In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 12-415V
(TO BE PUBLISHED)

MATTHEW MORRIS,	*	
	*	Special Master Corcoran
Petitioner,	*	
	*	Dated: April 1, 2016
v.	*	
	*	Vaccine Act; Entitlement; Ruling on
SECRETARY OF HEALTH AND	*	Record; Tetanus-Diphtheria-acellular
HUMAN SERVICES,	*	Pertussis ("TDaP") Vaccine;
	*	Fibromyalgia; Myalgias; Myositis.
Respondent.	*	Macrophagic Myofasciitis ("MMF")
	*	

Patricia Finn, Patricia Finn, P.C., Piermont, NY, for Petitioner.

Alexis Babcock, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION[1]

In this case arising under the National Vaccine Injury Compensation Program (hereinafter the "Vaccine Program"),[2] Matthew Morris ("Petitioner") seeks damages based on alleged injuries caused by his receipt of the Tetanus-Diphtheria-acellular Pertussis ("TDaP") vaccine on August 29, 2009. The parties have accepted my proposal to rule on the case based on the expert reports, record evidence, and pleadings submitted to date. After consideration of the Parties' arguments

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

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

and the evidence, I hereby **DENY** Petitioner's claim, for the reasons discussed in greater detail below.

I. FACTUAL BACKGROUND

Petitioner has offered various documents and medical records to support his claim. Pet'r's Exs. 1-10. It is undisputed that Mr. Morris received the TDaP vaccine on August 29, 2009, at Lake District Hospital in Lakeview, Oregon, after puncturing his finger on rusty barbed wire. Pet'r's Ex. 7 at ¶3; Pet'r's Ex. 2 at 1. At the time, Mr. Morris resided in rural Oregon and was without income or health insurance. Pet'r's Ex. 7 at ¶2.

Mr. Morris alleges that by September 5, 2009, he began to experience debilitating flu-like symptoms, accompanied by aches, pains, and fever, that made it difficult for him to participate in his normal activities. Pet'r's Ex. 7 at ¶¶5-6. These flu-like symptoms allegedly intensified greatly by the beginning of October of that year. *Id*. at ¶7. Petitioner began to experience numbness in his hands and shooting bilateral pains in his arms and legs, all of which caused him great fatigue. *Id.* at ¶¶9, 11-14. Although Petitioner claims to have continued to experience these symptoms through the spring of 2010, his financial situation, lack of insurance, and a harsh, snowy winter (which limited his ability to travel from his rural home) collectively caused him to postpone seeking medical attention for his alleged illness for more than nine months. *Id.* at ¶¶10, 12. Instead, he self-medicated with family prescription drugs during the intervening period. ECF No. 41 at 2.

Mr. Morris submitted several letters from his family and friends attesting to his deterioration after receiving the TDaP vaccine, and explaining why he did not immediately seek medical treatment. *See generally*, ECF No. 41. His parents wrote a letter, for example, averring that it was a "time of turmoil and change for our family" because Mr. Morris's father was also ill. *Id*. at 6. The letters also state that Mr. Morris communicated to various third parties that "his bones hurt" and he "felt sick." *Id*. at 9, 12-17. But, according to his parents, they were "snowed in for months" and it was "difficult to get in to town." *Id*. at 6. Mr. Morris's father corroborates Petitioner's statements that he was self-medicating with his family's prescription pills. *Id*.

As the medical records reflect, it was not until May of 2010 that Mr. Morris visited his family physician, Dr. Paul Johnson at the Johnson and Cade Family Practice in Bend, Oregon – although the purpose of the visit was for removal of a skin lesion on his hip. Pet'r's Ex. 1 at 4. Nevertheless, Petitioner mentioned to Dr. Johnson at that time that he was experiencing ongoing pain (which the record characterizes as "bone pain") throughout his body, and that he associated this pain with his August 2009 vaccination. *Id*. But Dr. Johnson's physical examination revealed normal joints, normal muscle strength, and normal tone. *Id*. Laboratory testing reported on May 7,

2010, were also normal, including Petitioner's rheumatoid factor, ESR,[3] CRP,[4] CM,[5] and complete blood count. *Id*. at 10-11. The laboratory results also reported an ANA[6] Titer of 1:80 with a homogeneous pattern. *Id*. Despite the lack of corroborative lab results, because of Mr. Morris's complaints, Dr. Johnson recommended that he see a rheumatologist for evaluation and prescribed Diclofenac, an anti-inflammatory drug. *Id*. at 2.[7]

Later, at a June 2010, follow-up visit with Dr. Johnson, Mr. Morris again complained of the same significant pain throughout his body, although most notably in his left arm, asserting that the drugs he was taking were not alleviating the pain. Pet'r's Ex. 1 at 2. He repeated to Dr. Johnson his belief that the TDaP vaccine was the source of his illness. *Id*. In July 2010, Mr. Morris next visited Dr. Ronald Rosen (an integrative medicine specialist) in Bend, Oregon, who diagnosed him with myalgias and paresthesias, although a physical exam performed at the time showed nothing out of the ordinary. Pet'r's Ex. 4 at 2. Dr. Rosen recommended a follow-up if Mr. Morris's condition did not improve within three weeks. *Id*. at 3.

