In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1710V

Filed: April 19, 2023

MIGUEL BRITO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	UNPUBLISHED Findings of Fact; Situs; Tdap Vaccine; Macrophagic Myofasciitis (MMF)

Mark Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner
Emilie Williams, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON SITUS[1]

Oler, Special Master:

On November 5, 2018, Miguel Brito ("Petitioner") 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"). Petitioner filed an amended petition on February 15, 2019. ECF No. 8. ("Amended Pet."). The petitions allege that Petitioner developed macrophagic myofasciitis ("MMF") as a result of the Tdap vaccine he received on November 5, 2015. Pet. at 1-2; Amended Pet. at 1-2.

[1] Because this Ruling contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[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).

After carefully considering the evidence presented in this case, to include the medical records, medical literature, and affidavits, I find there is preponderant evidence that Petitioner received the Tdap vaccine in his right arm.

I. Procedural History

Petitioner filed his petition on November 5, 2018. Pet. at 1. Petitioner filed his amended petition on February 15, 2019. Amended Pet. at 1. Petitioner filed supporting medical records on February 15, 2019; January 15, 2020; March 21, 2020; August 23, 2020; January 15, 2021; February 4, 2021; June 11, 2021; April 8, 2022; and February 6, 2023. ECF Nos. 9, 17, 22, 25, 30, 32, 41, 53, 66. Petitioner filed affidavits on July 11, 2022. ECF No. 57.

Respondent filed his Rule 4(c) report on April 20, 2020. Resp't's Rep.; ECF No. 23. Respondent argued that this case is not appropriate for compensation because Petitioner's medical records document symptoms such as upper extremity pain and weakness prior to vaccination. *Id.* at 17. Respondent also argued that Petitioner has not presented a theory for how the Tdap vaccine in his left arm (as Petitioner's vaccination record states) could have caused him to develop MMF in his right deltoid. *Id.*

I held a status conference on December 14, 2021, at which Petitioner's counsel stated his belief that the factual issue of situs should be resolved prior to moving forward with the case. ECF No. 51. Respondent's counsel stated that some of Petitioner's medical records had yet to be filed. I ordered Petitioner to file the remaining medical records within 60 days, at which time I would determine how best to proceed. *Id.*

On May 26, 2022, Respondent filed a status report stating his belief that the record was complete for a ruling on situs. ECF No. 55. On June 9, 2022, I held another status conference at which I informed the parties that I believed that the appropriate next step was for me to issue a fact ruling on situs. I granted Petitioner 30 days to file an affidavit and ordered the parties to file briefs on the situs issue within 45 days of the date Petitioner's affidavit was filed. *Id.*

Petitioner filed affidavits on July 11, 2022. ECF No. 57. The parties filed briefs on the situs issue on October 6, 2022. ECF Nos. 61, 62. In footnote 3 of his brief, Respondent indicated that there was a discrepancy between the number of pages of medical records obtained from Jackson Memorial Hospital and the number of pages Petitioner filed. ECF No. 61 at 8, fn 3.

I held another status conference on October 17, 2022, at which I ordered Petitioner to file the outstanding medical records from Jackson Memorial Hospital within 14 days. ECF No. 63. After multiple extensions of the deadline, Petitioner filed the medical records on February 6, 2023. On March 8, 2023, the parties filed a joint status report stating that the record is complete. ECF No. 67. This matter is now ripe for a factual determination.

II. Petitioner's Medical Records that Pertain to the Issue of Situs

On June 9, 2015, Petitioner saw Adriana Valbuena, MD, complaining of left shoulder pain

or weakness over the previous six months. Ex. 25 at 341. He reported difficulty when working out at the gym. *Id.* Petitioner also reported atrophy and scapular asymmetry but denied muscle weakness and numbness in his hands. *Id.* Petitioner had already scheduled a left shoulder MRI and Dr. Valbuena ordered an electromyography nerve conduction study ("EMG"). *Id.* at 342-43.

