written and what his literature says and what the medical records say.
>
> The Court: I will disagree with you that I don't think he misunderstood. I think he understood full well. I think that he has absolutely no literature or support for what he's saying. He just believes that she got the tetanus, she says she felt worse, and he didn't take into consideration all of the other issues in her medical records, including the fact that she has constant infections and had one the week before which could more than likely be responsible for the onset of this PMR, if it wasn't already starting with many of the complaints that she had before. So I will disagree with you, but I will indulge you.

Tr. 174-75.

Respondent moved for a ruling on the evidentiary record, submitting that Dr. Grewal's testimony and concessions did not support a theory causally connecting the vaccine to PMR or myositis. Tr. 177. Respondent pointed out that Dr. Grewal conceded that he did not know when petitioner's PMR and/or myositis started and therefore could not marry the alleged injury with the

vaccine. Tr. 177. Respondent stated that petitioner had the burden of proof and was unable to meet it. Tr. 177.

Following a discussion, the decision was made to hear testimony from Dr. Matloubian in order to secure the record. Tr. 178. Petitioner requested the opportunity to submit a post-hearing brief to address the inconsistencies between Dr. Grewal's testimony and his written opinions. Tr. 178.

At the conclusion of Dr. Matloubian's testimony, the parties rested. Dr. Grewal had left the previous day after the conclusion of his testimony, and was not offered for rebuttal. I confirmed with petitioner's counsel that it was not his intention to secure another expert report in this case. He responded that it was not his intention, "[u]nless there's some smoking gun that I hadn't seen before." Tr. 285. I pointed out to counsel that it would be unlikely, as the causation theory in this case was raised by the original special master assigned to this case and later by me when the case was reassigned. Tr. 285. At the pre-hearing conference, I again raised the issue of ASIA as the theory of causation and was corrected by counsel that the theory was "ASIA-like." Order at 1-2, ECF No. 68. Following the hearing, I pointed out that Dr. Grewal's testimony was consistent with his reports in putting forth ASIA as the theory of causation. Tr. 285. Petitioner's counsel agreed, stating that the basis was the aluminum in the vaccine. Tr. 285. I responded that Dr. Grewal was unable to explain how the aluminum would cause petitioner any injury, other than to say it was injected rather than ingested. Tr. 285.

The parties agreed to submit Post-Hearing Briefs, which were filed April 2, 2018 and May 31, 2018, respectively. ECF Nos. 74, 76. Petitioner did not attempt to reconcile the written opinions of Dr. Grewal with his testimony, but simply stated, "Dr. Grewal's testimony was not in line with his written medical record or his expert reporting. Whether it was his nervousness and confusion as a first time testifying expert witness, as undersigned believes is the case, or whether on cross-examination and examination by the Court, Dr. Grewal altered or felt unable to support his opinion, is ultimately for the court to decide." Pet. Post-Hearing Brief at 1-2.

Dr. Grewal testified that he has provided expert opinions in five other vaccine cases and has previously reviewed medical malpractice cases, but has not testified in court in any of those cases. Tr. 119-20.

Dr. Grewal was not confused or flustered at any time during the hearing, nor did he lack understanding of the questions asked of him. He testified honestly, graciously, and credibly, conceding that he had no support for his opinions other than his personal belief that petitioner's PMR and/or myositis was caused by the Tdap vaccine based on timing. Dr. Grewal did not lack academic prowess as suggested by counsel, nor was he misled by questions from respondent's counsel or the court. He simply testified honestly with testimony that was adverse to petitioner's case and cannot be rehabilitated.

In his Post-Hearing Brief, respondent stated that Dr. Grewal conceded having no sound scientific basis for his belief that the Tdap vaccination caused petitioner's PMR or myositis. The basis for his theory was that petitioner received the vaccine "and was never quite the same

afterwards." Resp. Post-Hearing Brief at 4 (*citing* Tr. 112). Respondent requested that the petition for compensation be denied and the case dismissed. *Id*. at 4.

This matter is now ripe for decision.

B. Medical History

1. Petitioner's Health Before Receiving the Tdap Vaccine

Petitioner's medical history is long standing and complicated. She has been under the care of Dr. Allison Faches (primary care), Dr. Fu Bai (rheumatology) and Dr. Richard Gan (neurology) for many years. She has a history of multiple sclerosis ("MS") treated with Copaxone, Avonex, and steroids; fibromyalgia treated with amitriptyline, Celebrex, and Lyrica; chronic fatigue syndrome, vertigo, recurrent herpes simplex virus II, alcoholism, drug abuse, central vein occlusion in the right eye, eczema, panic attacks, migraines, palpitations, allergies, high cholesterol, fibroids, right-sided facial numbness, numbness in her feet, hearing loss, insomnia, glaucoma, left knee pain, and thirty years of smoking. In the two years prior to, and in the years following her Tdap vaccination, petitioner has had repeated gastrointestinal viruses, rashes, sinusitis, and bronchitis requiring antibiotic treatment with Levaquin[3] and prednisone. *See generally* Pet. Ex. 2-3, 6, 8, 19-20, 40, 42.

On January 26, 2010, petitioner presented to Dr. Faches for fever, coughing, sinus pain, abdominal pain all over, and diarrhea, which had resolved. Pet. Ex. 6 at 88. She was smoking up to two packs of cigarettes per day. *Id.* She was diagnosed with acute sinusitis, prescribed Levaquin, guaifenesin,[4] and a Chantix starter pack. *Id*.

On March 9, 2010, petitioner presented to Dr. Gan. Avonex[5] was started in January of 2009, but had to be stopped due to increased blood pressure. Pet. Ex. 8 at 13. She had a left knee cartilage repair.[6] She was complaining of right facial tingling, drop feet, and diminished coordination. *Id*. Dr. Gan prescribed prednisone and ordered an MRI of the brain and cervical spine. *Id*.

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[3] Levaquin is the brand name for levofloxacin, an antibiotic used to treat bacterial infections like sinusitis, chronic bronchitis, and urinary tract infections. *Levofloxacin – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Levaquin-levofloxacin-271.8231#3 (last visited Oct. 19, 2018).

[4] Guaifenesin is an expectorant. It is prescribed for coughs, and thins and loosens mucus in the airways. *Guaifenesin – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Mucinex-guaifenesin-1275 (last visited Oct. 19, 2018).

[5] Avonex is the brand name for interferon beta-1a. It is prescribed for relapsing-remitting MS. *Interferon beta-1a – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Avonex-interferon-beta-1a-1623 (last visited Oct. 19, 2018).

[6] Petitioner did not file any medical records reflecting the surgical repair on her left knee.

On July 12, 2010, petitioner presented to Dr. Faches, complaining of a rash on her ankle and arm for a couple of weeks and pain in her right ear. Pet. Ex. 6 at 87. She was diagnosed with poison ivy and prescribed prednisone. *Id*.

On August 2, 2010, petitioner returned to Dr. Gan with dizziness, right facial numbness, and fatigue. Pet. Ex. 8 at 14. Dr. Gan noted her history of MS and the prednisone prescribed in March. *Id*. He wanted to "try Provigil."[7] *Id*.

On August 11, 2010, petitioner returned to Dr. Faches, with sinus complaints, frequent urination, urgency, and urinary incontinence. Pet. Ex. 6 at 86. She was diagnosed with sinusitis, prescribed Levaquin, and was advised to stop smoking and lose weight. *Id*. Dr. Faches noted that petitioner needed to get a Tdap vaccination when she was feeling well. *Id*.

On September 12, 2010, petitioner returned to Dr. Gan with increased vertigo, diplopia, clumsiness, numbness on the right side of her face, weakness and rash on her arms. Pet. Ex. 8 at 12. She was not taking the Lyrica[8] or Elavil[9] as prescribed. *Id*.

On October 8, 2010, petitioner presented to Dr. Faches, with complaints of being sick for a week, more severe "yesterday," with right ear pain, sinus pain, chest congestion that moved from her head into her chest, and a deep productive cough. Pet. Ex. 6 at 85. She reported a stomach virus prior to the head cold. *Id*. She was diagnosed with sinusitis and prescribed Levaquin, rest, fluids, Xanax,[10] and Valtrex.[11] *Id*.

On March 4, 2011, petitioner returned to Dr. Faches. She had stopped smoking and gained 20 pounds since July. She had joined a gym. Pet. Ex. 6 at 83. She had a rash under her breasts and complained of shortness of breath, which she attributed to increased weight. *Id*. She complained

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[7] Provigil is the brand name for modafinil, a central nervous system stimulant which increases mental alertness and decreases fatigue. It is used for narcolepsy and to reduce fatigue or excessive daytime sleepiness associated with sleep apnea or circadian rhythm disruptions. *Modafinil – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Provigil-modafinil-2332 (last visited Oct. 19, 2018).

[8] Lyrica is the brand name for pregabalin, an anticonvulsant used to treat neuropathic pain associated with several conditions, including fibromyalgia. *Pregabalin – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Lyrica-pregabalin-467.8329 (last visited Oct. 19, 2018).

[9] Elavil is the brand name for amitriptyline, a tricyclic antidepressant used to treat depression in adults. It is also used off-label to treat neuropathic pain. *Amitriptyline hydrochloride – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Amitriptyline-Hydrochloride-amitriptyline-hydrochloride-1001 (last visited Oct. 19, 2018).

[10] Xanax is the brand name for alprazolam, a short-acting benzodiazepine used for the management of anxiety. *Alprazolam – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Xanax-alprazolam-1873.31 (last visited Oct. 19, 2018).

[11] Valtrex is the brand name for valacyclovir, an antiviral drug used to treat infections caused by herpes viruses, including cold sores and herpes zoster. *Physicians Desk Reference* 1367, 1370 (66th ed. 2012).

of "a lot of fibromyalgia pain," increased blood pressure, and "problems sleeping due to pain." She said Lexapro[12] had worked for her pain in the past. *Id.* She reported that Dr. Gan had wanted to put her back on Lyrica, but she refused. *Id*. Dr. Faches prescribed Lexapro, Voltaren,[13] Lotrisone cream,[14] and Gold Bond powder for her rash. *Id*. at 84. She was to follow up in a month. *Id.*

On April 1, 2011, petitioner returned to Dr. Faches with an injured right great toe; she believed it was broken. It was swollen and she could not wear shoes. Pet. Ex. 6 at 82. She also reported having a sore throat, and a stomach virus with diarrhea and vomiting the week prior; it had since resolved. *Id*. Her sinuses were painful on palpation. *Id*. A strep test due to exposure was negative. *Id*. Dr. Faches concluded the sore throat was probably viral. *Id*. Petitioner received a Tdap vaccination in her left deltoid. *Id*. at 36, 82.

2. Petitioner's Health After Receiving the Tdap Vaccine

On April 18, 2011, petitioner presented to Dr. Bai, with complaints of a recent flare up of "arthralgia/myalgia."[15] Pet. Ex. 3 at 11. She was not taking her medications and had poor function, but her MS was stable. *Id*. She was antalgic[16] with a cane. *Id*. at 10. She reported recent toe trauma and a tetanus booster. *Id*. at 11. She was noncompliant with follow-up visits. *Id*. She was prescribed Celebrex, Lyrica, and Zanaflex. *Id*. at 10.

On April 26, 2011, petitioner returned to Dr. Bai reporting significant improvement since restarting medication. Pet. Ex. 3 at 9. She had no cognitive or other associated cluster symptoms at that time. *Id*. She did have an antalgic gait and was using a cane. *Id*. Celebrex, Lyrica, and Zanaflex were to be continued. *Id*.

Petitioner returned to Dr. Bai on May 9, 2011 reporting continued improvement on current medications and without any recent fibromyalgia flares. Pet. Ex. 3 at 8. She was tolerating Lyrica and Celebrex. *Id*. She was also taking Valtrex for a recent varicella zoster recurrence. *Id*. She was

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[12] Lexapro is the brand name for escitalopram oxalate, a selective serotonin reuptake inhibitor ("SSRI") used to treat depression and anxiety in adults. *Escitalopram oxalate – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Lexapro-escitalopram-oxalate-2214.2561 (last visited Oct. 19, 2018).

[13] Voltaren is the brand name for diclofenac sodium, a nonsteroidal anti-inflammatory drug ("NSAID") used to treat pain. *Diclofenac sodium – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Voltaren-XR-diclofenac-sodium-2033.6043 (last visited Oct. 19, 2018).

[14] Lotrisone is the brand name for betamethasone dipropionate/clotrimazole, a combination of corticosteroids and antifungals. It is used to treat skin infections. *Betamethasone dipropionate/clotrimazole – Drug Summary*, PDR.NET, http://www.pdr.net/drug-summary/Lotrisone-betamethasone-dipropionate-clotrimazole-2276 (last visited Oct. 19, 2018).

[15] "Myalgia" is muscle pain; "arthralgia" is joint pain. *Myalgia*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 150, 1214 (32d ed. 2012) [hereinafter DORLAND'S].