Dr. Daniel Evan Fohrman, a rheumatologist with Deschutes Rheumatology in Bend, Oregon, subsequently evaluated Mr. Morris for his reported musculoskeletal pain in September of 2010. Pet'r's Ex. 3 at 1. On physical examination, Mr. Morris displayed no "synovitis, effusion, deformity, laxity, or decreased range of motion," and his muscle strength was not abnormal. *Id*. at 4. Dr. Fohrman therefore diagnosed Mr. Morris with musculoskeletal pain of unknown etiology and recommended a trial of prednisone. *Id*. Dr. Fohrman also stated that he could "neither approve nor disprove" Mr. Morris's personal theory that the TDaP vaccine had caused his symptoms. *Id*. Dr. Fohrman's ultimate diagnosis of Mr. Morris was "fibromyalgia/myalgia/myositis." *Id*. at 7.

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[3] ESR means erythrocyte sedimentation rate. *Dorland's Illustrated Medical Dictionary* (32d ed. 2012) at 648 [hereinafter *Dorland's*]. This is one of the factors that Dr. Oddis later characterizes as part of Mr. Morris's rheumatology work-up.

[4] CRP means C-reactive protein. *Dorland's* at 436. This is also one of the factors that Dr. Oddis later characterizes as part of Mr. Morris's rheumatology work-up.

[5] CM means cytidine monophosphate. *Dorland's* at 376. This is yet another one of the factors that Dr. Oddis later characterizes as part of Mr. Morris's rheumatology work-up.

[6] ANA stands for antinuclear antibodies. *Dorland's* at 70. An elevated ANA is usually an indication of an autoimmune reaction. Pet'r's Ex. 17 at 3. The value of 1:80 is slightly elevated, although (as discussed below) there is disagreement between the parties and their experts as to the significance of this value. Resp't's Ex. A at 3 (ECF No. 53-1); Pet'r's Ex. 17 at 2 (ECF No. 57); Pet'r's Br. on Entitlement at 3 (ECF No. 65) ("Opp.").

[7] Dr. Fohrman also prescribed Lamisil (an anti-fungal drug) to Mr. Morris at this visit, presumably for treatment of his skin lesion. Pet'r's Ex. 1 at 4.

By November of 2010, Mr. Morris was still complaining of myalgias and joint pain, asserting that the steroid treatment prescribed by Dr. Fohrman had not improved his condition. Pet'r's Ex. 1 at 1. Dr. Fohrman saw Petitioner at this time but did not do an examination (although Petitioner once again reiterated his belief that there was a relationship between the vaccine he had received and his symptoms). *Id*. Mr. Morris returned to see Dr. Johnson in May of 2011, again complaining of chronic pain. Pet'r's Ex. 9 at 1. Mr. Morris's June 21, 2012, affidavit asserts that (as of that date) the pain he had experienced since receiving the TDaP vaccination had not ceased and responded only minimally to prescription pain medication. Pet'r's Ex. 7 at ¶¶18-20. As a result, he alleged that he could not work or live as a functioning independent adult, requiring him to rely on the financial support of family members for medical costs and other basic needs. *Id.* at ¶20.

Mr. Morris has not filed any additional medical records since September of 2012, and has filed no additional records relevant to the claim for the time period after his visit to Dr. Johnson in May of 2011, so his current condition or prognosis is unclear. However, On October 27, 2014, Petitioner filed a letter in this action further describing how his ailments were continuing to affect him. ECF No. 41 at 1-4. He also submitted a letter from Dr. Spencer Clarke, his "regular Doctor" as of 2014 who he had been seeing for the six-month period prior to the letter's creation. *Id*. at 5. In this letter, Dr. Clarke acknowledges that Mr. Morris's physical exam and previous serologic work up were fairly unremarkable, but nevertheless maintains the possibility of a relationship between Mr. Morris's pain complaints and his vaccination. *Id*.

II. EXPERT REPORTS

A. Dr. Beatrice C. Engstrand

Petitioner filed two reports from his expert, Dr. Beatrice C. Engstrand (on March 31, 2015, and August 20, 2015, respectively) in support of his claim. Pet'r's Ex. 11 (ECF No. 50-1); Pet'r's Ex. 17 (ECF No. 57-1). In preparing the reports, Dr. Engstrand reviewed Mr. Morris's entire medical record, plus the pleadings, affidavits, and other statements filed in the matter. Pet'r's Ex. 11 at 1-2.

Dr. Engstrand is a licensed physician in the State of New York and has been board certified in neurology for over twenty years. Pet'r's Ex. 11 at 1. She currently is in private practice and has, by her own assertion, treated thousands of patients with myalgia, fatigue, chronic pain, and paresthesias – although she has never treated or personally evaluated Mr. Morris. Pet'r's Ex. 12 at 1. Dr. Engstrand published several articles in the 1980s, specifically on issues concerning drug abuse. *Id*. at 4.

Dr. Engstrand opines that Mr. Morris has "persistent neurological sequelae, fatigue, myalgias, sensory changes and chronic diffuse pain disorder" caused by a "postvaccinal reaction"

to the TDaP vaccine he received in August of 2009. Pet'r's Ex. 11 at 2. She proposes that the most likely mechanism behind this reaction is Mr. Morris's exposure to "immunostimulatory compounds" in the vaccine, pointing to aluminum hydroxide as one such example. *Id*. at 2-3. According to Dr. Engstrand, this exposure could precipitate an adverse autoimmune reaction, as evidenced by Mr. Morris's elevated ANA levels. *Id*.; Pet'r's Ex. 17 at 2.