On June 23, 2015, Petitioner underwent an EMG of his left upper extremity. Ex. 25 at 185. The impression was left C5 and C6 root dysfunction without significant axon loss. *Id.*

On November 5, 2015, Petitioner reported to the emergency room with a mouth laceration that he sustained while trying to remove orthodontic glue from his tooth with a pair of rusted scissors. Ex. 1 at 514-15. The medical history for this visit lists "shoulder injury" without further detail. *Id.* at 516. Petitioner received a Tdap vaccination which he "tolerated well." *Id.* at 518. The site of the injection is not noted in the record for this visit. *Id.* at 514-18. Petitioner's immunization record specifies the injection site as the left arm. *Id.* at 9.

On December 8, 2015, Petitioner saw Terri Griffith, MD, for a follow up on his left shoulder pain and weakness. Ex. 1 at 512-14. Dr. Griffith reviewed the results of Petitioner's left shoulder MRI, which showed "[t]race subacromial subdeltoid bursitis, without underlying discrete cuff tear" and "[m]ild fraying posterior labrum without discrete labral tear." *Id.* at 513. Petitioner stated that he felt no pain at that time but would experience pain at about a 3 out of 10 when exercising and that certain movements made him feel that his shoulder was "not in the proper position." *Id.* Petitioner exhibited good range of motion and strength, and Dr. Griffith recommended that he continue his home exercise program. *Id.* at 514.

Petitioner continued to seek treatment for left shoulder pain in 2016. *See, e.g.,* Ex. 28 at 159, 175.

On February 3, 2017, Petitioner reported to the emergency room complaining of the sensation of choking and shortness of breath, as well as spasms in his feet and hands. Ex. 28 at 448. The medical record notes a history of tingling in his right shoulder and arm. *Id.*

On February 7, 2017, Petitioner saw Jacobo Wajner, MD, for a follow-up on his multiple emergency room visits over prior weeks. Ex. 28 at 694-96. Petitioner reported "arm pain that started in his [right] arm" and "intermittent [tingling] and pain in his [right] arm and shoulder." *Id.* at 694. Dr. Wajner's impression was of a pinched nerve secondary to chronic use. *Id.* at 695.

On March 16, 2017, Petitioner underwent EMG on his right upper extremity with "mildly abnormal" results. Ex. 28 at 827. The conclusion was that the [c]linical picture and electrophysiological findings [were] suggestive of a neuralgic amyotrophy[3] on the right, mostly chronic, with no evidence of active denervation." *Id.*

On May 18, 2017, Petitioner saw Andrea Rabassa, MD, complaining of "[r]ecurrent strangling and facial swelling sensations, fasciculations, and [right] winged scapula, among other

[3] Neuralgic amyotrophy is defined as "pain across the shoulder and upper arm, with atrophy and paralysis of the muscles of the pectoral girdle." DORLAND'S MEDICAL DICTIONARY ONLINE (hereinafter "DORLAND'S"), https://www.dorlandsonline.com/dorland/definition?id=55894 (last visited Apr. 12, 2023).

symptoms." Ex. 28 at 874-79. Petitioner reported that, three years prior, he had noticed that his left deltoid had shrunk in size and that he could feel the bone. *Id.* at 874. About a year later, he noticed that his right deltoid had also shrunk in size. *Id.* Petitioner was prescribed physical therapy ("PT"), of which he completed three sessions with about 10% improvement. *Id.* at 874-75.

