In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 26, 2023

DAVID T. MCDANIEL,	*	PUBLISHED
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Petitioner,	*	No. 17-1322V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; Influenza ("Flu") Vaccine; Immune-Mediated Myopathy; Dermatomyositis; Diagnosis; Onset.
	*	
Respondent.	*	
	*	

Douglas Lee Burdette, Burdette Law, North Bend, WA, for Petitioner.
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

I. INTRODUCTION

On September 25, 2017, David T. McDaniel ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018).[2] Petitioner alleges that he suffered "an auto-immune myopathy, more likely than not dermatomyositis," as the result of an influenza ("flu")

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it 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 Decision 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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

vaccination administered on December 12, 2016. Petition at Preamble (ECF No. 1); Amended ("Am.") Petition at Preamble (ECF No. 7). Respondent argued against compensation, stating that "this case is not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 1 (ECF No. 22).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that Petitioner has failed to provide preponderant evidence that his flu vaccine caused his immune-mediated myopathy. Thus, Petitioner has failed to satisfy his burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition shall be dismissed.

II. ISSUES TO BE DECIDED

The parties stipulate that Petitioner received the flu vaccine on December 12, 2016, and that Petitioner most likely suffered from an immune-mediated myopathy. Joint Submission, filed June 13, 2022, at 1 (ECF No. 77). However, "the experts appear to disagree on whether a more specific diagnosis (i.e., dermatomyositis, polymyositis, or dermatomyositis sine dermatitis) is appropriate." Id.

The parties also disagree on onset, specifically whether onset was before or after the flu vaccination administered on December 12, 2016. Petitioner's Brief on the Issue of Entitlement ("Pet. Br."), filed June 13, 2022, at 3-4 (ECF No. 78); Resp. Response to Pet. Br. ("Resp. Response"), filed Oct. 10, 2022, at 15-23 (ECF No. 91).

As for causation, the parties disagree as to whether Petitioner has satisfied all three Althen prongs. Joint Submission at 1. Petitioner contends he has presented preponderant evidence of all three Althen prongs, establishing his condition was caused-in-fact by his flu vaccine on December 12, 2016. Pet. Br. at 6-8. Respondent disagrees and argues Petitioner "failed to produce reliable evidence" of all three Althen prongs. Resp. Response at 13-19.

Petitioner does not allege a significant aggravation claim.[3] Joint Submission at 1; Joint Status Rept., filed Mar. 23, 2023 (ECF No. 89).

[3] In his brief, Petitioner identified the issues to include the following question: "Did Petitioner suffer an autoimmune inflammatory process (polymyositis/dermatomyositis) or an exacerbation of that process as a direct and proximate result of his vaccination on December 12, 2016?" Pet. Br. at 3. This statement suggested that Petitioner was pursuing a claim for significant aggravation, although Petitioner's expert reports and brief did not address the Loving prongs relevant to such a claim. See Loving v. Secretary of Health & Human Services, 86 Fed. Cl. 135, 142-44 (2009). To seek clarification, the undersigned issued an order asking Petitioner whether he was alleging a significant aggravation claim. Order dated Feb. 21, 2023 (ECF No. 88). Thereafter, the parties filed a joint status report advising that Petitioner was not claiming significant aggravation. Joint Status Rept., filed Mar. 23, 2023. Thus, the undersigned does not address or adjudicate such a claim herein. Even if Petitioner had pursued a significant aggravation claim, the outcome would have been the same, as he failed to prove by preponderant evidence all three Althen prongs, which constitute Loving prongs four, five, and six.

III. BACKGROUND

A. Medical Terminology

Inflammatory myopathies[4] are a group of disorders classified based on their distinct clinical and pathological characteristics into four subtypes, two of which are relevant here, dermatomyositis and polymyositis,[5] "characterized by the shared features of proximal skeletal muscle weakness and by evidence of muscle inflammation." Pet. Exhibit ("Ex.") 33 at 1;[6] see also Resp. Ex. A, Tab 7 at 1.[7] Dermatomyositis differs from polymyositis due to its "associat[ion] with a variety of characteristic skin manifestations."[8] Pet. Ex. 33 at 1. Both conditions are "multisystem disorders with a wide variety of clinical manifestations. Most patients exhibit proximal skeletal muscle weakness." Id. at 2. Muscles commonly affected include the "deltoids and the hip flexors." Id.

"Patients usually report a history of insidious or subacute development of the muscle weakness, with gradual worsening over a period of several months before medical attention is sought." Pet. Ex. 33 at 2. "However, an acute onset is occasionally reported. Patients may describe increasing difficulty climbing stairs, [and] getting up from a chair." Id. "Muscle atrophy is generally not seen in early cases, even in patients with marked weakness, but it may occur in severe, longstanding disease." Id.

Laboratory tests to assess for idiopathic inflammatory myopathies measure enzymes to determine whether there is muscle injury. Pet. Ex. 39 at 1.[9] Muscle enzymes are thought to be released from injured or dying muscle fibers. Id. at 2. Characteristic lab findings of dermatomyositis and polymyositis include "elevated levels of muscle enzymes," such as

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[4] Myopathies include "any disease of a muscle." Myopathy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32891 (last visited June 9, 2023).

[5] Other articles filed by the parties define dermatomyositis and polymyositis as "autoimmune myopathies." See, e.g., Resp. Ex. A, Tab 2 at 1 (Andrew L. Mammen, Dermatomyositis, Polymyositis, & Immune-Mediated Necrotizing Myopathy, in Current Diagnosis & Treatment in Rheumatology (3rd. ed. 2013)).