In support of her theory, Dr. Engstrand referenced six pieces of medical literature, five of which[8] specifically discuss an atypical form of myalgia known as macrophagic myofasciitis ("MMF").[9] *See* F. Authier, et al., *Central nervous system disease in patients with macrophagic myofasciitis*, 124 BRAIN 974-83 (2001) (ECF No. 50-3) [hereinafter "Authier"]; R.K. Gherardi, *Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminum hydroxide in muscle*, 124 BRAIN 1821-31 (2001) (ECF No. 50-4) [hereinafter "Gherardi"]; R.K. Gherardi, *Lessons from macrophagic myofasciitis: towards definition of a vaccine adjuvant-related syndrome*, 159(2) REV. NEUROL. (PARIS) 162-64 (Feb. 2003) (ECF No. 50-5) [hereinafter, "Gherardi II"]; P. Chérin, et al., *Macrophagic myofasciitis. Study and Research Group on Acquired and Dysimmunity-related muscular diseases (GERMMAD)*, 29(4) PRESSE MED 203-08 (Fed. 5, 2000) (ECF No. 50-6) [hereinafter "Chérin"]; and A. Ryan, et al., *Atypical presentation of macrophagic myofasciitis 10 years post vaccination*, 16 NEUROMUSCULAR DISORDERS 867-69 (2006) (ECF No. 58-2) [hereinafter "Ryan"]. However, Dr. Engstrand's reports do not specify the relevance of these articles to Mr. Morris's condition – for he has never been diagnosed with MMF, he does not allege in this case that he suffered from it (despite his lack of diagnosis), and he otherwise has not suggested that MMF is comparable in symptomology to what he claims to have experienced.

Dr. Engstrand briefly mentioned that the pathophysiology behind the development of vaccine-related MMF "is thought to be due to low-level stimulation of the immune system by the aluminum hydroxide adjuvant in certain vaccines." Pet'r's Ex. 17 at 3; Ryan at 868. Some of the literature she offered in support of her opinion explored the possibility of a link between MMF and vaccines containing aluminum adjuvants. Authier at 981; Gherardi at 1821; Gherardi II at 1; Ryan at 868. Dr. Engstrand pointed to Mr. Morris's elevated ANA as evidence that he had

[8] The last piece of literature offered by Petitioner is less directly relevant to his causation theory. N. Toplak, et al., *Autoimmune response following annual influenza vaccination in 92 apparently healthy adults*, 8(2) AUTOIMMUNITY REVIEWS 134-38 (Dec. 1, 2008) (ECF No. 58(1)) [hereinafter "Toplak"]. Toplak examined whether there was an increased autoimmune response – as evidenced by increased ANA values – after receipt of the annual influenza vaccine. *Id*. at 1. But not only did Toplak consider an entirely different vaccine, it also (i) acknowledged that 26 percent of apparently healthy adults already have elevated ANA values unrelated to vaccines; and (ii) concluded that there was no statistically significant difference in the percentage of those who had elevated ANA pre- and post-vaccination. *Id*. Toplak is otherwise not discussed in either of Dr. Engstrand's reports.

[9] According to the literature cited by Petitioner's expert, MMF is a newly-recognized condition manifested by diffuse pain in the muscle(s) and highly specific myopathological (muscle disease (*Dorland's* at 1224)) alterations. Authier at 974.

experienced this type of "low-level stimulation of the immune system" after receipt of the TDaP vaccine. Pet'r's Ex. 17 at 3.

Dr. Engstrand also opined, somewhat inconsistently, that the timing of Mr. Morris's symptoms was medically appropriate and consistent with the aforementioned theory. Pet'r's Ex. 11 at 3; Pet'r's Ex. 17 at 2. In her first report, Dr. Engstrand concluded that it was appropriate for Petitioner's symptoms to have begun within two days of his TDaP vaccination (as he alleges occurred). Pet'r's Ex. 11 at 3. Dr. Engstrand's supplemental report, however, argued that the continuation of those same symptoms ten months later (when Petitioner first sought treatment) "are consistent with the delayed adverse effects of vaccines." Pet'r's Ex. 17 at 2. In support of this second point, she referenced Ryan as underscoring that symptoms of vaccine-related problems could take up to ten years post-vaccination to develop. Pet'r's Ex. 17 at 2 (citing Ryan). But Ryan is a case study of a single individual who was diagnosed with MMF – again, not a diagnosis ever proposed for Mr. Morris.

B. Dr. Chester V. Oddis

Respondent's expert, Dr. Chester V. Oddis, filed a single expert report on June 8, 2015. Resp't's Ex. A (ECF No. 53-1). In preparing it, Dr. Oddis reviewed all the medical records and Mr. Morris's affidavit, the petition, and Dr. Engstrand's first expert report and accompanying medical literature. *Id*. at 1. Dr. Oddis is board-certified in internal medicine and rheumatology. *Id*. He is presently a Professor of Medicine in the Division of Rheumatology and Clinical Immunology in the School of Medicine at the University of Pittsburgh. *Id*. He also sees patients, specializing in the treatment of idiopathic inflammatory myopathies ("IIM"). *Id*.

Dr. Oddis's opinion mostly attempted to refute the concept that Petitioner suffered from any type of myositis (meaning inflammation of a voluntary muscle (*Dorland's* at 1225)). *See generally* Resp't's Ex. A at 3-4. Without any objective evidence of neurologic sequelae and sensory changes, and given Petitioner's unremarkable laboratory studies, such a diagnosis was inappropriate, Dr. Oddis opined, regardless of Petitioner's claims to the contrary.