On July 4, 2017, Petitioner saw Bjorn Oskarsson, MD, for a neurology consultation. Ex. 4 at 169-73. Petitioner stated that, while moving a couch the previous December, he heard his right shoulder pop. *Id.* at 169. Petitioner reported that he did not feel pain, but that his discomfort was "intense." *Id.* Petitioner also described feeling as though his head was going "explode like a balloon" and that he experienced blurred vision and lightheadedness. *Id.* Petitioner reported feeling that his right side was bigger than his left. *Id.* Examination revealed tension in Petitioner's right shoulder elevator muscles. *Id.* at 172. An MRI of Petitioner's right shoulder showed normal muscle bulk without atrophy, hypertrophy, or edema. *Id.* Dr. Oskarsson's assessment was possible focal shoulder dystonia secondary to trauma or focal myopathy. *Id.* Petitioner was scheduled for a muscle biopsy. *Id.*

On August 3, 2017, Petitioner underwent a right deltoid muscle biopsy which found "clusters of macrophages in the perimysium[4] and epimysium[5]" that were compatible with a diagnosis of MMF. Ex. 3 at 50. The diagnosis was MMF. *Id.*

That same day, Petitioner also reported to the emergency room for an insect bite on his right hand, which he believed to be a spider bite. Ex. 3 at 21. Petitioner reported that his last tetanus vaccination had been two years prior but did not specify the injection site. *Id.*

Petitioner returned to Dr. Oskarsson for a follow-up on September 1, 2017. Ex. 4 at 183-86. Petitioner reported that his muscular symptoms were "largely unchanged" and that he continued to experience feelings of pressure in his head. *Id.* at 183. Petitioner reported that he received his childhood vaccinations on time in his native Venezuela and that he believes he received the tuberculosis vaccine in both arms because he pulled away when the nurse tried to administer it in his left arm. *Id.* Petitioner reported that he had received tetanus and rabies vaccinations "quite possibly in the right shoulder" about six years before, and that he had received a tetanus vaccination about two years before; the medical record did not specify the injection site of the Tdap vaccine. *Id.*

Petitioner had a physical therapy evaluation on January 18, 2018. Ex. 29 at 57. The HPI section documents that Petitioner developed discomfort and weakness in his shoulder muscles about one year prior to this appointment. *Id.* The onset date is noted as "Several years. Patient believes symptoms began after tetanus shot – 11/2015." *Id.* The clinical impression noted "decreased strength, decreased ROM, scapular dyskinesia, and decreased functional use of R UE." *Id.* at 58.

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[4] The perimysium is "the connective tissue investing a fascicle of skeletal muscle fibers." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=37884 (last visited on Apr. 19, 2023).

[5] The epimysium is "the fibrous sheath about an entire muscle." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=16890 (last visited on Apr. 19, 2023).

On April 29, 2019, Petitioner underwent a second right deltoid muscle biopsy. Ex. 5 at 1-2. The results of the Morin stain test[6] were positive, which is consistent with the diagnosis of MMF. *Id.* at 1.

On May 29, 2019, Petitioner saw neurologist Alexandra Soriano Caminero, MD. Ex. 17 at 1-4. The patient history notes that Petitioner received a tetanus vaccination in his right upper arm three years prior and that he began experiencing muscle weakness and atrophy in his right arm about 10 months later. *Id.* at 1. Petitioner denied symptoms in his left arm and legs. *Id.* Dr. Caminero noted Petitioner's MMF diagnosis and remarked that Petitioner's condition had improved somewhat after two months of IVIG. *Id.*

On July 17, 2019, Petitioner saw Dr. Oskarsson for a neurology follow-up. Ex. 21 at 1-2. Dr. Oskarsson noted that Petitioner had undergone a muscle biopsy of his right deltoid in April 2019 and stated that "[a]luminum was identified in the muscle confirming that vaccination had taken place in the affected muscles. Current thinking is that it is causative." *Id.* at 1.