[6] Marc L. Miller & Ruth Ann Vleugels, Clinical Manifestations of Dermatomyositis and Polymyositis in Adults, UpToDate, https://www.uptodate.com/contents/clinical-manifestations-of-dermatomyositis-and-polymyositis-in-adults (last updated Jan. 30, 2017).

[7] Marinos C. Dalakas, Inflammatory Muscle Diseases, 372 New Eng. J. Med. 1734 (2015).

[8] For a discussion of common skin manifestations, see Resp. Ex. A, Tab 2, at 2. Petitioner did not have skin manifestations.

[9] Ira N. Targoff, Laboratory Testing in the Diagnostic and Management of Idiopathic Inflammatory Myopathies, 28 Rheumatic Disease Clinics N. Am. 859 (2002).

"[c]reatine kinase (CK)[10] . . . aspartate aminotransferase (AST),[11] and alanine aminotransferase (ALT)."[12] Pet. Ex. 33 at 7. CK has traditionally been thought to be the most useful lab test due to its specificity and sensitivity for skeletal muscle injury. Pet. Ex. 39 at 4. "The transaminases, AST and ALT, can be elevated in patients with muscle injury and vary with disease activity." Id. at 7. AST is "present in the liver" as well as "skeletal muscle," while ALT is "present primarily in the liver," and thus, a "more specific marker of hepatocellular cell injury." Pet. Ex. 41 at 2.[13] Gamma-glutamyl transpeptidase ("GGT") may also be tested to "evaluate elevations of other serum enzyme tests." Id. at 11. "Not infrequently, elevated AST and ALT levels are misinterpreted as evidence of liver disease in patients with myopathy. To rule out liver disease, a [] GGT level can be measured; GGT is usually released along with AST and ALT in liver disease but not from damaged muscle." Resp. Ex. A, Tab 2 at 4.

Dermatomyositis can occur in both children and adults and is characterized by "distinct skin manifestations accompanying or preceding muscle weakness." Resp. Ex. A, Tab 7 at 2. The skin abnormalities may include "periorbital heliotrope (blue-purple) rash with edema;

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[10] CK is "an Mg2+-activated enzyme of the transferase class that catalyzes the phosphorylation of creatine by ATP to form phosphocreatine. The reaction effectively stores the energy of ATP as phosphocreatine in muscle and brain tissue and holds the muscle concentration of ATP nearly constant during the initiation of exercise." Creatine Kinase, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=11582 (last visited June 9, 2023). "It occurs as three isoenzymes, each having two components composed of M (muscle) and of B (brain) subunits. CK_1 (BB) is found primarily in brain, CK_2 (MB) primarily in cardiac muscle, and CK_3 (MM) primarily in skeletal muscle. Differential determination of isoenzymes is useful for clinical diagnoses." Id.

[11] AST is "an enzyme of the transferase class that catalyzes the reversible transfer of an amino group from aspartate to α-ketoglutarate to form glutamate and oxaloacetate." Aspartate Transaminase, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4466 (last visited June 9, 2023). AST is "present in most eukaryotic cells, occurring as distinct isozymes in mitochondria and cytosol. Both isozymes participate in the malate-aspartate shuttle, and in the liver the reaction transfers excess metabolic nitrogen into aspartate for disposal via the urea cycle." Id. "The serum level of [AST] and that of other transaminases are frequently elevated in a variety of disorders causing tissue damage." Id.

[12] ALT is "an enzyme of the transferase class that catalyzes the reversible transfer of an amino group from alanine to α-ketoglutarate to form glutamate and pyruvate." Alanine Transaminase, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=1509 (last visited June 9, 2023). "The reaction transfers nitrogen for excretion or for incorporation into other compounds. The enzyme is found in serum and body tissues, especially in the liver. Serum enzyme activity (SGPT) is greatly increased in liver disease and also elevated in infectious mononucleosis." Id.

[13] Lawrence S. Friedman, Approach to the Patient with Abnormal Liver Biochemical and Function Tests, UpToDate, https://www.uptodate.com/contents/approach-to-the-patient-with-abnormal-liver-biochemical-and-function-tests (last updated Apr. 4, 2018).

erythematous rash on the face, knees, [and] elbows . . . ; and a violaceous eruption (Gottron's rash) on the knuckles, which may evolve into a scaling discoloration." Id. There may also be manifestations of the fingernails and palms. Id. "Polymyositis is rare as a stand-alone entity and is often misdiagnosed." Id. It is a diagnosis of exclusion and is defined as "a subacute proximal myopathy in adults who do not have rash, a family history of neuromuscular disease," exposure to drugs that are known to be toxic to muscle, or "the clinical phenotype of inclusion-body myositis." Id. at 2-4. Dermatomyositis and polymyositis can be "distinguished from each other . . . by their histopathologic findings" on muscle biopsy. Pet. Ex. 33 at 11. Polymyositis is "distinguished by the presence of T cells [endomysial inflammatory cell infiltrate] surrounding and/or invading nonnecrotic muscle fibers," whereas dermatomyositis is characterized by "perifascicular atrophy." Resp. Ex. A, Tab 4 at 3, 4 tbl.25.1.[14]

Increased rates of cancers have been noted in those with dermatomyositis and polymyositis, especially in patients with dermatomyositis. Pet. Ex. 33 at 5. "Colonoscopy is recommended for patients over the age of 50" who have been diagnosed with immune-mediated myopathy. Resp. Ex. A, Tab 2 at 7; see also Resp. Ex. A, Tab 4 at 10-11 (discussing cancer risks).