In his report, Dr. Oddis recounted the spectrum of IIM, which includes several subsets of myositis, including adult polymyositis ("PM"), the diagnosis he deemed most relevant in this case, given Mr. Morris's age and lack of dermatological symptoms, malignancy, and/or evidence of other accompanying autoimmune disorders. Resp't's Ex. A at 3. According to Dr. Oddis, there are several clinical features or criteria rheumatologists and neurologists use in order to diagnose adult PM: (i) symmetric proximal muscle weakness[10]; (ii) increase in serum skeletal muscle enzymes;

[10] According to Dr. Oddis, this is a generally painless, symmetric weakness, with difficulty performing activities which require both upper and lower limb strength. Resp't's Ex. A at 3.

(iii) presence of a characteristic electromyographic ("EMG") pattern; and (iv) muscle biopsy evidence of myositis. *Id*. But Dr. Oddis opined that Mr. Morris's medical records did not support an adult PM diagnosis. None of Petitioner's treating doctors ever found symmetric proximal muscle weakness upon examination, Petitioner's enzymes were never shown to be elevated, and he never even had an EMG or muscle biopsy. Dr. Oddis found it especially significant that none of Mr. Morris's treaters ever proposed that he even undergo a biopsy. *Id*. at 3-4.

Dr. Oddis further concluded that Petitioner's medical records did not support an MMF diagnosis. In support of that aspect of his opinion, Dr. Oddis's report discussed some of the medical literature previously submitted by Petitioner. Authier, he maintained, bulwarked his conclusion that Petitioner did not have MMF, because it recognized that MMF is manifested by "diffuse myalgias and is characterized by highly specific myopathological findings showing macrophages, T cell infiltration and myofiber damage." Resp't's Ex. A at 3 (citing Authier). Petitioner's medical records, by contrast, did not reveal any such findings. Dr. Oddis further opined that individuals properly diagnosed with MMF "have significant central nervous system features and abnormal MRI[11] findings." *Id.* at 4. But such symptoms were never noted by any treater, nor was an MRI ever performed for Mr. Morris. *Id*.

Moreover, Dr. Oddis continued, even if Petitioner had been diagnosed with some other muscle condition that would explain his pain, there was no evidence from the medical records that Petitioner ever experienced an autoimmune reaction to the TDaP vaccine. Resp't's Ex. A at 4. In so maintaining, Dr. Oddis addressed the relevance of the elevated ANA finding (which Dr. Engstrand highlighted in her supplemental report). *Id*. at 3. Dr. Oddis considered Mr. Morris's ANA value inconsequential, because Mr. Morris had not been shown to have an autoimmune disease by other, confirming evidence. *Id*. Such an ANA value is therefore a "non-specific finding as many individuals will have a 'false positive' ANA." *Id*.

Finally, Dr. Oddis questioned whether Petitioner could under the circumstances establish a medically acceptable temporal relationship between onset of his claimed symptoms and the TDaP vaccine's administration. In so doing, he referenced the Gherardi article filed by Petitioner's expert as supporting his opinion. Resp't's Ex. A at 4. Gherardi, he reasoned, established that the median onset of myalgias in individuals with MMF is 11 months. Gherardi at 1821. As a result, Petitioner's assertion that he began experiencing symptoms as early as one week post-vaccination was inconsistent with his theory of vaccine-induced MMF (assuming such a diagnosis was supported by the facts). Resp't's Ex. A at 4.

[11] MRI stands for magnetic resonance imaging. *Dorland's* at 1184.

III. PROCEDURAL HISTORY

Mr. Morris filed his petition on June 26, 2012. Pet. (ECF No. 1). The records setting forth the medical history summarized above were filed between July and mid-September of 2012. Pet'r's Exs. 1-10 (ECF Nos. 8, 10, 11). Mr. Morris thereafter filed a Statement of Completion on September 25, 2012. ECF No. 12. Respondent opposed Mr. Morris's claim, arguing that he could not carry the burden of proof necessary to obtain a Vaccine Program award. *See* Nov. 9, 2012 Rule 4(c) report (ECF No. 13). In particular, Respondent asserted that the medical records revealed merely that Mr. Morris had reported to his physicians his belief that the TDaP vaccine was related to his illnesses – not that any of the physicians had themselves so opined. *Id*. at 8.

Following the filing of the Statement of Completion, Mr. Morris's prior counsel represented him in three telephone status conferences held in this matter in 2012 and 2013, while Petitioner attempted to locate an expert. As reflected in Petitioner's April and July 2013, status reports, for a period of time the parties tried to resolve the matter informally. ECF Nos. 16, 18. But such settlement talks reached an impasse, and Mr. Morris and his counsel spent some time thereafter exploring how to proceed. ECF Nos. 22, 24.[12] Counsel subsequently expressed his intent to withdraw from the case.

In May of 2014, I granted Petitioner's prior counsel's request to withdraw,[13] and Mr. Morris proceeded with the case for a time as a *pro se* petitioner. Following a status conference held on July 30, 2014, I ordered Petitioner to obtain and file a causation expert report and any additional documents supporting his claim by October 31, 2014. ECF No. 40. Petitioner did so, and also relayed his attempts to find an expert to opine on causation as well as alternative counsel. ECF No. 41 at 1-2. Included in the filing were several exhibits, including a letter from Dr. Clarke, letters from Mr. Morris's family and friends, and three peer-reviewed journal articles. *Id*. at 5-49.

[12] During this time, the case was re-assigned to me. ECF No. 20.