[16] "Antalgic" means counteracting or avoiding pain; an "antalgic gait" is a limp adopted so as to avoid pain on weight-bearing structures, as in hip injuries. *Antalgic*, DORLAND'S at 97, 753.

noted to be well and clinically unchanged. *Id*. Dr. Bai's assessment was fibromyalgia, chronic fatigue syndrome, varicella, and MS. *Id*. Petitioner was prescribed Elavil, Lyrica, Celebrex, and Soma. *Id*.

On June 30, 2011, petitioner returned to Dr. Bai, with complaints of increased pain with stiffness in her lower extremities. Pet. Ex. 3 at 7. She was working two jobs, which she was usually able to handle, but now felt partially incapacitated. *Id*. She had 18 out of 18 classic fibromyalgia tender points, bilaterally.[17] *Id.* Dr. Bai's assessment was fibromyalgia and chronic fatigue syndrome; rule out MS flare. *Id*. Lyrica dosage was increased and she was advised to consult with her neurologist as soon as possible. *Id*.

On July 5, 2011, petitioner returned to Dr. Faches. She reported that, after her tetanus shot, her fibromyalgia "kicked in" and "I can't move." Pet. Ex. 6 at 80. She could not raise her arm above her head. *Id*. She reported that Dr. Bai gave her medications, but did not order blood work. *Id*. She complained of myalgias and arthralgias in all joints, with lower back pain causing pain when walking, but she could walk in her pool for exercise. *Id*. She was taking Lyrica, Celebrex, Elavil, Soma, Provigil, pantoprazole, Valtrex, and Xanax. *Id*. Dr. Faches noted no obvious joint swelling, redness, or warmth. *Id*. at 81. Her assessment was fibromyalgia, MS, and arthralgia/myalgia. *Id*. Petitioner was instructed to follow up with Dr. Bai and Dr. Gan. *Id*. Blood work was ordered. *Id*.

Blood work performed on July 6, 2011 showed an elevated C-reactive protein[18] ("CRP").

[17] Fibromyalgia patients must have pain in all four quadrants of their body for a minimum of 3 months and at least 11 of the 18 specific tender points, according to the classification criteria for fibromyalgia syndrome (FMS) published by the American College of Rheumatology (ACR) in 1990. *See* M. Fitzcharles et al., *2012 Canadian Guidelines for the diagnosis and management of fibromyalgia syndrome: Executive summary*, 18 PAIN RES MANAG 3: 119-26 (2013), filed as "Pet. Ex. 17."

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

Pet. Ex. 6 at 76. Erythrocyte sedimentation rate[19] ("ESR"), ALT/AST,[20] and CK enzymes, or muscle enzymes,[21] were normal. *Id*. at 74-76.

On July 11, 2011, petitioner underwent MRIs of the brain, thoracic spine, and cervical spine. An MRI of the thoracic spine did not show any cord lesions or significant changes. Pet. Ex. 8 at 10. An MRI of the cervical spine showed facet arthrosis and C5-6 bulge overall but no spinal cord lesions. *Id*. An MRI of the brain showed unchanged punctate white matter foci of signal alteration, with no new lesions or infarct. *Id*. at 9.

On July 13, 2011, petitioner returned to Dr. Gan complaining of pain. She had stopped taking Lyrica. Pet. Ex. 8 at 11. She was noted to be alert, cranial nerves were within normal limits, and sensory examination was 5/5. *Id*. Dr. Gan wrote "questionable fibromyalgia," and suggested a new medication and follow up for "TM." *Id*. It is unclear what "TM" refers to.

On July 18, 2011, petitioner returned to Dr. Bai with complaints of "incapacitating pain." Pet. Ex. 3 at 5. Her MS was stable, without exacerbation. *Id*. Petitioner "insist[s] she be treated w/steroids." *Id*. On examination, she had no "overt synovitis," but fibromyalgia tender points were 18 out of 18. Her CRP was elevated. *Id*. She also needed calcium and vitamin D supplements. Dr. Bai concluded that petitioner was having a flare up of fibromyalgia, and prescribed a trial of low dose steroids. *Id*.

On July 20, 2011, petitioner presented to Wade Toma, M.D., for a second opinion. Dr. Toma noted a 53 year old woman with complaints of pain in her hands, wrists, elbows, shoulders, hips, knees, lower back, and leg muscles. Pet. Ex. 5 at 3. She said her pain started after a tetanus shot in April. She stated after the shot, she had fever, flu-like symptoms, and arthralgia, then stiffness in her muscles, especially her neck, arms, and thighs, with difficulty getting up from a chair and with lifting her arms. *Id*. She had a history of MS, which was inactive. *Id*. She had fibromyalgia, and was treated with Lyrica, Soma, and Elavil, but did not feel better. *Id*. She described aching pain associated with morning stiffness lasting for one hour. *Id*. She experienced

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

[20] ALT stands for "alanine aminotransferase" and is also known as serum glutamic-pyruvic transaminase. *Mosby's* at 36-37. ALT is an enzyme found predominantly in the liver. *Id.* Injury or disease affecting the liver will cause elevated ALT levels; therefore, this test is used to help identify liver diseases. *Id.* A mildly elevated ALT is one indicator of myositis. *Id.* AST stands for "aspartate aminotransferase" and is also known as serum glutamic oxaloacetic transaminase. *Mosby's* at 107-09. AST is an enzyme found in the heart muscle, liver, and skeletal muscle. *Id.* Injury or disease affecting any of these organs will cause elevated AST levels. *Id.* If the injury or disease is chronic, the levels will be persistently elevated. *Id.* Increased AST levels are an indicator of primary muscle diseases like myopathy and myositis. *Id.*

[21] Creatine kinase ("CK") is an enzyme found in muscles. *Mosby's* at 167-68. CK levels are elevated when muscle or nerve cells are injured. *Id.* It is used to support the diagnosis of myocardial muscle injury and can also indicate neurologic or skeletal muscle diseases. *Id.*

gelling[22] throughout the day. *Id.* Her pain was steady all of the time, but worse in the morning. *Id*. She did not sleep well or feel rested in the morning. *Id*. She stated her blood work showed possible PMR. *Id*. She had stopped taking Lyrica, as advised by her neurologist. *Id*.

Dr. Toma noted a steady gait, intact coordination, and negative straight leg raising. Pet. Ex. 5 at 4. She had tenderness and fullness of the first and second MCP joints[23] and second, third, and fourth PIP joints[24] on the right side, and second, third, and fourth MCP joints and second, third, and fourth PIP joints on the left side. *Id*. There was pain on flexion of the wrist joints, pain on hyperextension of the elbows, and limited range of motion of the shoulders with diffuse tenderness. *Id*. There was crepitus of the knees and tenderness of the MTP joint.[25] *Id*. The rest of the joints revealed no synovitis and good range of motion. *Id*. She had multiple tender points of fibromyalgia, but no spinal tenderness, no sacroiliac joint tenderness, and no proximal muscle weakness or tenderness. *Id*. Blood work showed a normal CPK[26] and normal aldolase,[27] negative ANA, negative rheumatoid factor, CRP at 16.3 and uric acid at 7.2. *Id*. Dr. Toma's impression was fibromyalgia and osteoarthritis, but noted that it did not explain all of her presentation. "It is unlikely she has polymyalgia rheumatica given her age but she does have evidence of inflammatory process probably involving the joints given the involvement of the small joints of the hand and limited range of motion of the shoulders with the elevated CRP." *Id*. at 5.

On July 30, 2011, petitioner had x-rays of her left and right hands and wrists, which were normal. Pet. Ex. 5 at 8-9. An x-ray of the left shoulder was unremarkable except for slight AC joint[28] arthritic changes suspected. *Id*. at 10. An x-ray of the right shoulder was normal. *Id.* at 11.

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[22] "Gelling" or "gel phenomenon" is rheumatological stiffness after rest, typical of rheumatic diseases. R. Manno, *Osteoarthritis: Signs and Symptoms*, JOHNS HOPKINS ARTHRITIS CENTER, https://www.hopkinsarthritis.org/arthritis-info/osteoarthritis/signs-and-symptoms/ (last updated Aug. 16, 2017).

[23] The "MCP joints" are the metacarpophalangeal joints, which connect the metacarpal bones in the hand to the phalanges, the bones in the fingers. DORLAND'S at 1142, 1424.

[24] The "PIP joints" are the proximal interphalangeal joints, which connect the proximal and intermediate phalanges (the lower finger bone to the middle finger bone). DORLAND'S at 950, 1424.

[25] The "MTP joint" is the metatarsophalangeal joint, which connects the metatarsal bones in the foot to the bones in the toes. DORLAND'S at 1145, 1424.

[26] "CPK" is an abbreviation for creatine phosphokinase. *Mosby's* at 167. It is the same test as the test for creatine kinase (CK) levels. *Id.*

[27] Aldolase is an enzyme used in the breakdown of glucose. *Mosby's* at 38. This test is used to diagnose and monitor skeletal muscle diseases. *Id.* Elevated aldolase levels can indicate muscular dystrophy, dermatomyositis, or polymyositis. *Id.*

[28] The "AC joint" is the acromioclavicular joint. It connects the clavicle, or collarbone, to the scapula, or shoulder blade. STEDMAN'S POCKET MEDICAL DICTIONARY 10 (1st ed. 1987) [hereinafter STEDMAN'S].

On August 16, 2011, petitioner returned to Dr. Toma reporting significant improvement taking prednisone, but upon tapering, she had recurrence of pain in her hands, but not as bad as it used to be. Pet. Ex. 5 at 6. She noted occasional swelling in her hands. *Id*. She continued to complain of pain in her thumbs and knees and diffuse muscle pain. She did not sleep well or feel rested in the morning, and was tired during the day. *Id*. She had tenderness in the first CMC joint,[29] and her knees had crepitus with no warmth or effusion, but the rest of the joint exam revealed no synovitis with good range of motion. *Id*. at 7. She had several tender points of fibromyalgia, but no spinal tenderness, no sacroiliac joints tenderness, and no proximal muscle weakness or tenderness. *Id*. Dr. Toma concluded that petitioner had fibromyalgia and osteoarthritis. *Id*. Since there was evidence of inflammatory arthritis at petitioner's last visit but no synovitis on physical exam on that date, Dr. Toma felt rheumatoid arthritis was unlikely. *Id*. Dr. Toma wrote, "[A]lso, her presentation is not consistent with polymyalgia rheumatica." *Id*.

According to the record, petitioner presented to Dr. Faches on September 8, 2011. Pet. Ex. 6 at 30. However, there is no reason or treatment contained in the record for that visit.

On December 9, 2011, petitioner returned to Dr. Faches reporting that she had not felt well since July, was depressed, and "[H]er mood was much better when on prednisone." Pet. Ex. 6 at 27. She had been urinating in bed and having problems getting out of bed due to stiff muscles but had no weakness. *Id*. She reported her visits with Dr. Bai, medications, and MRI, stating she had "done all that was advised." *Id*. She stated that she asked Dr. Bai and Dr. Toma about whether she had PMR and neither agreed that she did. *Id*. She then went to Dr. Gan, who reassured her that she did not have muscular dystrophy; but he gave her a steroid and she "felt a million times better immediately." "The prednisone was like a miracle." *Id*. Dr. Faches documented fatigue, weight gain, headache with facial pain, occasional mild dyspnea, muscle pain, and myalgia, but no joint pain or weakness. *Id*. at 28. Petitioner was taking Provigil, naproxen, and Soma. *Id*. at 27. Dr. Faches' impression was steroid responsive myalgia and depression with anxiety. *Id*. at 29. Petitioner was referred to Dr. Grewal, a neuromuscular specialist. *Id*.

3. Petitioner's Treatment with Dr. Grewal

On January 5, 2012, petitioner presented to Dr. Grewal. On the initial visit questionnaire, she documented frequent falls, weight change, appetite change, excessive fatigue, night sweats, blurred vision, trouble focusing, double vision, hearing loss, high cholesterol, allergies to milk and eggs, shortness of breath, lower back pain, arm and leg pain, headache/migraine on the right side of her face, vertigo, concentration problems, weakness, pain, trouble walking, panic attacks, and insomnia. Pet. Ex. 4 at 12. She was taking Provigil and naproxen, was sedentary, and had quit smoking in September 2010 after 30 years of smoking two packs a day. *Id*. at 13. Petitioner has since resumed smoking. Tr. 29.