B. Procedural History

On September 25, 2017, Petitioner filed his petition, and on October 25, 2017, Petitioner filed a declaration and supporting medical records.[15] Petition; Pet. Exs. 1-9. On April 6, 2018, Petitioner filed an expert report from Dr. Thomas M. Zizic. Pet. Ex. 10. Additional medical records were filed on August 9, 2018. Pet. Ex. 31. Respondent filed his Rule 4(c) Report on November 13, 2018, arguing against compensation. Resp. Rept. at 1, 12. Respondent simultaneously filed a responsive expert report from Dr. Mehrdad Matloubian. Resp. Ex. A. On February 4, 2019, Petitioner filed a supplemental expert report from Dr. Zizic, and Respondent filed a responsive supplemental report from Dr. Matloubian on May 28, 2019. Pet. Ex. 32; Resp. Ex. C. Petitioner filed a second supplemental report from Dr. Zizic on June 11, 2019. Pet. Ex. 45.

Subsequently, Respondent filed a status report indicating the parties wanted to schedule an entitlement hearing. Status Rept., filed July 17, 2019 (ECF No. 32). The case was reassigned to the undersigned on July 30, 2020. Notice of Reassignment dated July 30, 2020 (ECF No. 35). At a status conference on August 27, 2020, the undersigned encouraged the parties to resolve the case informally and ordered Petitioner to file updated medical records and a status report indicating a demand was transmitted to Respondent. Order dated Aug. 27, 2020 (ECF No. 36). Seven months later, Petitioner had still not filed updated medical records or submitted a demand to Respondent. See Order dated Mar. 3, 2021 (ECF No. 45). Petitioner's counsel was warned that failure to show progress would result in an order to associate other counsel. Id.

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[14] Andrew Mammen, Autoimmune Muscle Disease, in 133 Handbook Clinical Neurology: Autoimmune Neurology 467 (Sean J. Pittock & Angela Vincent eds., 3rd. ser. 2016).

[15] Petitioner filed an amended petition on October 19, 2017. Am. Petition. It appears only the paragraph numbering was modified from the original. See id.

On March 15, 2021, Petitioner filed declarations of Petitioner and Petitioner's wife, Sandy McDaniel. Pet. Exs. 46-47. Petitioner filed additional medical records on May 17, 2021. Pet. Exs. 48-49. The parties engaged in settlement negotiations but reached an impasse and requested the case be submitted for a ruling on the record. Joint Motion for Ruling on the Record, filed Apr. 11, 2022, at 1 (ECF No. 75). Petitioner submitted his brief in support of entitlement on June 13, 2022, and Respondent filed his brief on October 10, 2022. Pet. Br.; Resp. Response.

On February 21, 2023, the undersigned issued an order requesting guidance as to whether Petitioner was pursuing a claim for significant aggravation, and the parties were directed to confer and file a joint status report providing clarification. Order dated Feb. 21, 2023 (ECF No. 88). Petitioner filed a joint status report on March 23, 2023, advising that Petitioner was not offering evidence of a significant aggravation claim, and advising that the record was complete for adjudication. Joint Status Rept., filed Mar. 23, 2023.

This matter is now ripe for adjudication.

C. Medical History[16]

1. Pre-Vaccination Records

Petitioner was born on February 5, 1952. Pet. Ex. 2 at 1. Prior to vaccination, he had a history myopia, gammopathy, hyperlipidemia, dermatitis, chronic neck and back pain, alcoholism, and was a former smoker. Id. at 1, 44-45, 166; Pet. Ex. 7 at 1, 4; Pet. Ex. 8 at 1. Petitioner sought treatment for intermittent arthralgias throughout 2015, but a rheumatology consultation in March 2015 ruled out a systemic inflammatory disorder. See Pet. Ex. 2 at 43, 50; Pet. Ex. 10 at 6-7; Resp. Ex. A at 2.

On December 1, 2016, Petitioner presented to his primary care provider ("PCP") where he saw Benjamin R. Cichon, certified physician assistant ("PA-C"). Pet. Ex. 2 at 50-52. Petitioner complained of a one-month history of fatigue, sore muscles, and chills. Id. at 50. He also complained of a tingling sensation in his arms and legs, "increased weakness," and back pain, and he felt "like he [was] losing a lot of his muscle tone." Id. Physical examination was normal, except for tenderness along his spine and some discomfort bilaterally in the cubital tunnel area. Id. at 50-51. Petitioner was diagnosed with paresthesias, possible carpal

[16] For the parties' respective medical record summaries, see Pet. Br. at 1-3; Resp. Response at 1-10.

tunnel/cubital tunnel syndrome,[17] and "increased arm and leg weakness with tingling." Id. at 51. Labs were ordered and Petitioner was referred to a neurologist.[18] Id. Testing completed that day revealed an elevated AST of 55 (normal range 10-35 U/L) and an elevated ALT of 57 (normal range 9-46 U/L).[19] Id. at 140.