[13] Respondent challenged counsel's withdrawal, arguing that Petitioner should be ordered to show cause why the claim should proceed if withdrawal was to be allowed. Resp't's Resp. at 1 (ECF No. 33). Petitioner replied on June 9, 2014, arguing that Petitioner believed there was reasonable basis to his claim and was attempting to secure alternative counsel to represent him. Pet'r's Reply at 3 (ECF No. 36). The following day I issued an Order granting Petitioner's counsel's Motion to Withdraw, despite Respondent's objections, allowing Petitioner to continue on a *pro se* basis. ECF No. 37.

Concurrent with his prior counsel's withdrawal request, Petitioner also filed an application for interim attorney's fees and costs on February 11, 2014. ECF No. 28. Respondent opposed the fees request, arguing that Petitioner had failed to demonstrate any of the necessary circumstances under *Avera v. Sec'y of Health & Human Servs*., 515 F.3d 1343 (Fed. Cir. 2008) to justify an interim fees award. ECF No. 29 at 3. Petitioner replied to Respondent's arguments, arguing, *inter alia*, that payment of interim fees was "consistent with congressional intent that Petitioners have access to competent attorneys" and that given the procedural posture of the case such payment was appropriate at that time. ECF No. 30. I deferred resolution of the interim fees request, finding that reasonable basis was an open and unresolved question. ECF No. 34.

After another status conference held on November 5, 2014, I again ordered Petitioner to retain a medical expert to opine on causation and file a report to that effect, setting a new deadline of January 9, 2015 by which to do so. ECF No. 43. In the intervening period, Petitioner obtained new counsel, who became attorney of record as of December 4, 2014. ECF No. 44. I then held a status conference on December 9, 2014, and extended Petitioner's deadline to file an expert report to February 13, 2015. ECF No. 45. The day before that deadline, Petitioner filed a motion requesting that the deadline be extended further to May 13, 2015. ECF No. 46. Given the repeated delays, I granted his request in part, extending the deadline only until March 31, 2015. Petitioner adhered to the deadline and filed Dr. Engstrand's first expert report. ECF No. 50. Respondent then filed her responsive expert report and supporting materials from Dr. Oddis on June 8, 2015.

Petitioner thereafter accepted my suggestion that he submit a supplemental expert report to further address the temporal gap between the alleged onset of Mr. Morris's symptoms and when he first presented for treatment eleven months later. ECF No. 55. Petitioner filed that supplemental expert report from Dr. Engstrand on August 20, 2015 (ECF No. 57), followed by the literature cited in her report. ECF No. 58. During a subsequent status conference held on September 29, 2015, I proposed, and the Parties agreed, to resolve the issue of entitlement on the basis of the record and pleadings, rather than by holding a hearing. ECF No. 59. After granting an extension of time, both Parties briefed the issue of entitlement.

Respondent briefed the matter by filing a Motion to Dismiss on January 19, 2016. ECF No. 64 ("Mot."). In it, she argued that Petitioner had failed to meet his burden under the first two prongs of the causation test established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). Specifically, Petitioner had failed to offer a plausible medical theory that establishes a logical sequence of cause and effect that is applicable and consistent with Petitioner's case. Mot. at 9-10. Respondent further argued that Petitioner had not established an appropriate proximate temporal relationship, pointing out that Dr. Engstrand vacillated in her analysis of what would constitute a medically-acceptable timeframe. *Id*. at 10-11.

Petitioner argued in favor of entitlement in a brief filed on January 22, 2016. ECF No. 65 ("Opp."). He supported his claim by reference to Dr. Engstrand's report, arguing that his myalgias, chronic fatigue, and muscle pain following vaccination were well-documented and attributable to receipt of immunostimulatory compounds used as vaccine adjuvants and contained in the TDaP. Opp. at 5-6. He further argued that his diagnosis of fibromyalgia/myalgia/myositis was consistent with Dr. Engstrand's theory, and that onset of his injury (within two days of receiving the TDaP vaccine) was consistent with the mechanism proposed by Dr. Engstrand. *Id*. at 6-8.

Petitioner also filed a reply on February 5, 2016, attempting to refute Respondent's claim that Dr. Engstrand had been inconsistent on the timing question, and pointing out purported logical

fallacies in Respondent's expert report. ECF No. 66 at 4-5 ("Reply").[14] Petitioner also requested in the reply (for the first time) that I defer ruling on entitlement (as the parties had previously agreed was appropriate) pending performance of a muscle biopsy. Reply at 8-9. The issue of entitlement is now ripe for a decision.

IV. APPLICABLE LEGAL STANDARDS

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[15] No Table claim is asserted in this case, nor do I find the facts would support one.

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006).

[14] Petitioner homed in on Respondent's statement that "30% of patients with MMF developed myalgias within 3 months after immunization, 61% within a year and 80% within 2 years," suggesting that it revealed a mathematical error (as the sum of cited percentages exceeded 100) undercutting the reliability of Dr. Oddis's opinion. Reply at 6. In fact, it is Petitioner who is in error, since the percentages discussed *encompass* the previously-referenced percentages; the 61 percent of MMF patients who develop myalgias within a year of vaccination logically includes the smaller subset of patients who develop myalgias within three months.

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

In attempting to establish entitlement to a Vaccine Program award of compensation, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. A petitioner may not receive a Vaccine Program award based solely on his assertions, however; rather, the claim must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

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

Vaccine Program claimants may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).[16]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

[16] The first *Althen* prong has been interpreted to require a petitioner to propose (via reference to some kind of evidence) a "plausible" causation theory, rather than establish with preponderant evidence. Nevertheless, the fact that the causation theory may be established with a slightly lower evidentiary burden does not negate or reduce a petitioner's **ultimate** burden to establish his entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). That standard of proof governs the entire claim.