On July 18, 2019, Petitioner had a neurology follow-up with Dr. Oskarsson. Ex. 15 at 1-2. The notes from this appointment indicate that aluminum was "believed to be the causative problem" and that the right deltoid was believed to be where "the bulk of the aluminum resides." *Id.* at 2. The notes acknowledge that a link had been proposed between vaccinations and MMF, but do not specify which of Petitioner's vaccinations might have been causative. *Id.*

On March 6, 2020, Petitioner visited A.P.R.N. Christy Wagner for evaluation of pressure in his head. Ex. 29 at 28. The requesting provider is listed as Dr. Oskarsson. *Id.* The HPI documents that Petitioner "has been diagnosed with macrophagic myofasciitis that has been attributed to a Tetanus vaccine in 2017 [sic], and he states his symptoms began at that time." *Id.*

No other medical records relevant to the issue of situs have been filed.

III. Affidavits that Address the Issue of Situs

A. Affidavit of Petitioner

In his affidavit, Petitioner avers that in early 2015, he injured his left shoulder while lifting weights and received a diagnosis of subdeltoid subacromial bursitis. Ex. 32 ("Pet. Aff.") at 1. Petitioner saw a physical therapist who recommended a home exercise program. *Id.* Petitioner was careful with exercise over the following months so as not to exacerbate his left shoulder injury. *Id.* at 2.

When he received the Tdap vaccine on November 5, 2015, Petitioner sat in a hospital room with his left shoulder facing a room divider and asked the nurse to administer the injection in his

[6] The interpretation/comment section of the results report indicates that Morin "is a flavonoid that forms a green-blue fluorescent complex with aluminum detectable by fluorescence microscopy…Presence of Morin positive macrophages in human muscle at a previous vaccine injection site is supportive of the diagnosis of [MMF]." Ex. 5 at 1-2.

right shoulder because of his left shoulder injury. Pet. Aff. at 2. Petitioner avers that he received the November 5, 2015 Tdap vaccine in his right shoulder. *Id.*

B. Affidavit of Karina Dunaeva

In her affidavit, Karina Dunaeva ("Ms. Dunaeva") avers that she is Petitioner's girlfriend and that she has known Petitioner since 2012. Ex. 33 ("Dunaeva Aff.") at 1. Petitioner injured his left shoulder in 2015 and was diagnosed with subacromial bursitis. *Id.* Ms. Dunaeva drove Petitioner to and from medical appointments and assisted him with his home exercise program. *Id.*

Ms. Dunaeva was not present at the hospital when Petitioner received the Tdap vaccination on November 5, 2015, but she avers that she advised Petitioner to request that the injection be administered somewhere other than his left shoulder due to his injury. Dunaeva Aff. at 2. Ms. Dunaeva avers that, when Petitioner returned from the hospital, he told Ms. Dunaeva that he had received the vaccine in his right shoulder and that she saw a band-aid on Petitioner's right shoulder. *Id.*

IV. Medical Literature that Addresses the Issue of Situs

Respondent did not cite medical literature in his brief on the issue of situs. Petitioner cited four articles in support of his position that the Tdap vaccine he received on November 5, 2015, was administered in his right arm.

A. Kim, et al. (2020) (Ex. 34)

In this article, the authors examined seven pediatric cases of aluminum hydroxide-containing vaccine-induced disease, of which six cases were MMF. Kim et al., *Macrophagic myofasciitis and subcutaneous pseudolymphoma caused by aluminum adjuvants*, 10 SCI. REPS. 1-9, 1 (2020) ("Kim") (filed as Ex. 34). Kim states that MMF is "an unusual inflammatory myopathy found in patients with arthromyalgia and muscle weakness that develops several months to years after administering aluminum-containing vaccines." *Id.* Kim also states that "MMF is not a simple local disease, but rather a systemic, complicated, and severe disease." *Id.* at 5. Kim notes that, in the six MMF patients the authors reviewed, the MMF lesions "were found in vaccination sites." *Id.*

B. Gherardi, et al. (2001) (Ex. 35)

In this article, the authors analyze 50 MMF patients, all of whom had received hepatitis B, hepatitis A, or tetanus vaccinations between three and 96 months prior to muscle biopsy. Gherardi, et al., *Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminum hydroxide in muscle*, 124 BRAIN 1821-31, 1821 (2001) ("Gherardi") (filed as Ex. 35). Together with experimental data concerning rats that had been injected with aluminum hydroxide, the authors conclude that "these results firmly establish that aluminum hydroxide-containing vaccines represent the direct cause of the MMF lesion." *Id.* at 1827-28.