Petitioner returned to his PCP on December 12, 2016. Pet. Ex. 2 at 55-59. He saw Dr. John Dinh who noted that Petitioner's recent lab results revealed "elevated liver enzymes" (AST and ALT), but there was no mention of Petitioner's symptoms reported on December 1, 2016. Id. at 55. Lab testing repeated on this date revealed continuously elevated AST (63) and ALT (73), and elevated ferritin[20] of 701 (normal range 20-380 ng/mL). Id. at 125, 138. Hepatitis A, B, and C titers were negative. Id. at 125, 139. Review of systems was negative and there were no documented abnormalities based on the physical examination. Id. at 55-57. Neurological examination documented normal sensation, normal strength in upper and lower extremities bilaterally, and normal gait. Id. at 57. Petitioner received the flu vaccine (Fluvirin) at this visit in his left deltoid. Id. at 58; Pet. Ex. 3 at 21.

2. Post-Vaccination Records

On Friday, December 16, 2016, four days after receiving his flu shot, Petitioner returned to his PCP and reported that since receiving the flu shot on Monday, December 12, he had developed weakness and paresthesias, mainly in his lower extremities. Pet. Ex. 2 at 60. Petitioner described difficulty "getting up out of a chair" and walking. Id. Petitioner also reported fatigue and painful joints, and that these symptoms "ha[d] been worsening daily since [his] last visit." Id. at 63. On examination, Petitioner exhibited "weakness below the hips," difficulty walking, and could not "get up out of the chair without assistance." Id. at 60. His

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[17] Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." Carpal Tunnel Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id =110370 (last visited June 9, 2023). Cubital tunnel syndrome is "a type of entrapment neuropathy with a complex of symptoms resulting from injury or compression of the ulnar nerve at the elbow, including pain and numbness along the ulnar aspect of the hand and forearm and weakness of the hand." Cubital Tunnel Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110481 (last visited June 9, 2023).

[18] It does not appear that Petitioner saw a neurologist prior to his admission to Good Samaritan Hospital on December 16, 2016.

[19] These were abnormalities for Petitioner. When these labs were checked in December 2015, they were normal (22 and 21). Pet. Ex. 2 at 143.

[20] Ferritin is "the iron-apoferritin complex, one of the chief forms in which iron is stored in the body; it occurs at least in the gastrointestinal mucosa, liver, spleen, bone marrow, and reticuloendothelial cells generally." Ferritin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=183386 (last visited June 9, 2023).

upper extremities were normal. Id. Dr. Robert M. Alston noted that Petitioner's elevated liver enzymes required further evaluation and that his elevated ferritin level was suggestive of inflammation. Id. Dr. Alston's assessment was Guillain-Barré syndrome ("GBS"), and he advised Petitioner to go to the emergency department ("ED") for further evaluation. Id.

Petitioner presented to the ED at Good Samaritan Hospital on Friday, December 16, 2016, where he was seen by John B. Gillum, PA-C, for "body aches and weakness." Pet. Ex. 5 at 103. Petitioner reported that his symptoms started five days prior when he had a flu shot. Id. The night of his flu shot, Petitioner "noted some tremors in his left fifth and fourth finger. This resolved and then he developed severe muscle aches in his calves and thighs. . . . Over the last 24 hours he felt more weakness and pain in his upper extremities." Id.

Nursing notes stated that Petitioner received a "flu shot on Monday and by Monday evening [Petitioner] was [complaining of] of lower extremity weakness that over the last couple of days had gotten worse and progressed up arms." Pet. Ex. 5 at 108. Petitioner was still able to walk but stated "it [was] hard to move around." Id. Onset was recorded as "3-7 days ago." Id.

Physical examination showed weakness in Petitioner's lower and upper extremities but intact deep tendon reflexes. Pet. Ex. 5 at 105, 108. Lab tests showed elevated AST at 76, ALT at 73, and CK at 674 (normal range 0-200 IU/L). Id. at 105-06, 189. A spinal tap revealed mildly elevated protein (53; normal range 15-50 mg/dL), only one white blood cell, and high CK of 687. Id. at 107, 190-91. Petitioner was admitted to the hospital for further evaluation. Id. at 106-08.

Later that day, Petitioner was evaluated by Dr. Nelson Yang. Pet. Ex. 5 at 93. Petitioner again reported that he received a flu vaccine on Monday, and by Monday night, he felt the "lateral [three] fingers of his left hand and were twitching. The next day, he woke up with pain going down from his umbilical area all the way to the distal lower extremities." Id. And on Thursday, the day prior to admission, Petitioner started noticing bilateral shoulder pain and mild arm weakness. Id. Petitioner also reported "he had a viral flu-like illness roughly [two] weeks ago from today [December 16, 2016] prior to getting the flu shot as well and had recovered prior to getting the flu shot." Id. Petitioner reported he was an industrial construction worker and worked with mercury light bulbs, and over the last five years he "must have had some exposure" (to mercury) because some light bulbs would break and he did not wear any protection when handling them. Id. at 93-94. On examination, Petitioner demonstrated minimal decease in strength, but sensation was intact and deep tendon reflexes were present. Id. at 94.

Dr. Yang's assessment was rhabdomyolysis and generalized weakness. Pet. Ex. 5 at 95. Dr. Yang noted Petitioner "likely had myalgias from post-vaccine syndrome," but that because Petitioner had "a viral-like illness [two] weeks ago, . . . delayed reaction and delayed autoimmune neuropathy could be on the differential as well." Id. Petitioner expressed concern for chronic mercury poisoning, which as Dr. Yang noted, can present with neurological symptoms including numbness and tingling. Id. Mercury lab testing revealed normal results. Id. at 219. Hepatitis C antibody test was positive with normal viral load.[21] Id. at 204. The plan

[21] These labs were collected on December 20, 2016. Pet. Ex. 5 at 204.

was to observe Petitioner's pain and weakness and if it continued, to have magnetic resonance imaging ("MRI") done. Id. at 95.