'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & 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) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 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. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344 (Sept. 29, 2011), *aff'd,* 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Fact Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master must consider "all [] relevant medical and scientific evidence contained in the record," including "any

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

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions 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 as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & 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").

Accordingly, if the medical records are clear, consistent, and complete, then 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 – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *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 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. Analysis of 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 (1993). *See 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)).[17]

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *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 a 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 (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 matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

[17] "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).

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & 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. 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 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & 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").

V. ANALYSIS

It is within a special master's discretion to determine whether, in resolving a petition, a hearing is required or rather if the matter can be resolved without live testimony, based solely on the paper filings in a case. Vaccine Rule 8(d). In this instance, I determined that Mr. Morris's entitlement to a Vaccine Program award could be resolved without hearing, and the Parties agreed to my proposed method of resolution. After a thorough and complete consideration of the pleadings, briefs, and record, I have concluded that Mr. Morris has not established by preponderant evidence entitlement to compensation in this case.

First, Petitioner's expert embraces a causation theory that relies on a factual determination – that Mr. Morris had MMF – that is unsupported by the record. Second, application of the *Althen* prongs reveals additional evidentiary deficiencies of Petitioner's claim: (a) Petitioner has failed to offer a persuasive or reliable medical theory; (b) the theory provided is not applicable to the facts of Petitioner's case; and (c) Petitioner has not established a medically acceptable timeframe in which his symptoms could have begun or developed.

A. Mr. Morris Cannot Demonstrate that He Suffered from MMF.

A prominent deficiency in Petitioner's case is the extent to which his causation theory assumes he suffered from a disease that is not established by the record. Petitioner's causation theory is heavily dependent on literature exploring an association between certain vaccines and

development of MMF, and thus implicitly relies on a determination that Mr. Morris's symptoms were consistent with MMF. *See, e.g.*, Authier; Gherardi. As the parties generally agree, MMF "is manifested by diffuse myalgias and is characterized by highly specific myopathological findings showing macrophages, T cell infiltration and myofiber damage" reflected in the results of a muscle biopsy. Resp't's Ex. A at 3; Authier at 974.[18]

In this case, however, there is no record evidence that Petitioner had MMF. First, none of Mr. Morris's treaters ever diagnosed him with MMF, opting instead (and mainly on the basis of his subjective reports of pain) to characterize his condition more vaguely, as "fibromyalgia/myalgia/myositis." Pet'r's Ex. 3 at 7.[19] Dr. Engstrand for her part does not offer a persuasive reading of the medical records to suggest that an MMF diagnosis is still possible under the circumstances, by pointing to actual evidence that would support it.

Second, there are no test results found in the record that would support such a diagnosis. Mr. Morris never received a muscle biopsy, which is, according to Dr. Oddis, the "gold standard" for diagnosing MMF as well as myositis more generally. ECF No. 53-1 at 3. Mr. Morris attempted to explain the absence of such testing as attributable to his lack of insurance and logistical hardships. Opp. at 6. However, there is no mention or suggestion by any of his treaters that such a test was recommended or even contemplated. I infer from the fact that the treaters in this case did not see the need to perform a muscle biopsy (given the absence of other confirmatory test results) as reasonably suggesting that those treaters were *not* concerned about the possibility of MMF under the circumstances. Such a record lacks preponderant evidence that Mr. Morris suffered from MMF – and in fact supports the opposite conclusion.

B. The *Althen* Prongs Have not Been Satisfied.

1. *Althen Prong One* - A petitioner's causation theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. Petitioner's causation theory, however, has several evident deficiencies. To begin with (as discussed above), Dr. Engstrand's literature focuses almost solely on studies demonstrating an association between vaccinations and MMF – even though the evidence does not suggest Petitioner suffered from

[18] Respondent's expert also asserted that central nervous system features and abnormal MRI findings are found with patients suffering from MMF (Resp't's Ex. A at 4), although the literature does not suggest that such symptoms are common to all or even most patients with MMF. *See, e.g.*, Authier at 974 (only 8 of 92 MMF patients had symptomatic demyelinating central nervous system disorders). I have therefore focused on the issue of muscle biopsy instead, which the parties agree is a relevant test for MMF. Opp. at 8-9.

[19] There is little difference between the symptoms of fibromyalgia, myalgia, and myositis. Fibromyalgia is characterized by pain and stiffness in the muscles and joints (*Dorland's* at 703); myalgia is pain in a muscle(s) (*Dorland's* at 1214); and myositis is an inflammation of a voluntary muscle. *Dorland's* at 1225.

MMF. As a result, regardless of whether these studies persuasively suggest a relationship between "aluminum-containing vaccines" (specifically the hepatitis-B vaccine; hepatitis-A vaccine, and/or tetanus toxoid vaccines) and MMF (Authier at 974, 976; Gherardi at 1821) they are not on point herein, weakening the "fit" between the expert opinion offered and the facts of the case. *Daubert*, 509 U.S. at 591. Insufficiently relevant literature has been offered linking the TDaP vaccine to the more vague symptoms Mr. Morris actually suffered.