In a letter to Dr. Faches dated January 5, 2012, Dr. Grewal noted petitioner's past medical history including MS, suspected demyelinating disease, and treatment with Copaxone and Avonex, from which she developed side effects. Pet. Ex. 4 at 14. He noted episodes of vertigo with facial

[29] The "CMC joint" is the carpometacarpal joint. The CMC joint is made up of five smaller joints which connect the carpal bones in the wrist to the metacarpal bones in the hand. DORLAND'S at 298, 1142.

numbness which were treated with solumedrol (steroids). *Id*. She did not take medication for MS until 2007, when she was hit by a car while working as a crossing guard after which she developed numbness and fatigue associated with vertigo and was treated with steroids. *Id*. She received a tetanus booster in April 2011, after a foot injury, and started having some discomfort involving her arms and legs. Since then, she has not been the same. She complained of pain with movements of her shoulder and hips, which interfered with her activities of daily living. *Id.* Dr. Bai prescribed Elavil, Celebrex, Savella, Lyrica, and carisoprodol for fibromyalgia. *Id.* Petitioner reported the medication was ineffective. *Id*. "You" (referring to Dr. Faches) thought she may have developed PMR and prescribed steroids. Taking steroids she "felt like a new woman," until the dose was reduced to 10 mg a day, at which point her symptoms recurred. *Id*. Her current medications included Provigil and naproxen. *Id*.

Dr. Grewal's examination revealed bilateral tenderness to palpation in the deltoid and biceps muscles, with strength limited due to discomfort in the biceps, deltoid, supraspinatus, and infraspinatus muscles. Pet. Ex. 4 at 15-16. Lower arms were strong. *Id*. at 16. She had weakness of hip flexion bilaterally associated with pain, but her knee and lower leg muscles were strong. *Id*. She was able to walk on her heels and toes without difficulty, and her gait was normal. *Id*. Dr. Grewal also reviewed the results of blood work performed on July 6, 2011 noting an elevated white blood cell count and C-reactive protein three times higher than normal. *Id*. Her ESR[30] was 32 but had been 10 on May 22, 2011. *Id*. Otherwise, her metabolic panel, testing for rheumatoid factor, ANA, Lyme serology, lupus anticoagulant, protein S, anti-cardiolipin antibody, anti-nuclear antibody, and homocysteine were all normal. *Id*. MRIs were unchanged. *Id*. Dr. Grewal acknowledged that he did not have petitioner's records of prior episodes of MS, but concluded that her muscle pain and weakness were not related to MS and it was "interesting that this condition occurred after the tetanus vaccination." *Id*. He requested an EMG/NCS to determine possible inflammatory myositis. *Id*.

On January 11, 2012, Dr. Grewal issued an addendum to his report, adding that the EMG showed mild evidence of myositis in a sampling of the right biceps muscle. Pet. Ex. 4 at 16. He recommended a left biceps muscle biopsy. *Id*. The EMG report stated, "This electrophysiological study shows no strong evidence of a neuropathy. The mild abnormalities on needle EMG in the right biceps are of unclear significance, but favor a myopathic[31] process." *Id*. at 8-9.

On January 18, 2012, petitioner presented to Dr. Gregory Przybylski for an exam in preparation for a biopsy of her left bicep. Pet. Ex. 9 at 82. She provided a history of having received a tetanus vaccine in April 2011, after which she "became ill with flulike symptoms right away and

[30] ESR measures the rate at which red blood cells settle in a solution over an hour. *Mosby's* at 199-201. The normal range for women is 0-20 millimeters per hour, but the upper threshold may vary from one medical practice to another, so petitioner's 32 is elevated but not grossly out of range. *Id.* The worse the disease is, the higher the ESR will be. *Id.* A mildly high ESR can indicate anemia, infection, or pregnancy. *Id.* A very high ESR usually has an obvious cause such as chronic renal failure, bacterial infection, necrotic disease, or inflammatory disease like PMR or temporal arteritis. *Id.*

[31] "Myopathic" or "myopathy" is any abnormal condition or disease of the muscular tissues, especially involving skeletal muscle. *Myopathy,* STEDMAN'S at 488.

has since developed severe persistent pain and stiffness in the proximal arms and legs." *Id*. Petitioner informed Dr. Przybylski that taking prednisone "resulted in substantial improvement," while discontinuing it resulted in recurrent pain. *Id*. Examination revealed normal upper and lower limb strength, tone, sensation, and 2+ upper limb and patellar reflexes without Hoffman's signs or ankle clonus. *Id*. at 83. Her casual gait and heel and toe walking were normal, but she had mild trouble with tandem gait. *Id*.

Petitioner returned to Dr. Faches on January 20, 2012 and reported that Dr. Grewal was "concerned that her myalgia could be related to the tetanus vaccine." Pet. Ex. 6 at 23. She complained of severe pain, and an inability to sleep more than three hours per night or do anything without pain. *Id*. She was taking Provigil and naproxen. *Id*. Dr. Faches noted complaints of neck pain, difficulty breathing on exertion, nasal congestion, anxiety, a change in sleep patterns, and depression. *Id*. at 24. Upper and lower extremity strength and gait were normal. *Id*. at 25. Reflexes were 2+ in both knees. *Id*. Dr. Faches's impression was steroid responsive myalgia, hypercholesterolemia, and herpes simplex virus II infection. Valtrex was prescribed. *Id*. A recent abnormal EKG was sent to petitioner's cardiologist, Dr. Panebianco, who thought the abnormal results were due to improper lead placement or body habitus. *Id*. at 22.

On January 23, 2012, a left bicep biopsy was performed, finding the "presence of selective type 2B fiber atrophy which can be seen in association with muscle disuse or the administration of corticosteroids." Pet. Ex. 9 at 92-93. The impression was "skeletal muscle with non-specific abnormalities." *Id*.

On January 31, 2012, petitioner presented to Dr. Faches with a sore throat and frequent urination. She made no other complaints. Examination was normal. Pet. Ex. 6 at 19-20. A strep test and urine analysis were both negative. *Id*. at 18, 21. Rest and fluids were recommended. *Id*. at 21.

Petitioner returned to Dr. Faches on February 1, 2012 with acute sinusitis. She was prescribed Levaquin. Pet. Ex. 6 at 17. She returned again on February 7, 2012, for the same complaints and was prescribed Proventil. *Id*. at 16.

Petitioner did not see Dr. Grewal again until March 5, 2012. At that visit he advised her that the muscle biopsy showed "there were mild nonspecific abnormalities with no clear evidence of an inflammatory myopathy, however, as I informed the patient this does not exclude an inflammatory myositis." Pet. Ex. 4 at 6. Petitioner had "a dramatic response to steroids." A taper was suggested. *Id*. Dr. Grewal discussed the use of IVIG for conditions like inflammatory myopathies, along with its side effects. *Id*. Petitioner's most recent blood work was normal.[32] Dr.

[32] "The following blood tests were ordered and were either negative or normal: CBC and differential, ANCA panel, comprehensive metabolic panel, serum protein electrophoresis and immunofixation, ENA, Sjogren's antibodies, B12, folate, ANA, rheumatoid factor, anti-double stranded antibodies, anti-Jo-1, anti-centromere B antibodies, anti-scleroderma-70 antibodies, homocysteine, ACE, vitamin B6, vitamin E, vitamin B1, anti-gliadin antibody, aldolase, CPK, Lyme serology, cryoglobulin, serum, magnesium, copper, zinc and amylase, and anti-GAD antibody." Pet. Ex. 4 at 6; *see also* Pet. Ex. 6 at 38, 56-62.

Grewal's assessment was "[P]ossible inflammatory myositis." *Id*. at 7. She was to restart the medications that she was on prior to the biopsy, including Elavil. *Id*.

On April 12, 2012, petitioner presented to Dr. Faches with complaints of gastroesophageal reflux disease ("GERD") and allergies ongoing for three weeks. Pet. Ex. 6 at 13. She reported increased heartburn "over the last week" and she "always needs an acid med [sic] when on a steroid." *Id*. She was taking Valtrex, Proventil, prednisone, Provigil, and omeprazole. *Id*. Her examination was normal. She was prescribed Clarinex. *Id*. at 14-15.

On May 8, 2012, petitioner returned to Dr. Faches with bronchitis. Pet. Ex. 6 at 10. She felt out of breath and had sinus pressure in her head and pain in her teeth. *Id*. She complained of sore throat with voice change, cough, post-nasal drip, sinus pain, swelling of the neck glands, and ear pain that was worse in her left ear. *Id*. Levaquin was "restarted". *Id*. at 12. Petitioner felt her dyspnea was worse, and agreed to see both a cardiologist and a pulmonologist. *Id*. She was referred to Dr. Mellilo.[33] *Id*.

On August 13, 2012, petitioner returned to Dr. Grewal with MS and muscle pain. Pet. Ex. 7 at 39. She was prescribed 20 mg of prednisone every other day, alternating with 15 mg. *Id*. at 40.

On October 1, 2012, petitioner returned to Dr. Grewal reporting severe myalgias with joint stiffness when prednisone was reduced to 15 mg a day. Pet. Ex. 4 at 17; Pet. Ex. 7 at 20. This was the third time a prednisone reduction was attempted. *Id*. Dr. Grewal increased her dose of prednisone to 20 mg a day. *Id*. He wrote, "[I]n terms of the etiology of her symptoms, it is likely that this is a vaccine related rheumatological condition. It was not present prior to the vaccination and there is a temporal relationship in the development of symptoms after the vaccination suggesting cause and effect." *Id*.

Petitioner returned to Dr. Faches on October 16, 2012 with fever, chills, diarrhea, loss of appetite, night sweats, sweating, and facial pressure. Pet. Ex. 6 at 7. She had lost some weight and felt better "body wise," but "felt lousey [sic] when [Dr. Grewal] tried to decrease her steroids." *Id*. Petitioner was diagnosed with probable viral syndrome which was improving. *Id*. at 9.

Petitioner returned to Dr. Faches on November 30, 2012, complaining of a cold, sore throat, cough, facial pain and pressure, headache, ear pain, shortness of breath, fatigue, weakness, chills, and body aches. Pet. Ex. 6 at 4. She was diagnosed with acute frontal sinusitis and prescribed Levaquin. *Id*. at 6.

On February 18, 2013, petitioner returned to Dr. Grewal reporting that she had tried to reduce the prednisone but was unable to tolerate less than 20 mg a day. Pet. Ex. 7 at 3. She did not have significant muscle or joint pain, and her neuromuscular examination showed 5/5 strength both proximally and distally. *Id*. Imaging studies done on January 29, 2013, showed no new spinal cord or brain lesions. *Id*. Because petitioner reported that her symptoms were worse in cold weather, Dr. Grewal suggested reducing her dosage of prednisone once the weather became

[33] No records of any treatment with Dr. Mellilo were filed.

warmer. *Id*. He again discussed IVIG, methotrexate, and Imuran as steroid-sparing medications. *Id*.

On May 13, 2013, petitioner returned Dr. Grewal for follow-up of "myositis." Pet. Ex. 7 at 35. She was alternating prednisone daily between 20 mg and 15 mg. *Id*. at 36. Dr. Grewal wrote, petitioner has an established diagnosis of MS and inflammatory myositis. "The diagnosis is not in doubt and has been made on the basis of a [sic] EMG which showed evidence of an inflammatory myositis. She has been responsive to prednisone, but now is becoming intolerant. Previous attempts to reduce the prednisone have resulted in increased weakness and inability to walk or perform activities of daily living." Pet. Ex. 9 at 75. Her physical examination showed proximal muscle weakness and muscle tenderness. *Id*. She had 4/5 strength in the deltoids, biceps, and hip flexion. *Id*. IVIG weekly for three months to treat inflammatory myositis was recommended. *Id*. "This can be used in conjunction with the prednisone which can then be slowly withdrawn." *Id*.

IVIG infusions consisting of solumedrol[34] with IV Benadryl first and Tylenol began. Pet. Ex. 9 at 5. Petitioner's neurological examination on June 30, 2013, prior to starting IVIG was normal. Pet. Ex. 7 at 32. Petitioner was also taking prednisone, alternating daily between 20 mg and 15 mg. *Id*. at 34. At the time of hearing, petitioner was still receiving IVIG treatments along with daily prednisone.[35] Pet. Ex. 10 at 1.

In a June 21, 2014 letter, Dr. Grewal wrote, petitioner developed a "polymyalgia rheumatica like" disorder following a tetanus vaccine. Pet. Ex. 10 at 1. She had a history of MS that had been clinically and radiologically stable. *Id*. She also had preexisting fibromyalgia, but her joint and muscle stiffness and pain with movement started after her tetanus shot in April of 2011. *Id*. These symptoms interfered with petitioner's activities of daily living. *Id*. Petitioner's symptoms improved with steroids, but weaning off steroids caused symptoms to recur. *Id.* Dr. Grewal opined that petitioner's EMG and muscle biopsy support a co-existing myositis, also an autoimmune /inflammatory disease. *Id*. He noted that the EMG provided evidence of myositis, not features of fibromyalgia. *Id*. "The clinical features and response to steroids are more indicative of PMR than of fibromyalgia. Fibromyalgia does not respond to steroids." *Id*.