Gherardi explains that aluminum hydroxide forms a deposit in the tissue upon vaccination, damages the injected tissue, and elicits an inflammatory response. Gherardi at 1828. The patient's body then breaks down the deposit into the blood, redistributes it to tissues, and excretes it. *Id*. Gherardi posits that MMF lesions may develop in "a predisposed subset of individuals with impaired ability to clear aluminum from the deltoid muscle." *Id.* (citing WHO Vaccine Safety Advisory Committee, 1999). Gherardi also concludes that "MMF lesions are usually detected in the deltoid muscle of patients with diffuse myalgias appearing subsequently to aluminum hydroxide-containing vaccine administration." *Id.* at 1829.

C. Gherardi & Authier (2012) (Ex. 36)

In this article, the authors examine 457 cases of MMF in adults identified between 1994 and 2011. Gherardi & Authier, *Macrophagic myofasciitis: characterization and pathophysiology*, 21 LUPUS 184-89, 185 (2012) ("Gherardi & Authier") (filed as Ex. 36). Gherardi & Authier describes how aluminum adjuvants can trigger the MMF disease process. *Id.* at 184. Gherardi & Authier note that these adjuvants "are generally well tolerated," but can cause "delayed onset of diffuse myalgia, chronic fatigue and cognitive dysfunction" along with "very long-term persistence of alum-loaded macrophages" at the injection site. *Id.* They also explain that aluminum particles "can first translocate to draining lymph nodes, and thereafter circulate in blood within phagocytes and reach the spleen, and, eventually, slowly accumulate in the brain." *Id.*

D. Dias, et al. (2020) (Ex. 37)

This article is a case report in which the authors describe a single atypical case of MMF. Dias, et al., *Macrophagic myofasciitis: an atypical presentation for a rare disease with a challenging approach*, 58 RHEUMATOLOGIA 167-72, 167 (2020) ("Dias") (filed as Ex. 37). Dias presents the case of a 15-year-old girl who received an aluminum-adjuvanted vaccination in her deltoid (which side is not specified) and in whom MMF was later confirmed by muscle biopsy in her right forearm. *Id.* at 168.

Dias notes that muscle biopsy findings consistent with MMF lesions "seem to be the result of an abnormal presence at the inoculation site of aluminum used as a vaccine adjuvant, which can induce an immune-mediated muscular disease in susceptible persons." Dias at 170-71. Dias also notes that some particles of the injected aluminum "are rapidly phagocytosed by macrophages and escape from the immunization site to lymph nodes and tissues." *Id.* at 171. This means that "there is a possibility of muscle damage at other places distant from the inoculation site." *Id.*

V. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claim by a preponderance of the evidence. 42 U.S.C. § 300aa-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 or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs*., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

In order to make a determination concerning factual issues, such as the timing of onset of petitioner's alleged injury, the special master should first look to the medical records. "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2006 WL 3734216, at *8 (Fed. Cl. Spec. Mstr. Nov. 29, 2006). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete. *Doe/70 v. Sec'y of Health & Hum. Servs.,* 95 Fed. Cl. 598, 608 (2010).

Contemporaneous medical records generally merit greater evidentiary weight than oral testimony; this is particularly true where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 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")). "Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Reusser v. Sec'y of Health & Hum. Servs*., 28 Fed. Cl. 516, 523 (1993).