Next, specific elements of the theory by which the TDaP vaccine could cause myalgia to develop are highly unreliable (at least under the present state of the science). In particular, Dr. Engstrand's medical theory proposes that an adjuvant (aluminum hydroxide) in the TDaP vaccine Mr. Morris received stimulated and precipitated an autoimmune reaction resulting in his symptoms. This is not the first time that this medical theory has been asserted in the Vaccine Program, although it is often referred to as "Autoimmune Syndrome Induced by Adjuvants" or "ASIA." *See, e.g., Rowan v. Sec'y of Health & Human Servs*., No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014), *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. May 18, 2015). But no special masters have ever found ASIA or ASIA-related theories to be persuasive. *See, e.g., Rowan*, 2014 WL 7465661, at *12 (denying entitlement to Petitioner who claimed the aluminum adjuvant in the HPV vaccine caused her headaches, migraines, and chronic fatigue syndrome); *see also Bushnell v. Sec'y of Health & Human Servs*., No. 02-1648V, 2015 WL 4099824, at *18 (Fed. Cl. Spec. Mstr. June 12, 2015) (denying compensation in a case that alleged that an aluminum adjuvant allegedly exacerbated a mitochondrial disorder and precipitated autism); *Harris v. Sec'y of Health & Human Servs*., No. 10-322V, 2014 WL 3159377, at *16 (Fed. Cl. Spec. Mstr. June 10, 2014) (noting that aluminum adjuvants are considered to be safe and have been used for nearly a century); *Hennessey v. Sec'y of Health & Human Servs*., No. 01-190V, 2009 WL 1709053 (Fed. Cl. Spec. Mstr. May 29, 2009) (petitioner failed to prove by preponderant evidence that the adjuvant in a hepatitis B vaccine caused type 1 diabetes), *mot. for review den'd,* 91 Fed. Cl. 126 (2010).

Dr. Engstrand's report presents the adjuvant component of her theory as accepted science, when this is anything but the case. *See, e.g., Rowan*, 2014 WL 7465661, at *6-7 ("ASIA is not a proven theory…the data only 'suggest the possibility of accelerated autoimmunity/inflammation following vaccination'" and "precisely how adjuvants cause autoimmune illness 'is not always known'"). Absent corroborative evidence – whether in the form of additional literature or a reliable scientific study – lending support to the concept, I cannot accept her conclusory views as to the impact an adjuvant could have under such circumstances, and I therefore do not find that she has provided a persuasive explanation for how the TDaP vaccine might have resulted in symptoms akin to those experienced by Petitioner.[20]

[20] In addition, testimony about the biochemical effects of a vaccine and/or its subcomponents is also well outside of Dr. Engstrand's individual expertise. In determining whether a particular expert's testimony is reliable or credible, I may consider whether the expert is offering an opinion that exceeds the expert's training or competence. *Walton v.*

Beyond the above, Dr. Engstrand's opinion simply does too little to offer a plausible scientific or medical explanation for how the TDaP vaccine could affect an individual in the manner alleged to have been experienced herein – an immediate reaction followed by months of pain that was nevertheless tolerable enough to delay medical treatment. Otherwise, Petitioner has not put forth any opinions, case studies, or medical literature putting forth a theory by which the TDaP vaccine could have caused his injury. Accordingly, Petitioner has not offered a sufficiently plausible causation theory.

2. *Althen Prong Two* – Even if Petitioner's causation theory was not contingent upon finding that he suffered from MMF, there is no evidence in Mr. Morris's medical records that the TDaP vaccine he had ***any*** injury via an autoimmune response. Mr. Morris's own statements about his immediate post-vaccination condition are not corroborated by contemporaneous medical records, as Mr. Morris did not seek medical treatment for months after the vaccination. *Compare* Pet'r's Ex. 7 at ¶¶ 5-6 *with* Pet'r's Ex.1 at 4. When Mr. Morris finally did so, his treaters found no objective evidence of anything wrong with him. Pet'r's Ex. 1 at 4, 10-11; Pet'r's Ex. 4 at 2. In addition, his physical exams and laboratory results were largely normal and not indicative of any underlying problem. *Id.* And none of his treaters accepted or endorsed Petitioner's belief of a possible link between his symptoms and the TDaP vaccine, nor did they see evidence of an autoimmune reaction, such as inflammation. Pet'r's Ex. 3 at 4.

Mr. Morris has offered his own statements, plus those of family members, to supplement holes in the medical records and thus to establish that he was in fact suffering the effects of the TDaP vaccine sooner than the medical records establish. Mr. Morris has also provided an explanation for why he did not seek earlier treatment. Nevertheless – the absence of medical evidence for so long a time from the date of vaccination to his first doctor's visit strongly, and reasonably, suggests that Mr. Morris's condition was not sufficiently severe to pursue treatment, which casts doubt on the likelihood that he was experiencing a debilitating autoimmune reaction that began in August 2009. Certainly his personal testimony, and that of the other witness statements, is by itself insufficient to establish his claim, where not corroborated by other independent, reliable evidence. Section 13(a)(1); *See, e.g.*, *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522, 2010 WL 5185485, at *4 (Fed. Cl. Spec. Mstr. Aug. 9, 2010) (dismissing a

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). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I read and have evaluated all of the testimony of the experts offered in this case, I may give 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) (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).

case on the grounds that petitioner failed to meet burden under *Althen* two because there were no medical records or medical expert testimony to corroborate petitioner's claim).

Dr. Engstrand's supplemental report does reference Petitioner's somewhat elevated ANA level as evidence of an autoimmune response. Pet'r's Ex. 17 at 2. But I find Respondent's evaluation of that test result to be more persuasive. As Dr. Oddis explained in his expert report, an ANA at a low positive titer of 1:80 in a homogeneous pattern (Mr. Morris's value) is nonspecific and likely a false positive. Resp't's Ex. A at 5. Tellingly, Dr. Engstrand agreed (at least in her initial report) that Mr. Morris's rheumatology work up was "essentially negative," (Pet'r's Ex 11 at 2) and Petitioner's entitlement brief also downplayed the value of this test result. Opp. at 3.