Almost a year later, on May 7, 2015, Dr. Grewal documented that petitioner had "deteriorated." Pet. Ex. 39 at 12. She had documented MS and associated autoimmune rheumatological disorder which had features consistent with an inflammatory myositis, sensitive to prednisone and to the combination of IVIG and prednisone. *Id.*

On November 5, 2015, Dr. Grewal wrote that petitioner required a cardiac workup due to shortness of breath, which he suspected was related to deconditioning. Pet. Ex. 39 at 11. She had a "polymyalgia rheumatica like" disorder which "possibly" had a component of inflammatory

[34] Solumedrol is an anti-inflammatory glucocorticoid, which contains methylprednisolone sodium succinate as the active ingredient – a steroid. *Solumedrol*, DORLAND'S at 1154, 1731.

[35] Petitioner developed a rash due to an albumin allergy and the IVIG was switched without event. Pet. Ex. 9.

myositis. *Id*. She was receiving weekly IVIG and was taking 10 mg of prednisone per day. IVIG reduction to every other week was recommended. *Id*.

On March 28, 2016, according to Dr. Grewal, petitioner was taking 10 mg of prednisone a day, "the lowest dose that she has been on for more than a year." Pet. Ex. 39 at 9. She was off IVIG for several months but felt worse, with discomfort in her joints, muscle tenderness, and weakness. *Id*. Petitioner advised that she slipped, fell, and was unable to get up. *Id*. On examination, she was unable to walk on her heels and toes and had a positive Romberg sign.[36] *Id*. Dr. Grewal recommended resuming IVIG every two weeks. *Id*. He concluded that the recurrence of petitioner's symptoms on 10 mg of prednisone while off of IVIG meant that a component of her symptoms was responsive not only to the prednisone, but also to IVIG. *Id*. He further noted that petitioner was intolerant to medications for MS and the IVIG had the additional benefit of being a known useful alternative treatment for patients with relapsing-remitting MS. *Id*. at 10.

In his record of June 13, 2016, Dr. Grewal documented that petitioner had MS and myositis. Pet. Ex. 39 at 17.

Thereafter, Dr. Grewal's records fluctuate between a diagnosis of myalgia/myositis and MS, myositis and MS, and inflammatory myositis and MS. PMR is no longer listed. *See* Pet. Ex. 39 at 7-39; Pet. Ex. 41 at 2-4. At hearing, Dr. Grewal stated his working diagnosis all along was "PMR-like" and "myositis-like" disease because petitioner's "autoimmune process… [is] affecting not just the connective tissue but perhaps the muscles as well." Tr. 105.

On November 28, 2016, Dr. Grewal wrote that petitioner had an established diagnosis of inflammatory myositis and MS. Pet. Ex. 39 at 7. She continued to have double vision in addition to weakness and imbalance. *Id*. Dr. Grewal noted that some of these symptoms were related to petitioner's MS and some to her inflammatory myositis. *Id*.

The most recent record filed was from Dr. Faches dated August 4, 2017. It documented that petitioner was doing well, though "still depressed a little." Pet. Ex. 42 at 6, 8. She presented for management of hyperlipidemia and associated symptoms of decreased exercise tolerance and edema. She had GERD, but no chest pain or dysphagia. *Id*. at 6, 8. She continued to smoke and likely had COPD. *Id*. She was on 10 mg of prednisone daily and IVIG every 10 days. *Id*. at 6. A GI specialist was recommended. *Id*. at 8.

[36] A positive Romberg sign occurs when the patient's balance is more unsteady when his or her eyes are closed, and "indicates a loss of proprioceptive control." *Romberg sign*, STEDMAN'S at 684.

C. Testimony of Petitioner[37] Julie Suliman

Petitioner testified that 23 years ago, she consulted a neurologist[38] due to weakness in her left arm and loss of balance. She was diagnosed with MS. Tr. 7. She opted not to take medications, and remained without any significant issues related to her MS until about 2007, when she was hit by a car while working as school crossing guard. Tr. 8. Six months later, she developed symptoms of MS with facial and tongue numbness. Tr. 8, 21. She took Copaxone for about two years until it caused her to develop hives. Tr. 9, 24. Avonex made her sick as well. Tr. 9, 24. Infusions of solumedrol "cleared it up." Tr. 8, 24-25. She may have had additional steroid infusions thereafter. Tr. 8. She also developed episodes of shingles, which were treated with Valtrex. She continues to have repeated "break outs" of shingles and left leg weakness during her menstrual cycle. Tr. 22.

The following winter, petitioner began "feeling achy." Dr. Faches referred her to Dr. Bai, a rheumatologist. Tr. 8. Dr. Bai diagnosed her with fibromyalgia and prescribed medication. Tr. 8. She stopped taking the medications in the spring and was able to work and live her life normally. Tr. 9. Petitioner did not recall seeing Dr. Bai again until after the tetanus shot. Tr. 26. She did not follow up with Dr. Bai regularly. She went only if she had a problem with her fibromyalgia. Tr. 26. Petitioner stated she would report all of her health-related issues to Dr. Faches. Tr. 27.

Petitioner smoked for 30 years; she tried to quit in July 2010 and gained 30 pounds. Tr. 28, 30. She was able to quit for a few years, but returned to smoking again. Tr. 29. She has gained 50 pounds in total since 2010. Tr. 29-30.

Petitioner was questioned about her visit with Dr. Faches a month prior to the Tdap vaccination, on March 4, 2011, which documented complaints of "a lot of fibromyalgia pain," "problems sleeping due to pain," and Dr. Gan's prescribing Lyrica, but petitioner refusing it and requesting Lexapro instead.[39] Tr. 30; Pet. Ex. 6 at 83. Petitioner denied having any pain or problems sleeping the month before the tetanus shot. She did not recall seeing Dr. Faches on that date. Tr. 30-31.

Petitioner testified that she tripped in her house and a staple went under the nail bed of her toe. Tr. 9, 33. The next day, April 1, 2011, she saw Dr. Faches and informed her that she was taking Lexapro, Valtrex, Xanax, and Provigil,[40] which helped with clarity and was prescribed by Dr. Gan. Tr. 33; Pet. Ex. 6 at 82. Petitioner did not recall having a sore throat or advising Dr.

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[37] Petitioner never filed an affidavit with her petition. The statute and the rules require the documentation supporting the claim be filed with the petition. 42 U.S.C.A. § 300aa-11(c); RCFC, Appendix B, Vaccine Rule 2. The Vaccine Rules specifically state that "if the required medical records are not submitted, the petitioner must include an affidavit detailing the efforts made to obtain such records and the reasons for their unavailability. If petitioner's claim does not rely on medical records alone but is also based in any part on the observations or testimony of any person, the petitioner should include the substance of each person's proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition." RCFC, Appendix B, Vaccine Rule 2(c)(2)(B)(i)-(ii).

[38] Petitioner did not supply any medical records pertaining to this initial visit. However, the record is replete with references to petitioner's MS diagnosis. *See, e.g.*, Pet. Ex. 3 at 22; Pet. Ex. 5 at 3; Pet. Ex. 9 at 76.

[39] There is no record of petitioner seeing Dr. Gan during this timeframe.

[40] There are no records from Dr. Gan of this prescription.

Faches that she was exposed to strep, or had a stomach virus the week before, as reflected in her record. Tr. 34. She did recall receiving Tdap vaccine, but did not recall in which arm. She did not recall receiving any information about the vaccine or being told to contact the doctor's office if she had any adverse effects. Tr. 35-36. Petitioner confirmed that she had tetanus vaccines in the past. Tr. 34.

According to petitioner, she awoke the next day with flu-like symptoms, was unable to get off her couch, and felt like "somebody beat [her]." Tr. 10. Her arm hurt where she received the vaccine, but she could not remember which arm. She felt feverish, but did not take her temperature. She did not recall having a sore throat. Her "primary concern was the muscular pain." Tr. 36. She did not call Dr. Faches about her symptoms, but she did cancel a hair appointment scheduled for that day. Tr. 37.

Petitioner recalled going to see Dr. Bai two weeks later on April 18, 2011, because she was having muscle pain. She confirmed that Dr. Bai was the first doctor she saw after the tetanus shot. Tr. 10, 37-38. She told Dr. Bai that she had muscular and joint pain in her arms, hips, and legs, trouble getting up and lifting her arms following receipt of a tetanus shot. Tr. 10-11, 38. Petitioner could not remember if Dr. Bai did a fibromyalgia examination. She told Dr. Bai that she felt different, that her symptoms did not feel like fibromyalgia pain. Tr. 11, 39; 48-49. Celebrex and Lyrica were prescribed; petitioner could not recall if she had been on those medications before. Tr. 40; Pet. Ex. 3 at 10.

Petitioner was questioned about Dr. Bai's record for April 26, 2011, which noted "significant improvement since restarted meds." Pet. Ex. 3 at 9. Petitioner did not recall getting better in the weeks that followed, but if Dr. Bai's records said that she did, she must have appeared to get better. Tr. 40. "I could have had a good day and then that's what [Dr. Bai] wrote." Tr. 44. She stated, within a month or two of receiving the Tdap vaccine, "I went downhill to the point where I couldn't roll over in bed. I couldn't get up." Tr. 10. "I ended up getting worse and seeking another opinion….Definitely by sometime in June and then going into July…So it was definitely in that June to July where this was not working for me anymore." She added "I was always symptomatic. It always felt like it was, you know, there. Maybe some days were better than others, but past June it started getting consistent and worse." Tr. 40-41. When questioned about the accuracy of Dr. Bai's record regarding improvement once on medications for fibromyalgia, petitioner responded "I don't remember. I don't remember. I only remember the end result was that getting worse." Tr. 45.

Petitioner was questioned about her visit with Dr. Bai on June 30, 2011, which documented complaints of stiffness in her lower extremities for the first time. Tr. 43. Petitioner stated that she had lower back problems, stiffness and difficulty getting up prior to that appointment, but Dr. Bai must not have written it down. Tr. 43. She stated the pain may not have been there; it may have developed later.[41] Tr. 43, 48. Petitioner was questioned about the change in her condition between April and June of 2011. She admitted that the medication Dr. Bai prescribed did help her, but "then

[41] This statement was contrary to her prior testimony that, after the vaccine, her "primary concern was pain," and that she complained to Dr. Bai of pain. Tr. 10, 36-38.

it got worse. Whatever she had me on was not working anymore, which is why I went back." Tr. 47-48. She explained,

> …I felt like I was getting worse where I couldn't, like, get out of bed, get off the toilet. It was getting increasingly more difficult for me to get up. It would take me like two hours in the morning in my office to just, like, get my body moving…In my opinion, it was going on all along. But it got significantly worse in June and into July. It was a progression. I don't know—I don't remember—I only remember the bad. Not the good.

Tr. 46.

Petitioner stated after the medications stopped working, she went to Dr. Toma for a second opinion. Tr. 11, 41. He prescribed steroids, and "[t]he minute I took the steroids, I felt like a new person," but as soon as the steroids were tapered, her symptoms returned. Tr. 11-12, 41-42. Petitioner agreed that she had taken steroids for her MS several times since 2008, and that she always felt better while on prednisone. Tr. 54-57.

Petitioner stated that she went to her neurologist, Dr. Gan, on July 13, 2011, and he "didn't know what to do with me. He had no idea." Tr. 12. Petitioner stated she told all of the doctors that her symptoms began after the tetanus vaccine. Tr. 12.

According to petitioner, she did not see a doctor again until she saw Dr. Faches on December 8, 2011. She claimed that she was unable to see Dr. Faches, because Dr. Faches moved her offices.[42] Tr. 12, 49-50. At that visit, she told Dr. Faches that she did not want to go back to Dr. Bai or Dr. Toma because they did not believe her or have any theory about what was wrong with her. Dr. Faches referred her to Dr. Grewal. Tr. 12. According to petitioner, she self-medicated with steroids until she could get in to see Dr. Grewal.[43] Tr. 12. She could not recall which doctor first suggested PMR to her. Tr. 62.

Petitioner saw Dr. Grewal in January of 2012; he took her off steroids in order to do a muscle biopsy, and then she went back on steroids. [44] Tr. 12-13. She started IVIG treatments in June of 2013. Tr. 13. Now she takes multiple medications in addition to IVIG to treat her weight gain and high blood pressure. Tr. 13.

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[42] Dr. Faches' record shows that there was an appointment in September of 2011, but the reason was not documented. Pet. Ex. 6 at 30.

[43] There is no record of who prescribed the steroids that petitioner was taking at that time, or of the dosage that petitioner was taking. Dr. Grewal's record does not include a prescription for steroids until March 2012.

[44] It appears that petitioner was off steroids from January through March 2012 when Dr. Grewal prescribed them again; she continued working during that time. *See* Pet. Ex. 9 at 83 (Dr. Przybylski noted on January 18, 2012, "She had been taken off of steroids, and Dr. Grewal did not want to resume them until after a biopsy specimen was obtained."); Pet. Ex. 4 at 6 (Dr. Grewal noted on March 5, 2012, that petitioner had "been restarted on prednisone.").