However, there are situations in which compelling oral testimony may be more persuasive than written records--for instance in cases where records are found to be incomplete or inaccurate. *Campbell*, 69 Fed. Cl. at 779 ("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).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

A special master making a determination whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at a hearing, must have evidence suggesting the decision was a rational determination. *Burns by Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993); *see also Sprinkle v. Sec'y of Health & Hum. Servs.,* No. 20-960V, 2023 WL 246702, at *3 (Fed. Cl. Spec. Mstr. Jan. 18, 2023) (finding that the

petitioner's vaccination record erroneously documented left arm situs where the vaccination record "lack[ed] later corroboration – whereas the entire body of medical records following vaccination indicate[d] administration of the flu vaccine in Petitioner's right arm."); *McCabe v. Sec'y of Health & Hum. Servs.*, No. 19-1916V, 2021 WL 6755494, at *4 (Fed. Cl. Spec. Mstr. Dec. 29, 2021) (finding that eyewitness testimony from the petitioner's wife provided support for finding that the petitioner had received the vaccination in his right arm despite the vaccination record's documentation of left arm administration); *Steinbach v. Sec'y of Health & Hum. Servs.,* No. 15-1546V, 2016 WL 4751772, at *2 (Fed. Cl. Spec. Mstr. Aug. 4, 2016) (finding that the petitioner's vaccination record incorrectly stated that she had received the vaccination in her left arm because the petitioner's pre-existing left shoulder injury constituted "a reasonable and plausible explanation for why she would not have received the vaccination in her left arm.").

VI. Findings of Fact

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a preponderance of the evidence. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

After reviewing the medical records, medical literature, and affidavits presented in this case, and after my careful examination of the record as a whole, I find that Petitioner has provided preponderant evidence that he received the Tdap vaccine in his right shoulder.

A. Situs

First, Respondent argues, and Petitioner acknowledges, that Petitioner's vaccination record documents that he received the Tdap vaccine in his left arm. Ex. 1 at 9. However, the vaccination record is the only evidence in the medical record that directly supports left situs. Documentation of vaccination situs in the medical records is an important fact that I have considered in my analysis of this question. However, I find that Petitioner has rebutted the accuracy of this entry.

1. Medical Record Evidence

Petitioner's medical records are silent as to situs until a PT evaluation on January 18, 2018. During that appointment, Petitioner complained about decreased strength and range of motion in his right upper extremity. Ex. 29 at 57-58. Petitioner attributed his condition to his November 2015 Tdap vaccine. *Id.* This medical record supports Petitioner's position that he received the allegedly causal Tdap vaccine in his right shoulder.

Petitioner's neurology appointment with Dr. Caminero on May 29, 2019, also supports his position. Ex. 17 at 1. Dr. Caminero's notes reflect that Petitioner had received the Tdap vaccine in his right arm three years prior and that his right shoulder muscle weakness and atrophy began roughly 10 months later. Ex. 17 at 1. This note specifically associates the Tdap vaccine at issue here with Petitioner's right shoulder injury, thus providing support for Petitioner's claim that the vaccine was administered in his right arm.

Although the March 6, 2020, evaluation with A.P.R.N. Christy Wagner associates his MMF with a *2017* tetanus vaccine, this record still supports Petitioner's contention that the vaccine was administered in his right arm. *See* Ex. 29 at 28. There is no documentation in Petitioner's medical records that he received a tetanus vaccine in 2017, so it is reasonable to assume this is a typo, and the record instead refers to the 2015 Tdap vaccine.

2. Affidavits

In his affidavit, Petitioner avers that he specifically asked to have the Tdap vaccine administered in his right arm because of pain in his left shoulder from a pre-existing injury. Pet. Aff. at 2. Petitioner's pre-existing left shoulder injury is well documented in the record. Ex. 25 at 185, 341-43. In fact, the medical history for the November 5, 2015 visit documents that Petitioner had a "shoulder injury". Ex. 1 at 516. This injury was to his left shoulder. Petitioner's wish not to exacerbate his left shoulder pain with an injection comports with common sense and my experience and knowledge of human behavior. *See Christensen v. Sec'y of Health & Hum. Servs.,* 2022 WL 1020386 (Fed. Cl. Spec. Mstr. Feb. 28, 2022) (finding Petitioner's history of left shoulder surgery a compelling factor in determining vaccine situs was in the right arm, not the left, as documented in the medical records).