Additional diagnostic testing included a pelvic MRI done December 19, 2016, which was abnormal, showing "diffuse and bilaterally symmetric abnormal [] signal involving nearly all of the imaged muscular structures" in the pelvis to the mid-thigh area, as well as "mild subcutaneous edema" and "presacral edema." Pet. Ex. 5 at 187. The findings were "concerning for myositis." Id.

Petitioner had a neurology consultation on December 19, 2016 with Dr. Traci D. Ryan. Pet. Ex. 5 at 96. Petitioner reported "that about [two] weeks ago he had a viral infection and had, in general, been feeling pretty badly." Id. "He had some blood drawn for his upcoming physical and decided that he should go ahead and have a flu shot. He had a flu shot on Monday and then about [three] days later developed a sense of weakness and pain and noticed that some of the fingers on his left hand were twitching." Id. Dr. Ryan noted Petitioner's elevated labs. Id. at 97. The assessment was "more likely [] a viral myositis." Id. at 98. "How this [was] related to his flu shot [was] uncertain. It may more likely be related to his recent viral illness." Id. She did "not see any other risk factors for him to develop rhabdomyolysis and therefore suspect[ed] that this [was] a viral syndrome." Id.

Also on December 19, Petitioner was seen by Helen Ward, a licensed independent clinical social worker ("LICSW"), who wrote that Petitioner stated that "he [did not] have very much trust in the medical field and he will 'never get another flu shot again.'" Pet. Ex. 5 at 268. Petitioner did not "think he was sick when he got his flu shot, he [thought] he was 'fighting something off.'" Id. Petitioner also reported that he had been "losing some muscle strength for a while." Id.

The next day, Dr. Ryan followed up with Petitioner and noted his CK elevated from the day before. Pet. Ex. 5 at 122. Her assessment was rhabdomyolysis, with "viral etiology most likely." Id. Cytomegalovirus ("CMV") immunoglobulin M ("IgM") and immunoglobulin G ("IgG") test results from December 22, 2016 were positive. Id. at 209. A progress note authored by Dr. Ryan on December 23 noted that CMV and Epstein-Barr virus ("EBV") testing was positive on quantitative PCR. Id. at 145, 219-20. She stated that "[w]ithout other signs of inflammatory myositis [] viral myositis is the most likely diagnosis." Id. at 145.

On December 24, 2016, Petitioner was seen by Dr. Elizabeth A. Lien, an infectious disease specialist. Pet. Ex. 5 at 146. She did not believe the etiology of Petitioner's illness was infectious and suspected a "muscle issue." Id.

The same day, a gastroenterology consult was performed by Dr. Abhishek Agarwal, who noted that Petitioner's CK had increased to 11,600. Pet. Ex. 5 at 98-99. AST and ALT were also

elevated, AST greater than ALT. Id. at 99. Liver sonogram showed patchy hepatic steatosis.[22] Id. Dr. Agarwal opined that elevation of liver enzymes was "likely secondary to muscle injury." Id. at 101. Dr. Agarwal observed that "mild elevation of AST/ALT can also be seen with hepatotropic virus such as CMV/EBV[,] but the AST should not be [three] times the ALT." Id. at 102.

Petitioner was transferred to University of Washington Medical Center ("UW") on December 25, 2016, where he remained hospitalized for one month. Pet. Ex. 4 at 135. Admission note by Dr. John Kyle Feller noted that Petitioner was transferred for a workup of "worsening diffuse muscle aches and weakness." Id. at 136. Petitioner reported that he had been "in his usual state of health until roughly [three] weeks ago when he began feeling 'crummy' with no specific symptoms he could pinpoint." Id. On December 12, "he went for a flu shot and routine labs and in the following days reported that his symptoms began to worsen." Id. He was then referred to the ED by his PCP where he was admitted at Good Samaritan Hospital, and subsequently transferred to UW for additional workup. Id. His labs on arrival to UW included elevated AST of 634, elevated ALT of 114, and elevated CK of 16,000. Id.

That day, Petitioner was seen by rheumatologists Dr. Percy Guanzon Balderia and Dr. Scott Pollock, who noted that Petitioner had "flu-like symptoms [two] weeks before onset of muscle pain and a[] [flu] vaccine [two] days before." Pet. Ex. 4 at 774. They noted his prior lab results including abnormal AST, ALT, and CK, as well as positive CMV IgM and IgG, and positive hepatitis C antibody with undetectable viral load. Id. Physical examination did not reveal abnormalities of the skin or nails. Id. at 775. Diagnosis was "acute myositis with rhabdomyolysis, differential include[d] viral myositis, necrotizing autoimmune myositis, toxic myositis (alcohol),[23] polymyositis, [and] inclusion-body myositis." Id. at 776. Additional labs and diagnostic studies, including muscle biopsy, were ordered. Id.