I asked petitioner to describe the differences in her symptoms from an MS flare, a fibromyalgia flare, and those she experienced in April 2011. She responded that an MS flare presents as facial paralysis and feeling drunk, like "jelly," with her whole body feeling like it is on Novocain. Tr. 58. A fibromyalgia attack is muscle aches, fatigue, and a burning sensation when someone touches her skin. Tr. 15, 58-60. The muscle pain after the vaccination felt like somebody had beaten her, or she lifted weights and "overdid it." Tr. 14-15, 58-60. It was movement restriction, with pain in her shoulder, lower back, and upper thighs. Tr. 14. Although petitioner received the Tdap vaccine in her left arm, she described joint pain in her hand, especially her right thumb, as well as her ankles and knees, with stiffness on both sides of her body. Tr. 14-15, 59. Petitioner claims since the vaccination, she has not had any fibromyalgia flares, only MS flares. Tr. 60-61.[45]

Petitioner stated that prior to April of 2011, other than when she had MS attacks, she was a single working mom. She took care of her house, worked as a crossing guard for an elementary school, and worked for an insurance company doing audits as well as reviewing other auditors' work. Tr. 16-17. She used to work up to eight cases in a day; now, she works one or two days a week, two or three cases. Tr. 18-19. Before the vaccination, she painted, hung wallpaper, mowed the lawn, and cared for her pool. Tr. 17. She now knows her limitations and has to make accommodations; she cannot walk too far or overdo it, or she will be unable to do anything for days. Tr. 15. Stairs are hard for her, and she cannot walk freely; she has to hold onto something. Tr. 11, 20. Cold weather bothers her as well. Tr. 18. Petitioner continues to treat only with Dr. Faches and Dr. Grewal. Tr. 41.

III. The Experts

A. Petitioner's Treating Physician and Expert, Dr. Raji Grewal

Dr. Grewal specializes in neurology at LifeCare Physicians of Hamilton in New Jersey. Pet. Ex. 12 at 1. He is a staff neurologist at the Neuroscience Institute of Saint Francis Medical Center and a Professor of Neuroscience at the School of Graduate Medical Education at Seton Hall University. *Id*. Dr. Grewal received his medical degree in 1982 from the University of Alberta at Edmonton in Alberta, Canada. *Id*. He completed residencies in internal medicine, biochemistry, and neurology. *Id*. at 2. In his current practice, Dr. Grewal provides second opinions on neuromuscular cases, as well as for patients with unclear diagnoses. Tr. 65. Because of this, he tends to get undiagnosed patients who are not always clearly neuromuscular cases. Tr. 65. Prior to 2010, Dr. Grewal saw 40 to 50 patients a week; now he sees 30 to 35, with a mixture of new patients and follow-ups. Tr. 66. Dr. Grewal does not treat patients with PMR. Tr. 117-18. Dr. Grewal has not authored or coauthored any peer-reviewed publications on vaccines, ASIA, PMR, fibromyalgia, or inflammatory myositis. Tr. 118-19. He has never submitted a case report that a neuromuscular condition for a patient he treated may have been caused by a vaccine. Tr. 119. He has not been involved in immunology research, or taught immunology. Tr. 119.

[45] This is confusing since Dr. Grewal noted that steroids would work on MS but have no effect on fibromyalgia. Tr. 105.

B. Respondent's Expert, Dr. Mehrdad Matloubian

Dr. Matloubian is an Associate Adjunct Professor at the University of California at San Francisco School of Medicine. Resp. Ex. T at 2. Dr. Matloubian received his bachelor's degree in biochemistry, Ph.D., and medical degree from UCLA. *Id.* at 1. He completed his residency in internal medicine and a fellowship in rheumatology. *Id*. Dr. Matloubian is an immunologist and board certified rheumatologist who actively evaluates and treats patients with complex autoimmune diseases, including rheumatoid arthritis, lupus, mixed connective tissue disease, PMR, different types of inflammatory myositis, and vasculitis. Tr. 189; Resp. Ex. A at 1. He sees patients who have been referred by general practice physicians for evaluation as well as those who have been referred by rheumatologists for second and third opinions. Tr. 189-90. Often, his patients either are not responding to treatment, have complex autoimmune diseases affecting many organs, or do not fit into one disease category. Tr. 190-91. Dr. Matloubian also has a Ph.D. in microbiology and immunology with an emphasis in virology. Tr. 209. His post-doctoral training focused on how lymphocytes, or white blood cells, travel from different tissues and different organs, and immune responses to acute and chronic viral infections focusing on both innate and adaptive immune responses. Tr. 275-76. Therefore, he is familiar with the mechanics of immunology and how the immune system responds to various antigens. Tr. 276. He has published several articles on immunology, particularly on lymphocyte trafficking, in peer-reviewed journals. Tr. 276; *see also* Resp. Ex. T at 10-13 (listing Dr. Matloubian's articles published in peer-reviewed journals). His other research interests include autoimmune disease, interferons, plasmacytoid dendritic cells, antibody responses in chronic viral infection, chemokines, and chronic inflammation. Resp. Ex. T at 2.

IV. Findings of Fact

A. Legal Standard Regarding Fact Finding

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("Given 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."). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in an accurate manner, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d. 1525 (Fed. Cir. 1993)("[I]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of

neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred.").

Where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—particularly where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health and Human 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) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")). In making contemporaneous reports, the declarant's motivation for accurate explication of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec'y of Health & Human Servs*., 28 Fed. Cl. 516, 523 (1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs*., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs*., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (explaining that §13(b)(2) "must be construed so as to give effect also to §13(b)(1) which directs the special master or court to *consider* the medical records [reports, diagnosis, conclusions, medical judgment, test reports, etc.] but does not require the special master or court *to be bound* by them.") (emphasis in original). There are situations in which compelling oral testimony may be more persuasive than written records—for instance, in cases where records are deemed to be incomplete or inaccurate.[46] *Campbell v. Sec'y of Health & Human 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 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.") (quoting *Murphy*, 23 Cl. Ct. at 733 (1991). However, when such testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, it must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). A determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Serv*s., 991 F.2d 1570, 1575 (Fed. Cir.

[46] 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 & Human Servs*., 110 Fed Cl. 184, 203-04 (2013), *aff'd,* 746 F.3d 1334 (Fed. Cir. 2014).

1993). The special master must then determine whether to afford greater weight to contemporaneous medical records or testimony given at hearing. This decision must in turn be supported by evidence that it was the result of a rational determination. *Burns by Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993). Ultimately, "the record as a whole" must be considered. 42 U.S.C. § 300aa-13(a).

B. Petitioner Alleges that She Suffers from PMR Caused by the Tdap Vaccine

In his reports and records, Dr. Grewal's diagnosis varied between PMR, PMR-like, myositis, inflammatory myositis and a hybrid autoimmune complex with features of both PMR and myositis. Dr. Matloubian disagreed, and submitted that petitioner has PMR, not myositis.

Inflammatory myositis is a heterogeneous group of disorders classified into several subtypes, including dermatomyositis and polymyositis. Resp. Ex. Q[47] at 2. Dermatomyositis is an autoimmune disease which mainly affects muscle and skin, typically characterized by muscle weakness, elevated muscle enzymes, and skin lesions. Pet. Ex. 22[48] at 1. Dermatomyositis is thought to be caused by hyperactivation and dysregulation of the adaptive immune system, with both humoral and cellular components, although recent studies have highlighted the activation of the innate immune system as an important pathological hallmark of dermatomyositis. *Id*. at 1, 3; *see also* Pet. Ex. 23[49] (summarizing evidence supporting the involvement of the innate immune system in the pathogenesis of juvenile dermatomyositis).[50] Polymyositis presents with proximal symmetric weakness in adults. Resp. Ex. Q at 4. Polymyositis is a diagnosis of exclusion, which requires other causes to be ruled out before the diagnosis can be made. *Id*. In diagnosing polymyositis, several factors are considered, including timing of disease progression, pattern of muscle involvement, level of muscle enzymes, results of EMGs and muscle biopsies, and presence of certain autoantibodies. *Id*. at 5.

[47] Marinos C. Dalakas, *Inflammatory Muscle Diseases*, 372 N ENGL J MED 18: 1734-47 (2015), filed as "Resp. Ex. Q."

[48] Thorsten Hornung et al., *Innate Immune-Response Mechanisms in Dermatomyositis: An Update on Pathogenesis, Diagnosis and Treatment*, 74 DRUGS 981-98 (2014), filed as "Pet. Ex. 22."

[49] Sahil Khanna et al., *Immunopathogenesis of Juvenile Dermatomyositis*, 41 MUSCLE NERVE 5: 581-92 (2010), filed as "Pet. Ex. 23."

[50] Dr. Grewal cited an additional article discussing polymyositis and dermatomyositis, which petitioner filed as Pet. Ex. 24; however, petitioner filed only the first page of the article. The remainder of the article is missing. *See* Kanneboyina Nagaraju, *Polymyositis and Dermatomyositis: Pathophysiology*, 37 RHEUM DIS CLIN N AM 159-71 (2011), filed as "Pet. Ex. 24."

PMR is an inflammatory syndrome characterized by aching and morning stiffness in the shoulder and pelvic girdle. Pet. Ex. 13[51] at 1; Pet. Ex. 18[52] at 1. Because there are no specific diagnostic tests or pathologic findings determinative for PMR, it is defined by its clinical features: (1) aching and morning stiffness which lasts for half an hour or longer in the shoulder, neck, and/or hip girdle, (2) ongoing for one month or longer, (3) in a person 50 years or older, and (4) whose bloodwork shows systemic inflammation, such as an elevated ESR. *Id*. Some definitions also include a rapid response to small doses of prednisone. Pet. Ex. 18 at 1.

PMR patients are typically in good health prior to onset and more than half initially present with low-grade fever, weight loss, and malaise. Pet. Ex. 18 at 7. "Arthralgias and myalgias may develop abruptly or evolve insidiously over weeks or months." *Id*. Most patients experience onset of pain in the shoulder girdle first; others first experience pain in the hip or neck. The pain may start on one side, but usually becomes bilateral within weeks. *Id*. Patients often experience pain at night which wakes them up. *Id*. PMR can be isolated or related to giant cell arteritis ("GCA"). Pet. Ex. 13 at 1. However, "[t]he presence of another specific disease other than GCA, such as rheumatoid arthritis ("RA"), chronic infection, polymyositis, or malignancy excludes the diagnosis of PMR." Pet. Ex. 18 at 1.

In his reports, Dr. Grewal distinguished PMR and inflammatory myositis, explaining that myositis is autoimmune, characterized by elevated CPK and aldolase, with abnormal EMGs and muscle biopsies. Pet. Ex. 11 at 4. In PMR, muscle biopsies are often negative or nonspecific, as in petitioner's case.[53] *Id*. Dr. Grewal cautioned, "You have to be very confident that that's what you are treating because the treatment can be long and prolonged and involve potentially toxic medication such as steroids." Tr. 69-71; Pet. Ex. 11 at 3; Pet. Ex. 21 at 2.

Dr. Grewal wrote that his diagnosis has never been definitive, except for, perhaps, PMR, but stated that it was not unusual for patients with diagnostically challenging cases to be treated "empirically," without certainty of a given diagnosis. Pet. Ex. 21 at 2. If the treatment for a particular condition, or combination/hybrid of conditions is effective, it makes for a better basis for diagnosis. *Id*. Dr. Grewal opined petitioner had a complex disease process which does not allow for simple categorization; it is a "hybrid autoimmune complex with features of both conditions." *Id*. at 2-3.

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[51] Alessandra Soriano et al., *Polymyalgia rheumatica in 2011*, 26 BEST PRACT RES CLIN RHEUMATOL, 91-104 (2012), filed as "Pet. Ex. 13."

[52] David B. Hellmann, *Giant Cell Arteritis, Polymyalgia Rheumatica, and Takayasu's Arteritis*, *in* KELLEY'S TEXTBOOK OF RHEUMATOLOGY at 1461-80 (Elsevier 8th ed. 2009), filed as "Pet. Ex. 18."

[53] Dr. Grewal cited an article that was not filed into the record as "Medicine (Kaunas) 2003: 39(5): 489-93." Pet. Ex. 11 at 4. A Google search indicated that this citation refers to a case report entitled "A rare case of differential diagnosis of myopathy," published in 2003 in Medicina, a peer reviewed journal of the Lithuanian University of Health Sciences. *See* "Medicina – Open Access Journal" http://www.mdpi.com/journal/medicina ; *see also* "A rare case of differential diagnosis of myopathy," M. Pileckyte, PubMed, https://www.ncbi.nlm.nih.gov/pubmed/12794374

At hearing, however, Dr. Grewal stated when he first met petitioner, seven months after her vaccination, she did not have symptoms of myositis. Her tests results were either normal or negative. Tr. 141-42,145-46, 171. He wrote in his initial report petitioner's "clinical features best fit with a 'polymyalgia rheumatica like' condition rather than an inflammatory myositis…." Pet. Ex. 11 at 4. He admitted his "thinking has always been really kind of confused with it," because her symptoms did not fit solely with PMR or myositis. Tr. 148. He further admitted that the mild abnormalities on the EMG suggested a myositis component, but was not diagnostic of myositis. Tr. 145, 148. But he was thinking autoimmune process, so "even though the muscle biopsy was not conclusive, it didn't support the diagnosis of myositis, I thought on the basis of an autoimmune process, perhaps she could benefit from [IVIG]." Tr. 103. He prescribed IVIG as a way of minimizing the potential side effects of prednisone and preventing MS attacks. He later admitted that IVIG is not used as a sparing agent for steroids. Tr. 102-04, 150-51; Pet. Ex. 4 at 6.