Although Ms. Dunaeva was not present when Petitioner received the vaccine, her account corroborates Petitioner's pre-existing left shoulder injury and provides some support for his having refused vaccine administration in his left arm. Dunaeva Aff. at 2.

3. Medical Literature

Petitioner provides medical literature supporting the conclusion that MMF is directly attributable to vaccines containing aluminum adjuvants. Gherardi, et al. at 1827-28 (finding that the results of their case review and rat study "firmly establish" that aluminum hydroxide-containing vaccines represent the direct cause of the MMF lesion."); Gheradi & Authier at 184 ("MMF lesion is now universally recognized to assess long-term persistence of [aluminum oxyhydroxide] at site of previous intramuscular (i.m.) immunization."); Dias at 170 ("[Histological findings in MMF] seem to be the result of an abnormal presence in the inoculation site of aluminum used as a vaccine adjuvant, which can induce an immune-mediated muscular disease in susceptible persons."); Kim at 2 ("MMF itself is aluminum hydroxide induced granulomas in the vaccine injected sites, but it is not a local lesion but manifests severe systemic disease.").

As shown above, Petitioner's medical literature refers variously to "aluminum," "aluminum hydroxide," and "aluminum oxyhydroxide," as being causative of MMF. Per the CDC, both Tdap vaccines, Boostrix and Adacel, contain aluminum adjuvants.[7] The package inserts for each product disclose that Boostrix contains aluminum hydroxide, while Adacel contains

[7] CTRS. FOR DISEASE CONTROL & PREVENTION: ADJUVANTS AND VACCINES, https://www.cdc.gov /vaccinesafety/concerns/adjuvants.html (last visited Apr. 5, 2023).

aluminum phosphate.[8] Petitioner's vaccine record does not list a manufacturer, so it is not possible to determine which aluminum adjuvant was used. *See* Ex. 1 at 9. Petitioner's medical literature causally linking aluminum hydroxide-containing vaccines to MMF supports his position. Because Petitioner's diagnosis of MMF is not in dispute, the lack of certainty as to the adjuvant in the vaccine Petitioner received does not undermine the medical literature he provided.

4. Medical Opinion

Finally, upon reviewing Petitioner's right-shoulder muscle biopsy results, Dr. Oskarsson concluded that "[a]luminum was identified in the muscle *confirming that vaccination had taken place in the affected muscles*." Ex. 21 at 1 (emphasis added). Although Dr. Oskarsson does not specifically identify the November 5, 2015, Tdap vaccine, this note nevertheless lends some credence to Petitioner's argument that he received the Tdap vaccine in his right arm because it draws a reasoned conclusion from an undisputed part of the medical record (i.e., the record of Petitioner's April 29, 2019, right shoulder muscle biopsy, Ex. 5 at 1-2). Further, Petitioner's Tdap vaccine was the most proximate vaccine to the onset of his MMF, lending additional credence to Dr. Oskarsson's opinion as supportive of Petitioner's position on situs.

VII. Conclusion

I have considered Petitioner's medical records, the affidavits submitted by Petitioner and Ms. Dunaeva, the medical literature Petitioner filed, and Dr. Oskarrson's opinion. I find that the totality of this evidence provides preponderant support for Petitioner's position that he received the November 5, 2015 Tdap vaccine in his right shoulder.

The following is therefore ORDERED:

By **May 19, 2023**, the parties shall file a joint status report updating me on their proposed next steps in the case based on the facts articulated in this ruling.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[8] FOOD & DRUG ADMIN., BOOSTRIX PACKAGE INSERT 18 (2023), https://www.fda.gov/media/124002/download; FOOD & DRUG ADMIN., ADACEL PACKAGE INSERT 13 (2023), https://www.fda.gov/media/119862/download.