Labs reported on December 26, 2016 showed positive CMV IgM and IgG, and CMV on quantitative PCR. Pet. Ex. 4 at 1050. Antinuclear antibody ("ANA") was positive (1:80),[24] but

[22] Steatosis is a fatty change. Steatosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=47052 (last visited June 22, 2023). Hepatic refers to the liver. Hepatic, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=22172 (last visited June 22, 2023).

[23] Physicians noted that while Petitioner reported drinking alcohol daily, he "denied binge drinking and exposure to other medications that can cause myositis." Pet. Ex. 4 at 776. "Moreover, the urine drug screen . . . was negative." Id.

[24] ANAs are antibodies "found in the circulations of patients with various connective tissue disorders." Julius M. Cruse & Robert E. Lewis, Illustrated Dictionary of Immunology 65 (3rd ed. 2009).

other autoimmune markers were negative. Id. at 1052. Repeat myositis panel was negative, except for "borderline" anti-PM/SCL-100.[25] Id. at 1053, 1055.

Muscle biopsy done December 27, 2016 showed "myopathic changes" with "features suggestive of an inflammatory myopathy." Pet. Ex. 4 at 1059. The features that suggested an inflammatory myopathy included "patchy HLA-class-I upregulation and some macrophage and T-cell infiltrates . . . in addition to some patchy areas of perifascicular atrophy" that "can be seen in dermatomyositis or immune myopathy with perimysial pathology (IMPP)." Id. Because Petitioner had been on steroids, the "histological findings of an inflammatory/autoimmune process may [have] be attenuated." Id. The pathologists also discussed the "clinical concern of a CMV-mediated process," noting "at least one report . . . that CMV may propagate the inflammatory myopathies dermatomyositis and polymyositis."[26] Id. The pathologists noted there were "fewer reports of CMV-associated cases of rhabdomyolysis" as compared with flu, coxsackie virus, and herpes viruses. Id. "Overall, the muscle demonstrate[d] non-specific myopathic changes which may be related to inflammatory myopathy with possible etiologies including autoimmune[], viral[,] or other infectious processes." Id. An amended report was filed following the findings after toluidine blue staining. Id. at 1061-62. These "additional studies . . . include[d] mild, nonspecific changes." Id. at 1062.

Petitioner was seen by infectious disease physician Dr. Wayne Liles on December 28, 2016. Pet. Ex. 4 at 692. Dr. Liles noted that Petitioner's CMV PCR was positive, and there were "two possible explanations for this:" (1) "low level reactivation of a virus in the context of illness," and (2) "CMV viremia at a much higher level previously (possibly causing his myositis) and the infection [was then] in the process of resolving with low levels of virus." Id. Dr. Liles ordered that the CMV PCR be repeated. Id.

Steroids were administered for three days, followed by three days of intravenous immunoglobulin ("IVIG"), and then Petitioner began a "course of methotrexate[27] and

[25] Anti-PM/Scl autoantibodies are "[m]yositis-associated autoantibodies specific for the nuclear antigen PM/Scl found among many patients with overlap syndrome with features such as scleroderma and polymyositis/dermatomyositis." Illustrated Dictionary of Immunology at 67.

[26] The article referenced was filed as Resp. Ex. A, Tab 10 (Andreas E. R. Fasth et al., T Cell Infiltrates in the Muscles of Patients with Dermatomyositis and Polymyositis Are Dominated by CD28^{null} T Cells, 183 J. Immunology 4792 (2009)).

[27] Methotrexate is "a folic acid antagonist . . . used as an antineoplastic in treatment of a wide variety of malignancies . . . administered orally. It is also used as an antipsoriatic and antiarthritic." Methotrexate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30930 (last visited June 11, 2023).

rituximab"[28] on January 11, 2017. Pet. Ex. 4 at 136. A myositis antibody panel on January 10 did not reveal any abnormalities. Pet. Ex. 5 at 221-22.

During his hospitalization, Petitioner experienced acute left calf deep vein thrombosis; spontaneous retroperitoneal hematoma and thigh hematoma; factor XI deficiency[29] requiring extensive blood products for treatment; neuropathic pain that was improving; anasarca that resolved with treatment; acute blood loss resulting in anemia that was stable at time of discharge; and urinary retention that also resolved prior to discharge. Pet. Ex. 4 at 136-37; Pet. Ex. 5 at 496. Additionally, with treatment, Petitioner's CK trended downward, and on discharge was in the normal range. Pet. Ex. 4 at 136. On January 25, 2017, Petitioner was discharged to inpatient rehabilitation. Id. at 136-38; Pet. Ex. 5 at 494, 988. His discharge diagnosis was "autoimmune myositis, possibly [dermatomyositis] sine dermatitis."[30] Pet. Ex. 5 at 496; see also Pet. Ex. 4 at 136.

Petitioner received inpatient rehabilitation from January 25, 2017 until his discharge on February 12, 2017. Pet. Ex. 5 at 985. Discharge summary notes indicated that during admission, Petitioner had "episodic confusion." Id. Neuropsychological testing was done which showed "diffuse cognitive change[s]." Id. Labs showed normal CK throughout his stay. Id. At the time of discharge, he required "24/7 supervision and supervision for all mobility and [activities of daily living]." Id. at 986. He was able to walk with a walker for 250 feet but otherwise used a wheelchair for mobility. Id.

Petitioner saw Dr. Balderia (rheumatology) for follow-up on March 2, 2017. Pet. Ex. 4 at 93. Dr. Balderia noted that Petitioner was "now able to walk with a cane," but that he had "weakness of both lower extremities." Id. He was on prednisone 50 mg daily and tolerating his medications. Id. Diagnosis was "acute myositis complicated by rhabdomyolysis, likely autoimmune, biopsy consistent with dermatomyositis without associated typical skin findings."