Dr. Grewal stated since he began treating petitioner, his diagnosis has "sort of been the same. It's a history of MS and this neurological disorder/myositis which is responding to the combination of prednisone and IVIG." Tr. 107-08. He wrote in his report that steroids would only alleviate the symptoms of PMR, not myositis, and IVIG would not work on PMR; he corrected this statement at hearing, conceding he was wrong – steroids are also effective on myositis. Pet. Ex. 21 at 2; Tr. 136, 148-49. Dr. Grewal explained that once petitioner was on both prednisone and IVIG, attempts to reduce either resulted in recurrence of symptoms; therefore, he concluded she had a combination of PMR and myositis, evidenced by her response to both treatments and inability to be weaned from either. Tr. 107-08; Pet. Ex. 21 at 2 ("multiple attempts have been made to decrease…both the IVIG and steroids…. [W]hen either of these medications has been reduced, the patient's symptoms returned….")(emphasis in original). Dr. Grewal admitted that his only basis for diagnosing petitioner with myositis was her response to IVIG and his inability to wean her from it without an increase in symptoms. Tr. 146.

Dr. Grewal agreed that steroid response can be nonspecific, adding that steroids can mask symptoms of a variety of serious conditions, including rheumatoid arthritis, cancer, infection, and rotator cuff problems. Tr. 152. I asked Dr. Grewal how he knew that it was not one of her other co-morbidities that got worse when he reduced her medications. He responded that the IVIG was controlling her MS. Tr. 152.

Dr. Matloubian disagreed with Dr. Grewal's diagnosis of inflammatory myositis. He explained that myositis is inflammation of the muscle; it can be caused by rare viral or bacterial infections, but more often, the cause is unknown. Tr. 200. "Dermatomyositis and polymyositis are two major types of inflammatory myopathies that affect the proximal muscles of the upper and lower extremities in a symmetric fashion. They are considered systemic autoimmune diseases since more than 80% of those affected have some type of auto-antibodies, such as ANA in addition to involvement of other organs, such as skin and lung." Resp. Ex. A at 4; Resp. Ex. C at 2.[54] The classic presenting complaint of myositis is the insidious onset of muscle weakness. Resp. Ex. A at 4. Muscle pain is generally mild and stiffness is unusual. *Id.* Clinical signs of inflammatory myositis are elevated liver and muscle enzymes, including CK, aldolase, AST, and ALT. Tr. 200-01. Additionally, both dermatomyositis and polymyositis typically show inflammatory cellular

[54] M. Zong and I. Lundberg, *Pathogenesis, Classification and Treatment of Inflammatory Myopathies*, 7 NAT REV RHEUMATOL 297-306 (2011), filed as "Resp. Ex. C."

infiltrate, also known as lymphocytes, on muscle biopsy. Resp. Ex. A at 4; Tr. 209. "Inflammatory markers such as ESR are often normal even in patients with active disease." Resp. Ex. A at 4. Up to 10% of patients may have a normal EMG, but special MRI studies may show muscle inflammation and edema. *Id*. Inflammatory autoimmune myositis kills muscle cells, which is why people present with weakness over time. Tr. 220. Dr. Matloubian clarified that patients with myositis experience "true weakness," not weakness resulting from pain. Tr. 200, 204. Myositis does not have a rapid response to prednisone, but takes months of treatment for strength to return. Tr. 219-20, 224.

Dr. Matloubian pointed out that petitioner's objective testing did not show any of the characteristics typical of myositis which Dr. Grewal recognized when he initially wrote, "[H]er clinical features best fit with a polymyalgia rheumatica like condition rather than an inflammatory myositis." Resp. Ex. A at 5; Pet. Ex. 11 at 4. Specifically, petitioner's blood tests, EMG/NCS, and muscle biopsy did not show elevated muscle enzymes, autoantibodies, inflammatory cellular infiltrate, muscle damage, or electrophysiological changes associated with inflammatory myositis. Resp. Ex. A at 4-5. Further, petitioner had a "miraculous" recovery with prednisone; patients with myositis take months to fully recover. Tr. 219-20, 224. Dr. Matloubian pointed out that there was no complaint of muscle weakness by petitioner, only stiffness, at her medical appointments in December of 2011 and January of 2012. Tr. 226; Pet. Ex. 6 at 24-25, 27. Based on petitioner's objective test results and lack of weakness, the key symptom of myositis, Dr. Matloubian concluded petitioner had PMR, not myositis. Tr. 219-20, 226.

I asked Dr. Matloubian why IVIG was working if petitioner did not have myositis. He explained, every time petitioner receives an IVIG treatment, she receives solumedrol, a form of methylprednisolone, which is a high-dose steroid, just prior to the IVIG.[55] Tr. 231-32. Therefore, it is impossible to tell what effect the IVIG has on petitioner due to the amount of prednisone equivalent she receives at each treatment. Tr. 231-33; Pet. Ex. 9 at 15. When the IVIG is stopped, the solumedrol is also stopped. The pain petitioner experiences when the IVIG treatments are stopped may be due to the sudden cessation of solumedrol infusions, not the lack of IVIG. Tr. 231-32.

Dr. Matloubian concluded that petitioner does not meet the criteria for myositis and has no objective testing to support a diagnosis of myositis. Furthermore, it is not the IVIG controlling petitioner's symptoms, but rather the blast of steroids she receives prior to the IVIG, adding that everyone has an increase in symptoms following reduction of steroids and it takes about a week for the pain to resolve. Tr. 218-19.

The experts agree that petitioner has PMR. Pet. Ex. 11 at 4; Resp. Ex. A at 6. There was no objective proof submitted to support that petitioner suffers from inflammatory myositis, which petitioner's expert conceded.

[55] Dr. Matloubian explained that 4 mg of methylprednisolone is equivalent to 5 mg of prednisone. At every IVIG treatment, petitioner would receive 125 mg of solumedrol (methylprednisolone). Pet. Ex. 9 at 15. Therefore, she was actually receiving 150 mg of prednisone. Tr. 231-32.

C. When Did Petitioner's PMR Develop?

The experts agreed that petitioner developed PMR. They also agreed there is no known cause of PMR. Tr. 153, 213-16; Pet. Ex. 11 at 3; Resp. Ex. A at 5. They initially disagreed on when petitioner's PMR began.

Petitioner alleges that the onset of her PMR was the day after the vaccination or within two weeks after the vaccination. Tr. 282. In his reports, Dr. Grewal distinguished petitioner's "symptoms of pain and discomfort that worsened after receiving the vaccine" from her fibromyalgia symptoms, but did not suggest a specific date of onset. Pet. Ex. 11 at 4. At hearing, Dr. Grewal conceded that he did not know when petitioner's PMR began. Tr. 141. Dr. Matloubian opined that the onset of petitioner's PMR was June 2011. Tr. 222-23, 233.

In his report, Dr. Grewal opined that petitioner may have had fibromyalgia prior to the receipt of the Tdap, but after the vaccination, her pain, discomfort, and clinical features best fit with a polymyalgia rheumatica like condition. Pet. Ex. 11 at 4. At hearing, Dr. Grewal attempted to parse out petitioner's complaints of arm stiffness and joint pain from the remainder of the complaints she made to Dr. Bai on April 18, 2011, concluding that those specific complaints were symptoms of PMR, not fibromyalgia or MS. Tr. 85-86; *see also* Pet. Ex. 3 at 11. However, he could not explain her significant improvement after restarting her fibromyalgia medications, Celebrex and Lyrica, when he had previously testified that those medications would not work on PMR. Tr. 87, 138-39; Pet. Ex. 3 at 8-9. He conceded if petitioner had PMR at that time, he would not expect her to have improvement on Celebrex and Lyrica. Tr. 89.

Dr. Grewal never addressed onset in his reports, other than to say petitioner developed PMR/myositis like symptoms after her tetanus vaccination in April 2011. Pet. Ex. 10 at 1; Pet. Ex. 11 at 4; Pet. Ex. 21 at 4. He agreed at hearing that there was a significant difference in petitioner's clinical presentation in April and June 2011. Tr. 139-40, 169. He was asked if the onset of PMR could have been in June. He responded, "You just don't know." Tr. 141. When presented with Dr. Faches' record of December 2011, which documented petitioner's report of not feeling well since July, and being asked if June was a more likely onset date for petitioner's PMR, he stated "I'm guessing yes, but I don't know." Tr. 170. Dr. Grewal admitted that he did not know when petitioner's PMR and/or myositis began. Tr. 170, 173-74.

Dr. Matloubian described the onset of PMR as abrupt; most people initially attribute it to having engaged in some physical activity. Resp. Ex. A at 5. Though described as muscle pain and stiffness, it is thought to be a disease of the joints underlying these muscle groups due to occasional signs of arthritis on physical exam. *Id*. Bursitis and synovitis are typical of PMR and can be found via MRI or ultrasound. *Id*. Because the PMR population is over 50, many patients have preexisting conditions like osteoporosis, fibromyalgia, or other musculoskeletal problems which muddle the diagnosis. Tr. 199; Resp. Ex. A at 5 (PMR "occurs quite commonly…after the age of 50…ranging from 10-100 cases per 100,000 people").

Dr. Matloubian described fibromyalgia as a non-inflammatory and non-autoimmune syndrome of unclear etiology characterized by diffuse musculoskeletal pain and other symptoms. Resp. Ex. A at 5. Like PMR, fibromyalgia is a diagnosis of exclusion. *Id*. Patients with

fibromyalgia have a lower pain threshold and are more sensitive to pain, which is why medication that targets the neurological pathways are used to treat fibromyalgia. Tr. 218.[56]

According to Dr. Matloubian, petitioner's PMR diagnosis and treatment were complicated by her fibromyalgia. Further, there was an absence of objective data to firmly establish the onset of her PMR relative to her vaccination. Resp. Ex. A at 4. Bilateral shoulder ultrasound or MRI is particularly important in treating someone who suffers from other diseases, like the petitioner, to distinguish between those diseases and PMR. Tr. 235-36, 262-64. MRIs were not ordered.

Dr. Matloubian discussed petitioner's prior history of myalgias and muscle pain, and her description of full body soreness and feeling as though she had been beaten the day after the vaccination, stating that those complaints were more indicative of fibromyalgia than PMR. Tr. 270-71. Dr. Matloubian qualified that he could only go by the medical record, but suggested that petitioner's symptoms the day after the vaccination could have also been part of the viral illness she reported to Dr. Faches the day before. Tr. 273.

Dr. Matloubian acknowledged petitioner's testimony that she complained of joint pain and stiffness to Dr. Bai on April 18, 2011, stating that the stiffness in the morning could have been a complaint of PMR. But Dr. Matloubian explained many diseases have the same symptoms; just because she complained of morning stiffness in April did not mean that she had PMR at that time. Tr. 269. He also noted that the records document "Musculoskeletal: Intact," "well appearing," "antalgic with cane,"[57] no muscle weakness, and full range of motion all joints.[58] Tr. 280; Pet. Ex. 3 at 10. More importantly, her symptoms improved with Celebrex and Lyrica, which would not happen if it were PMR; PMR responds only to prednisone. Tr. 267-68; Pet. Ex. 6 at 10-11. Then in June, petitioner presented with confusing complaints of pain in her hands, wrists, elbows, shoulders, hips, knees, lower back, and leg muscles. Only the complaints of shoulder and hip stiffness with difficulty getting up from a chair were consistent with PMR. Tr. 222-23; Pet. Ex. 3 at 7; Pet. Ex. 5 at 3; Resp. Ex. A at 5-6.

Dr. Matloubian concluded that, because petitioner's symptoms in April and May responded to her medication for fibromyalgia, and PMR would not respond to those medications, those symptoms were more likely related to her fibromyalgia. Tr. 221. He opined that the onset of PMR was more likely in June, when petitioner first reported pain and stiffness in her hips and shoulders. Tr. 222-23, 233.

[56] Fibromyalgia will respond to steroids, but steroids are not the standard of care for fibromyalgia. Tr. 216.

[57] Petitioner used a cane due to her broken toe. Pet. Ex. 6 at 82.