There is thus insufficient evidence in the medical records of any type of autoimmune reaction in response to the TDaP vaccine for me to find that the TDaP vaccine "did cause" Mr. Morris's symptoms.

3. *Althen Prong Three* - Petitioner alleges that his reaction to the TDaP vaccine began within a week of its administration, which in turn produced pain and related symptoms that purportedly went on for months. To satisfy his initial burden on the third *Althen* prong, Petitioner needed to demonstrate that this was a medically appropriate timeframe. In her initial report, however, Dr. Engstrand conclusorily represents that this is the case, with little explanation for why. Pet'r's Ex. 11 at 3. At best, she relies on Ryan, which avers that symptoms of vaccine-related problems can develop any time up to ten years post-vaccination – an open-ended proposition that would be enough to establish nearly any timeframe. Pet'r's Ex. 17 at 2 (citing Ryan). Moreover, Ryan also involves MMF – a diagnosis not supported by the facts in this case. Such factors, coupled with the other problems with Petitioner's causation theory, make it impossible for me to find that he has met this *Althen* prong.

There is also a contradiction between Dr. Engstrand's explanation of the timing element in her theory and the record. Dr. Engstrand's supplemental expert report (filed after I ordered Petitioner to better explain the delay between onset as alleged by Petitioner and Petitioner's first doctor's visits 10 months later (ECF No. 54 at 1)), opined specifically that "[t]hese symptoms occurring 10 months later are *consistent with the delayed adverse effects of vaccines*." *Id*. at 2 (emphasis added). Indeed, one of the articles relied upon by Dr. Engstrand supports the conclusion that the median time to develop MMF (again, not a diagnosis supported by the evidence) is 11 months. Pet'r's Ex. 14. Dr. Oddis accepted the same time period of time as reasonable in actual cases of MMF. ECF No. 53-1 at 4. But this is completely ***inconsistent*** with Petitioner's allegations that he experienced a reaction within days of the vaccination, and that his resulting pain and weakness persisted for months thereafter. To the extent it is Petitioner's contention that he actually suffers from MMF (as the thrust of Dr. Engstrand's report and literature suggests), his own allegations of onset would undermine the core aspect of his own expert's causation theory.

VI. REQUEST TO DEFER RULING PENDING TESTING

Petitioner's Reply proposes that I defer ruling pending his receipt of a muscle biopsy, which, he argues, would potentially corroborate his contention that he suffered from vaccine-induced MMF. Reply at 8-9. I shall not do so, for both substantive and procedural reasons.

Substantively, Petitioner has not shown that the results of a muscle biopsy test would likely alter the outcome of the case in his favor. *Vant Erve v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 607 (1997), *aff'd after remand*, 232 F.3d 914 (Fed. Cir. 2000) (allowing reopening of the record to introduce new evidence where, among other things, the probative nature of the proposed new evidence outweighs other considerations, such as delay or prejudice to the nonmoving party); *Snyder*, 88 Fed. Cl. at 739 (upholding denial of petitioners' motion to supplement the factual record). Grounds for additional testing might be compelling if one of Mr. Morris's treaters had previously proposed it, or if other test results performed on Petitioner provided direct or circumstantial support for an MMF diagnosis that could be corroborated with a muscle biopsy. But no such evidence or treatment recommendations exist under present circumstances. Indeed, Petitioner has filed no medical records detailing his treatment history after mid-2011. Absent some reliable, persuasive indication that taking the time to allow further testing would be fruitful, I need not refrain from deciding entitlement at this late stage of the proceeding simply because Petitioner hopes that additional evidence could swing the balance in his favor. Vaccine Rule 7(a) ("[t]here is no discovery as a matter of right").

Procedurally, the request for more testing is dilatory. *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1385-86 (Fed. Cir. 2012) (not an abuse of discretion for special master to deny motion to submit additional evidence, when (i) the "new" evidence was known and available earlier, and thus could have been submitted in a timely fashion; and (ii) it was unclear if the additional evidence would have strengthened the case). This case is four years old, and Petitioner has had representation for most of its history. Thus, the possibility that additional testing could strengthen his claim should have been discovered long ago.[21] I also alerted Petitioner to the facial weaknesses of his claim in my June 23, 2015, scheduling order (after having reviewed Dr. Oddis's expert report, which expressly identified a muscle biopsy as useful in diagnosing MMF). *See, e.g.*, ECF No. 54 at 1. Such testing should have been requested before Petitioner accepted my proposal that the case be resolved on the papers – not in a reply brief.

[21] Indeed, Petitioner's original counsel's request for an award of interim attorney's fees establishes that they had the case for almost ***two years before*** it was filed (*Morris v. Sec'y of Health & Human Servs.,* No. 12-415V, 2014 WL 8661863, at *7 (Fed. Cl. Spec. Mstr. June 4, 2014)), and took additional time afterwards to locate an expert before withdrawing from the matter. Petitioner has had ample time to determine the benefits of a muscle biopsy, let alone obtain one.

CONCLUSION

I do not question Mr. Morris's sincerity in proceeding with his claim. But the factual record does not support his contention that his symptoms were caused by – or are even related to – his receipt of the TDaP vaccine. I therefore **DENY** an entitlement award in this case. I instruct the Clerk of Court to enter judgment dismissing the case unless a motion for review is filed.[22]

IT IS SO ORDERED.

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

[22] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.