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[28] Rituximab is "a chimeric murine/human monoclonal antibody . . . used as an antineoplastic in the treatment of CD20-positive, B-cell non-Hodgkin lymphoma; administered intravenously." Rituximab, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=43977 (last visited June 11, 2023).

[29] Factor XI deficiency is "an autosomal bleeding disorder caused by mutations in the F11 gene [], which encodes factor XI. It is characterized by reduced plasma factor XI levels, recurring episodes of minor bleeding and mild bruising, menorrhagia, severe prolonged postsurgical bleeding, and prolonged recalcification and partial thromboplastin times." Factor XI Deficiency, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=68742 (last visited June 11, 2023).

[30] Dermatomyositis sine dermatitis is a condition in which patients have all of the clinical criteria of dermatomyositis, with the exception of rash. Resp. Ex. A, Tab 4 at 5 tbl.25; see also Pet. Ex. 33 at 1; Resp. Ex. A, Tab 3 at 1 (Marc L. Miller, Diagnosis and Differential Diagnosis of Dermatomyositis and Polymyositis in Adults, UpToDate, https://www.uptodate.com/contents/diagnosis-and-differential-diagnosis-of-dermatomyositis-and-polymyositis-in-adults (last updated Dec. 20, 2017)).

Id. at 95. Petitioner was advised to have screening for colorectal cancer due to association of dermatomyositis with cancer.[31] Id.

On March 26, 2017, Petitioner saw neurologist Dr. Michael David Weiss in a consultation for evaluation and management of his weakness. Pet. Ex. 4 at 67. Petitioner reported that he had improved and was "now 80% of normal." Id. at 68. He had ongoing pain and weakness of his right thigh. Id. His family reported that Petitioner "ha[d] not quite been himself and can get confused." Id. His family attributed his confusion to the steroids. Id. Petitioner's gait was steady, and he used a cane. Id. at 69. He was noted to have "tangential and circumferential speech." Id. Dr. Weiss suspected that Petitioner had "acute autoimmune myopathy" although the cause was "unclear." Id. at 70. He stated he "[m]ay consider [] [flu] vaccine, though only rare case reports [were] found. Post-viral process may also be considered. However, [Petitioner] did not report a clear [history] of infection prior to onset of symptoms. Though did report that he did have general malaise." Id. "As etiology [was] unclear, [Dr. Weiss] plan[ned] on reviewing biopsy results with the neuropathologist on [March 31]."[32] Id. Prednisone taper was considered due to confusion and mood disturbances. Id.

An electrodiagnostic evaluation (electromyography ("EMG")) was performed by Dr. David A. Judish on May 11, 2017 for Petitioner's right thigh weakness and atrophy. Pet. Ex. 9 at 5. Dr. Judish's impressions were "severe right femoral neuropathy," and "possible right lumbosacral radiculopathy," which could be "associated with his prior chronic low back pain," with "no [] evidence of myopathy." Id. at 7. Dr. Judish recommend a "trial of bracing" for his right thigh weakness. Id. at 13. Dr. Judish also recommended that Petitioner follow up with Dr. Weiss at UW for "continued diagnostic input." Id.

Petitioner was seen by Dr. Ingeborg Sacksen at the UW rheumatology clinic on June 28, 2017 for follow-up. Pet. Ex. 4 at 32-33. He remained on methotrexate 15 mg weekly and prednisone 5 mg daily. Id. He had undergone an EMG which showed "right femoral neuropathy," and was otherwise doing well. Id. Physical examination revealed that Petitioner was "comfortable appearing" and in "no apparent distress." Id. at 34. He had "no tender or swollen joints." Id. He did have "right quadriceps [] atrophy with mild edema." Id. Neurological examination revealed that Petitioner was "alert and oriented," and that he had normal strength in his upper extremities and lower extremities, except for right knee extension, which was 2/5. Id. at 34-35. He also had "diminished sensation to light tough bilateral lower extremities." Id. at 35. Dr. Sacksen diagnosed Petitioner with "autoimmune myopathy, most likely [dermatomyositis]." Id. at 37. He noted that Petitioner had experienced significant improvement since his earlier hospitalizations, and the plan was to continue the current regimen of methotrexate and to continue the taper of prednisone. Id. at 38. Petitioner was also referred to physiatry for his persistent right leg weakness. Id.

[31] Records dated December 5, 2017 reference that Petitioner had a prior colonoscopy (one year ago), but the results were not noted. Pet. Ex. 48 at 15.

[32] There does not appear to be a note in the record reporting on any review with the neuropathologist on March 31, 2017.

On December 5, 2017, Petitioner returned to Dr. Sacksen for follow-up of his "inflammatory myopathy." Pet. Ex. 48 at 14. Physical examination revealed that Petitioner had a "moderate sized effusion of the right knee," with "mild [] laxity of the right lateral collateral ligament [and] pain on the medical joint line." Id. at 17. He also had "atrophy of the right thigh." Id. CK was normal at 98. Id. at 18. Impression was "inflammatory autoimmune myopathy." Id. Petitioner was on methotrexate, but due to his "heavy alcohol use," it was recommended that he transitioned to azathioprine. Id. at 18.