[58] During the hearing, I pointed out that Dr. Bai's records seem to be two pages for each visit, front and back, but the visits on April 26, 2011, and May 9, 2011 do not have the back page filed. Petitioner's counsel was asked to look into the possibility of incomplete records. Tr. 281. No additional records were filed, nor was any response from counsel filed regarding these records.

Petitioner's testimony supports an onset date of June 2011. According to petitioner the medication Dr. Bai prescribed in April had worked, but "then it got worse…which is why I went back." "…I felt like I was getting worse…. [I]t was getting increasingly more difficult for me to get up…. [I]t got significantly worse in June and into July." Tr. 45-46, 47-48, 40-41, 44; Pet. Ex. 3 at 9.

Furthermore, one month prior to her receipt of Tdap vaccine, petitioner presented to Dr. Faches with complaints of "a lot of fibromyalgia pain" and "problems sleeping due to pain." Pet. Ex. 6 at 83. These symptoms are consistent with those she presented to Dr. Bai with on April 18, 2011. Pet. Ex. 3 at 11.

Based on the medical records and testimony, I find that the onset of petitioner's PMR was in June 2011.

V. Causation and Analysis

A. Legal Standard Regarding Causation

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352 (Fed. Cir. 1999).[59] Petitioners are not required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs*., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs*., 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes"). Once a petitioner has proven causation by preponderant evidence, "the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs*., 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing 42 U.S.C. § 300aa-13(a)(1)(B)).

To prove causation, petitioners must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical

[59] The Vaccine Act also requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. § 11(c)(1)(D)(i). It is undisputed that this six-month requirement is satisfied in this case.

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

Each of the *Althen* prongs requires a different showing. Under the first *Althen* prong, petitioner must provide a "reputable medical theory" demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id*. at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde*, 746 F.3d at 1341.

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs*., 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id*. at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

However, medical records and/or statements of a treating physician's view 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 12(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 & Human 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 also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., (100 Fed. Cl. 742, 749 (2011) (determining it is not arbitrary or capricious for a special master to weigh competing treating physicians' conclusions against each other), *aff'd*. 698 F.3d 1355 (Fed. Cir. 2012); *Caves*

v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 Fed. Appx. 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 229, 2011), *mot. for review den'd*, 100 Fed. Cl. 344 (Sept. 29, 2011), *aff'd*, 475 Fed. Appx. 765 (Fed. Cir. 2012).

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

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

B. The Expert Reports and 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 & Human 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 (1991).[60] *Cedillo v. Sec'y of Health & Human Servs*., 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs*., 195 F.3d. 1302, 1316 (Fed. Cir. 1999)).

The *Daubert* factors are usually employed by judges in the performance of their evidentiary gatekeeper roles to exclude evidence that is unreliable and/or could confuse the jury. In Vaccine Program cases, by contrast, these factors are used in the weighing of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67

[60] The *Daubert* 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).

(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 of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this case, as in numerous other Vaccine Program cases, *Daubert* has not been employed to determine what evidence should be admitted, but rather to determine whether expert testimony offered is reliable and/or persuasive.

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 & Human 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. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Human 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 v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1325-26 (Fed. Cir. 2010) ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human 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.").

Application of the *Althen* prongs reveals evidentiary deficiencies in petitioner's claim: (1) petitioner failed to offer a persuasive or reliable medical theory; (2) the theory provided is not applicable to the facts of petitioner's case; and (3) petitioner has not established a medically acceptable timeframe in which her symptoms could have begun or developed.

1. Petitioner Has Failed to Articulate a Plausible Medical Theory Causally Connecting Tdap Vaccine to PMR and/or Myositis.

To satisfy *Althen* Prong I, petitioner must present a "sound and reliable medical or scientific explanation" causally connecting the vaccine to her alleged injuries. *Knudsen*, 35 F.3d at 548. Petitioner's causation theory has several deficiencies.

In his reports, Dr. Grewal relied on ASIA theory, stating that it "is a well known and studied reaction to vaccine adjuvants." Pet. Ex. 11 at 3. However, Dr. Grewal did not explain how the aluminum adjuvant in the Tdap vaccine is capable of causing or triggering PMR and/or myositis.

ASIA theory, or "Autoimmune Syndrome Induced by Adjuvants," groups together "a range of emerging autoimmune diseases with possible adjuvant-associated causes." Resp. Ex. H[61] at 1.

[61] David Hawkes et al., *Revisiting adverse reactions to vaccines: A critical appraisal of Autoimmune Syndrome Induced by Adjuvants (ASIA)*, 59 J AUTOIMMUN 77-84 (2015), filed as "Resp. Ex. H."

To qualify for a diagnosis of ASIA, a person must have been exposed to an external stimuli such as an infection, vaccine, or adjuvant, prior to experiencing clinical manifestations which typically include muscle weakness, joint pain, chronic fatigue, and/or neurological symptoms, particularly those associated with demyelination. *Id*. at 2. Suggested "minor criteria" for ASIA include the presence of autoantibodies against the suspected stimulus, specific HLA markers, or development of an autoimmune disease such as MS. *Id*.

In setting forth his theory, Dr. Grewal compared PMR and myositis to GCA and dermatomyositis, stating that all four of these diseases involve inflammation thought to be induced or triggered by a combination of genetic and environmental factors. Dr. Grewal posited that the Tdap vaccine can act as an environmental factor capable of triggering an inflammatory disease in a genetically predisposed person. Pet. Ex. 21 at 3. Dr. Grewal did not focus on the Tdap vaccine or ASIA theory itself, but rather addressed the immune system's role in both PMR and myositis, submitting literature which elaborated on the immunological points of both diseases. Dr. Grewal described the role of interferons ("IFNs") in GCA and dermatomyositis appearing to suggest that aluminum adjuvants could induce interferon production, causing or triggering PMR and/or myositis, like interferons trigger GCA and dermatomyositis. However, despite the literature offered by Dr. Grewal, none supported this theory, but rather distinguished PMR from GCA, and myositis from dermatomyositis. *See* Pet. Ex. 22 at 3 ("[S]everal potential autoantigens of DM are IFN regulated and therefore enhanced under inflammatory conditions…"); Pet. Ex. 23 at 7 ("Type I IFNs contribute to the pathogenesis of autoimmune diseases, including [juvenile dermatomyositis]"); Pet. Ex. 33[62] at 4 ("…interferon [gamma] seems to play a specific pivotal role in…the pathogenesis of GCA…*The absence of interferon [gamma] expression in…samples from patients with isolated PMR suggests that its production may be crucial to the development of GCA*")(emphasis added); Pet. Ex. 18 at 3-4 (*interferon gamma is "abundantly expressed" in GCA but absent from PMR*)(emphasis added). The literature provided by Dr. Grewal contained extensive information on the symptomatology, diagnosis, mechanics, and immunological processes of PMR and myositis. *See generally* Pet. Ex. 34-37. The literature did not identify any known causes or triggers of PMR or myositis, and none of the articles suggested that aluminum adjuvants could induce interferon production. Dr. Grewal testified that his theory was based on literature he read about aluminum, then conceded that he did not provide copies of any of that literature in this case. Tr. 155; Pet. Ex. 11 at 3. He further conceded that none of the articles filed suggested that aluminum adjuvants induce interferon production. Tr. 164.

At hearing, Dr. Grewal was unable to articulate what ASIA or "ASIA-like" theory was. When asked to explain how aluminum triggers an autoimmune condition, Dr. Grewal responded that there was "something within the vaccine itself….Perhaps it's the aluminum." "[T]he body produces antibodies against that particular—what's in the vaccine. And then there's some cross-reactivity between some other components of the body which results in the second autoimmune disease in this particular case." Tr. 112-13. Dr. Grewal suggested that there was a difference between exposure to aluminum via injection and exposure to aluminum through typical environmental sources such as air or food. Tr. 112-13. He provided nothing further.

[62] Miguel A. Gonzalez-Gay et al., *Giant Cell Arteritis and Polymyalgia Rheumatica: Pathophysiology and Management*, 23 DRUGS AGING 8: 627-49 (2006), filed as "Pet. Ex. 33."

Dr. Grewal appeared to be similarly out of his depth when discussing Tdap vaccine. He could name the main antigenic components – tetanus, diphtheria, and pertussis toxoids – but was unaware of whether or how any of these antigens could trigger the development of PMR or myositis. Tr. 162-63.

Dr. Grewal ultimately admitted that there was no scientific basis to support a connection between Tdap vaccine and PMR or myositis. Tr. 166. When I asked Dr. Grewal to articulate his theory in this case, he responded:

> …there's nothing else that I can pinpoint when I go back in the history. And I take her at face value. She got the vaccine and she started to become symptomatic and got much worse. The thing continued to get worse as time went on. And the only response, the only medication she responded to were the steroids, suggesting it's autoimmune.

Tr. 167.

Dr. Matloubian stated that, while Tdap vaccine contains 0.33 mg of aluminum, it is slowly absorbed over time and insufficient to cause aluminum toxicity. Tr. 241; Resp. Ex. A at 8; *see also* Resp. Ex. L[63] at 4-5 (discussing the rate of absorption of aluminum adjuvant delivered by intramuscular injection). None of the components of the Tdap vaccine, including aluminum, is associated with PMR or myositis. Tr. 238-39.

Dr. Matloubian voiced several criticisms of ASIA theory, most significantly that a recent critical analysis of 27 studies on ASIA reached the conclusion that "there is currently a lack of reproducible evidence for any consistent relationship between [aluminum] adjuvant and autoimmune conditions." Resp. Ex. A at 6, citing Resp. Ex. H at 1. Dr. Matloubian explained that the criteria for ASIA theory do not specify a temporal relationship between the stimulus and the clinical manifestations; therefore, ASIA could apply to any person who has been exposed to a stimulus and develops an autoimmune condition even if there are years between stimulus and condition. Tr. 240; Resp. Ex. H at 2. It is also too broad in its classification of possible autoimmune diseases. For example, Dr. Matloubian explained, MS, inflammatory myositis, and PMR are "entirely different diseases," but ASIA theory lumps them all together in an "artificial category," despite differences in their mechanisms and underlying pathologies. Tr. 240. Due to the variety of diseases encompassed by ASIA theory, the theory is too broad to be reproduced scientifically and therefore cannot be tested. Tr. 240.

Dr. Grewal agreed with many of Dr. Matloubian's criticisms of ASIA theory, including that the theory is so broad as to apply to any person who has ever been exposed to an adjuvant and later developed an autoimmune condition, even if the condition occurred years after the stimulus. Tr. 159. He further agreed that ASIA theory is controversial and uniformly unaccepted by both immunologists and rheumatologists. Tr. 159. Yet, he still maintained that ASIA could apply to a

[63] R. Mitkus et al., *Updated aluminum pharmacokinetics following infant exposures through diet and vaccination*, 29 VACCINE 9538-43 (2011), filed as "Resp. Ex. L."

unique situation, like petitioner, and that as a neuromuscular doctor, he is "in tune to patients having vaccine-related events."[64] Tr. 115. He provided no explanation for this statement.

Dr. Grewal and Dr. Matloubian agreed that there are no known causes or triggers for PMR and myositis. Tr. 153-54, 237. The only known environmental risk factors for myositis are statins and UV exposure. Tr. 154. Dr. Matloubian opined that a temporal connection between Tdap vaccine and an autoimmune disease alone is insufficient as many of these diseases take years to develop before they are clinically apparent. Tr. 237.

In assessing the reliability and credibility of an expert's opinion, I must consider whether the expert offering the opinion is testifying within his training or expertise. *Walton v. Sec'y of Health & Human Servs*., No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). In recognizing the liberality with which evidence offered in Vaccine Program cases is treated, I read and evaluated all of the testimony of the experts offered and all of the literature filed in this case, and gave appropriate weight to whether certain testimony is beyond a particular expert's purview. *See, e.g., King v. Sec'y of Health & Human Servs*., No 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (finding petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications.). To that end, by his own admission, Dr. Grewal specializes in neurology and treats chronic inflammatory demyelinating polyneuropathy, Guillain-Barré Syndrome, myositis, and myasthenia gravis, all of which are autoimmune nerve diseases. Tr. 117. He does not treat PMR, nor is PMR a neurological disorder. He would refer someone with PMR to a rheumatologist. Tr. 117-18. He also does not treat patients with fibromyalgia. Tr. 118. Dr. Grewal admitted that he has never seen a case like petitioner's before. Tr. 66. In contrast, Dr. Matloubian is a rheumatologist who routinely treats patients with PMR, fibromyalgia, and myositis. Resp. Ex. A at 1. While Dr. Grewal's testimony was clearly outside of his area of expertise, Dr. Matloubian's opinions were grounded in literature and relevant experience.

Furthermore, ASIA theory has been proffered several times in the Vaccine Program and repeatedly rejected. *See, e.g., Rowan v Sec'y of Health & Human Servs*., No. 10-272V, 2014 WL 7465661, at *12 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. May 18, 2015) (denying entitlement to petitioner who claimed the aluminum adjuvant in the HPV vaccine caused her headaches, migraines, and chronic fatigue syndrome). No special masters have ever found ASIA or ASIA-like theories to be persuasive. *See, e.g., Rowan*, 2014 WL 7465661, at *6-7 ("ASIA is not a proven theory….[T]he data only 'suggest the possibility of accelerated autoimmunity/inflammation following vaccination,'" and "precisely how adjuvants cause autoimmune illness 'is not always known'"); *see also Bushnell v. Sec'y of Health & Human Servs*., No. 02-1648V, 2015 WL 4099824, at *8 (Fed. Cl. Spec. Mstr. June 12, 2015) (denying compensation in a case that alleged that an aluminum adjuvant exacerbated a mitochondrial disorder and precipitated autism); *Harris v. Sec'y of Health & Human Servs*., No. 10-332V, 2014 WL 3159377, at *16 (Fed. Cl. Spec. Mstr. June 10, 2014) (noting that aluminum adjuvants are

[64] He did not state whether he has had any patients other than the petitioner who have reported adverse events following vaccination.

considered to be safe and have been used for nearly a century); *D'Angiolini v. Sec'y of Health & Human Servs*., No. 99-578V, 2014 WL 1678145, at *60 (Fed. Cl. Spec. Mstr. Mar. 27, 2014), *mot. for review den'd*, 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. App'x. 1002 (Fed. Cir. 2016)(noting that ASIA "is not generally accepted in the medical community and its diagnostic criteria do not differentiate between healthy and ill people").

Dr. Grewal's conclusory statements do not constitute a "sound and reliable" theory for how Tdap vaccine could cause PMR or myositis. Additionally, he failed to provide any corroborating evidence or reliable scientific studies to support his theory that Tdap or aluminum could cause PMR or myositis. Furthermore, despite his reliance on ASIA theory, he appeared to have only passing familiarity with it, as evidenced by his inability to articulate the theory. Dr. Grewal did not provide evidence or a plausible theory of causation in this case.

Petitioner has not put forth opinions, case studies, or medical literature presenting a plausible medical theory by which Tdap vaccine could cause or trigger PMR and/or myositis. Alone, Dr. Grewal's belief that Tdap vaccine caused petitioner to develop PMR and/or myositis is insufficient to support causation. *See Langland v. Sec'y of Health & Human Servs*., 109 Fed. Cl. 421, 438 (2013)(quoting *Langland ex rel M.L. v. Sec'y of Health & Human Servs*., No. 07-36V, 2011 WL 386985, at *24 (Fed. Cl. Spec. Mstr. Feb. 4, 2011)) ("…a treating doctor's opinion that a vaccination caused a particular injury 'cannot substitute for the explanation of a plausible theory as to how a given vaccine can cause the alleged injury.' In other words, in the absence of a theory showing a vaccine *could* cause a particular injury, a doctor's belief that it *did* will not prove causation….") (emphasis in original).

Accordingly, petitioner has not satisfied Prong I.

2. Petitioner Has Failed to Demonstrate a Logical Sequence of Cause and Effect Connecting Tdap Vaccine to Her Development of PMR and/or Myositis.

Even if petitioner had been able to sustain her burden of causation under Prong I, that Tdap vaccine can cause PMR and/or myositis, she could not sustain her burden under Prong II to show that it did so in this case.

According to Dr. Grewal, when a person is exposed to some antigen, whether via ingestion or infection, there is some kind of reaction from the body. Tr. 71-72. A person with a preexisting autoimmune condition like MS, lupus, or arthritis, has a propensity for autoimmunity. Tr. 72. Because petitioner already had MS, she had a propensity for autoimmune reactions. Tr. 115.

Dr. Grewal's PMR-like/myositis-like diagnosis rested solely on petitioner's positive response to a combination of IVIG and steroids. Petitioner's response to the treatment "provides [a] very strong kind of empirical proof that this is an autoimmune process." Tr. 148-51, 113-14; Pet. Ex. 21 at 2. He then concluded, "[S]he has a complex disease process which does not allow simple categorization. My diagnosis is that she has features of PMR and myositis, both of which are autoimmune." Pet. Ex. 21 at 2. He stated that epidemiology is not helpful in determining petitioner's diagnosis because her condition is not straightforward, but "whatever is going on with her is autoimmune. Autoimmune/inflammatory." Tr. 114-15. He then theorized that the aluminum

in Tdap vaccine caused an autoimmune reaction. Tr. 112. Dr. Grewal supported his theory by discussing interferon activity as a potential cause of GCA and dermatomyositis. Pet. Ex. 21 at 3. Petitioner does not have dermatomyositis or GCA. At hearing, he conceded that there was no literature to support that aluminum adjuvants induce interferon production. Tr. 164. He also agreed that petitioner had taken Avonex, an interferon, in the past, but did not develop myositis or PMR. Tr. 164. He further acknowledged that the Shoenfeld article he relied on for the ASIA theory requires the detection of HLA on muscle biopsy to support an ASIA-provoked autoimmunity. HLA was not detected on petitioner's muscle biopsy; her muscle biopsy was essentially normal. Tr. 171-72.

Dr. Grewal concluded that petitioner developed PMR or "PMR-like disease" as a direct result of the tetanus vaccine, based on the development and worsening of clinical features after the vaccination, the mechanism he described as related to vaccine adjuvant, the dramatic clinical response to prednisone, and the presence of an elevated CRP. Pet. Ex. 11 at 4. Dr. Grewal's opinion hinged on his belief that petitioner developed an autoimmune condition, not present prior to the vaccination, but present after, establishing cause and effect based on temporal relationship. Tr. 166-67; Pet. Ex. 4 at 17; Pet. Ex. 7 at 20; Pet. Ex. 21 at 4. "In determining a cause, one must consider immune insults occurring at or near the time the disease process began. In [petitioner's] case, it was the tetanus shot." Pet. Ex. 21 at 4. At hearing, he stated, "[I]t's been my feeling since I first started to take care of her that if she had not received that vaccine, I doubt that she would have developed this problem. But I don't know that." Tr. 174; *see also* Tr. 97 ("… [I]n April she got the vaccine, something happened and she got worse."). He agreed that, despite petitioner's supposed propensity for autoimmune disease, she would not automatically develop an autoimmune disease in response to a vaccine. "…[S]he had this vaccine before and didn't get any symptoms. I think a lot of this is sort of hit and miss and bad luck on the part of the patient." Tr. 115.

It is the law of the Vaccine Program that evidence of the development of a disease and/or injury temporally following a vaccination is insufficient on its own to establish causation. *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Merely identifying the vaccine as causal because of its existence as a known, pre-onset occurrence is insufficient to establish causation without corroborative record proof demonstrating the "logical sequence of cause and effect" required. *Id*. A wide variety of indirect and circumstantial evidence can support that determination, whether in the form of test results or witness testimony.

Here, the evidence is lacking. Dr. Grewal testified honestly and without hesitation. He was respectful and pleasant with the Court. He had no trouble responding to any of the questions asked of him. However, his opinions simply lacked the foundation necessary to show that petitioner's Tdap vaccination caused her to develop PMR, other than his personal belief that petitioner did not have it before, but developed it after, and therefore it was caused by the vaccine. Dr. Grewal's conclusions were not enough to demonstrate a "logical sequence of cause and effect" connecting petitioner's receipt of Tdap vaccine to her development of PMR and/or myositis.

Dr. Matloubian's opinions were more persuasive and grounded in science rather than personal belief. According to Dr. Matloubian whether petitioner has PMR, myositis, or both, neither is related to her tetanus vaccination. He explained that, for vaccine-induced immune complexes to lead to organ damage, a large amount of antigen is necessary to form these

complexes. This may theoretically occur with a live, attenuated vaccine, where there is viral replication, but the amount of antigen in Tdap vaccine is comparatively low. Resp. Ex. A at 7. Additionally, petitioner did not display signs of immune complexes, like high complement levels or positive autoantibodies. She tested negative for autoantibodies like rheumatoid factor, cryoglobulins, and ANA. *Id*. Therefore, petitioner's PMR was not due to formation of immune complexes as a result of Tdap vaccine. *Id*.

Dr. Matloubian disagreed with Dr. Grewal's contention that petitioner's MS made her more susceptible to autoimmune disease from vaccines. Tr. 244-45. Studies have shown that, in patients with preexisting autoimmune diseases, vaccines do not exacerbate existing autoimmune diseases and do not cause new autoimmune diseases. Tr. 245. The American College of Rheumatology guidelines recommend that patients with rheumatoid arthritis receive influenza vaccine. Tr. 245; Resp. Ex. M.[65] It was notable that Tdap vaccine did not elicit aggravation of petitioner's MS.

I also do not find persuasive Dr. Grewal's conclusory statement that petitioner was more susceptible to autoimmune attack due to her pre-existing MS. Dr. Grewal provided no proof of such susceptibility other than circular reasoning that because petitioner developed PMR at some point after receipt of the Tdap vaccination and did not have it before, but she had MS before, she was somehow more susceptible to autoimmunity from Tdap vaccine, which he agreed did not trigger her MS, but triggered PMR.

The experts agreed, and the literature supports, that PMR is an idiopathic disease with no known cause. Tr. 153; Resp. Ex. A at 5. The experts further agreed that there is no known component in Tdap vaccine that has been linked to PMR. Tr. 166, 239. Given the above, the evidence best supports the conclusion that petitioner's PMR was idiopathic in origin, as opposed to vaccine caused. Accordingly, petitioner has failed to sustain her burden under Prong II.

3. Petitioner Has Failed to Show an Appropriate Temporal Relationship Between Her Receipt of Tdap Vaccine and Her Development of PMR and/or Myositis.

Having already determined that onset in this matter was in June 2011, over two months after receipt of Tdap vaccine, to satisfy her burden on the third *Althen* prong, petitioner needed to demonstrate an appropriate timeframe for the development of PMR following Tdap vaccine. However, since petitioner cannot show Tdap vaccine could cause PMR and/or myositis, petitioner cannot show what a reasonable timeframe for the onset of PMR and/or myositis following Tdap vaccine would be. *Langland*, 109 Fed. Cl. at 443 ("[T]o satisfy the 'proximate temporal relationship' prong of the *Althen* test, petitioners must demonstrate, by a preponderance of the evidence, that the onset of symptoms occurred within a time frame for which it is medically acceptable to infer causation-in-fact….With no reputable theory as to how the vaccination could cause the injury, this exercise is not possible.") (citing *De Bazan*, 539 F.3d at 1352).

Dr. Grewal did not provide any explanation for how Tdap vaccine could cause PMR, myositis, or a combination of the two diseases, or how it could do so within one day, two weeks, or two months of the vaccination. Rather, he repeatedly insisted that because petitioner developed

[65] Johanna Westra et al., *Vaccination of patients with autoimmune inflammatory rheumatic disease*, 11 NAT REV RHEUMATOL 3: 135-45 (2015), filed as "Resp. Ex. M."

PMR and/or myositis after receiving Tdap vaccine, the vaccine was the cause of the disease. However, a temporal correlation alone is not enough to establish vaccine causation. *LaLonde*, 746 F.3d at 1341.

Dr. Matloubian concluded that temporal association without biological plausibility is not enough. ASIA theory is controversial and not accepted by most immunologists and rheumatologists. Resp. Ex. A at 8. In response to petitioner's testimony that she woke up the morning after the vaccination and felt like she had been beaten, Dr. Matloubian gave an example of post-infectious reactive arthritis, to describe the time it takes for autoimmune reaction, noting "it takes about one to three weeks after immunization to get [post-infectious reactive arthritis] because it takes about that time for T-cells and B-cells to get activated." Tr. 282-83. Based on that timeframe, if Dr. Grewal's theory were correct that environmental events such as infection or vaccine can trigger PMR, then it was more likely that her gastrointestinal virus the week prior to her vaccination were the cause. Resp. Ex. A at 8.

Petitioner failed to present evidence to support a temporal relationship between her Tdap vaccination on April 1, 2011 and the onset of her symptoms in June 2011. Accordingly, petitioner has failed to present preponderant evidence to support Prong III.

VI. Conclusion

When petitioners fail to carry their burden, the Secretary is not required to present an alternate explanation for the vaccinee's condition. *De Bazan*, 539 F.3d at 1352. The petitioner in this matter has failed to put forth a prima facie showing of causation; therefore, respondent is not required to demonstrate that a "factor unrelated" was the sole cause of petitioner's condition.

While petitioner suffers greatly from a host of debilitating and chronic conditions, a situation that is sad and for which I am greatly sympathetic, she has not put forth preponderant evidence that Tdap vaccine that she received on April 1, 2011, caused her to develop PMR and/or myositis. She has not demonstrated entitlement to compensation. Her petition is therefore dismissed.

In the absence of a timely filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[66]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[66] Pursuant to Vaccine Rule 11 (a), if a motion for review is not filed within 30 days after the filing of the special master's decision, the clerk will enter judgment immediately.