Thereafter, the records show visits from May through October 2018 (Holistic Health Clinic Medical Records), which are difficult to read. Pet. Ex. 47 at 37-59. The note from August 7, 2018 reflects that Petitioner continued to have problems with his right thigh and knee, but he did not have pain, was very active, trimming trees, doing yard work, and "always moving." Id. at 47. The physician signature was illegible. See id. at 48.

On September 30, 2019, Petitioner presented to Holistic Health Clinic complaining of low back pain that improved with stretching. Pet. Ex. 48 at 66. Physical therapy was discussed. Id. He returned on February 12, 2020, complaining of shortness of breath with exertion for the past six to eight months. Id. at 71. He also reported a cough for the past three months. Id. He was active, "remodeling house," mowing his yard, walking stairs, jumping rope, and walking. Id. Mild wheezing was noted in the left upper lobe of the lung. Id. at 73. Chest x-ray was normal with no acute findings. Id. at 79.

Records from August 27, 2020 noted Petitioner's energy level was "getting better," and he continued to exercise by doing yardwork and landscaping. Pet. Ex. 48 at 81. Petitioner had donated blood twice since February 2020. Id. On October 14, 2020, Petitioner again reported shortness of breath, and he also reported right ear pain, nasal stuffiness, sneezing, and watery itchy eyes. Id. at 89. There is also a reference to swelling in the leg. Id.

No additional records have been filed.

D. Declarations

1. Petitioner

Petitioner executed declarations in September 2017 and March 2021. Pet. Exs. 1, 46. Petitioner recalled being "in a state of good health" prior to December 12, 2016. Pet. Ex. 1 at ¶ 3. He said he had a physical that day and the doctor described him as a "well man." Id. That same day, he "had a flu shot and [his] life changed." Pet. Ex. 46 at 1. "Within a few days after the vaccination, [he] began feeling unusual pain in [his] joints and suffered from fatigue." Pet. Ex. 1 at ¶ 5. His "legs seemed weaker and [he] began having some numbness and tingling with pain in [his] legs, but also to a lesser degree in [his] arms. [He] was having trouble getting up from a chair and trouble walking." Id.

On December 16, 2016, he went to Good Samaritan Hospital and was later transferred to UW. Pet. Ex. 1 at ¶ 7. While at UW, he "was told that the flu shot had caused [his] muscles to

react and that some of the muscle tissue was dead and/or dying, which was what was causing the pain and weakness." Id. at ¶ 8.

2. Sandy McDaniel

Petitioner's wife, Mrs. McDaniel, executed a declaration in March 2021. Pet. Ex. 47 at 2. Prior to Petitioner's vaccination, Mrs. McDaniel described him as "a champion for his health" and "very active." Id. at 1. She alleged Petitioner "never missed a physical" and "[kept] a record of any symptom that seemed out of the norm." Id. She also alleged "[h]e would get his blood work done prior to his appointment with the doctor so they could go over his notes and blood work." Id.

Mrs. McDaniel alleged Petitioner was "a healthy active man" that went for a physical on a Monday and got the flu shot while he was there. Pet. Ex. 47 at 1. By Wednesday, he was not feeling well and called the doctor and "told them that he thought he was having a reaction to the flu shot." Id. The doctors allegedly told him "it [was not] a live virus" and to take Tylenol and rest. Id. "By Friday[,] he could barely walk." Id. When he was admitted to Good Samaritan Hospital that same day, she recalled Petitioner being in "immense pain." Id.

According to Mrs. McDaniel, Petitioner was transferred to UW because "[t]hey couldn't figure out what was happening or what was wrong with him." Pet. Ex. 47 at 1. She "heard talk of . . . myositis of some type but no diagnosis." Id. "His urine just kept getting darker and darker and was told that he was losing muscle. He kept getting weaker and weaker with no diagnoses." Id. Even after Petitioner's biopsy came back, Mrs. McDaniel alleged "they didn't agree as to the [diagnosis]. [They] were told it was [d]ermatomyositis, but he never had any skin rash, the one symptom common to the disease." Id. She recalled they had "[n]eurologists disagree and state that they didn't agree with that [diagnosis], but they couldn't give us any other reason for his symptoms." Id. Mrs. McDaniel recalled Petitioner was "very confused and psychotic" during his hospitalization. Id. at 1-2.

Mrs. McDaniel questioned "how [] a perfectly healthy man go[es] in for his annual physical one day[,] and five days later, after a flu shot[,] ha[s] his life turned completely upside down." Pet. Ex. 47 at 2. It follows that she "[does not] understand how the government lawyers say [Petitioner] had pre-existing conditions prior to the flu shot." Id.

E. Expert Reports

1. Petitioner's Expert, Dr. Thomas M. Zizic[33]

a. Background and Qualifications

Dr. Zizic has "more than [] 35 years of "medical training, experience providing clinical care, and more than [] 15 years of full-time academic experience as a clinician, researcher and teacher." Pet. Ex. 10 at 1. Dr. Zizic earned his M.D. from Johns Hopkins University School of

[33] Petitioner submitted three expert reports by Dr. Zizic. Pet. Exs. 10, 32, 45.

Medicine ("Johns Hopkins"). Id.; Pet. Ex. 51 at 1. His internship, residency, and post-doctoral fellowship in rheumatology were all at Johns Hopkins. Pet. Ex. 10 at 1. He is currently an Associate Professor of Medicine and Physician at Johns Hopkins. Id.; Pet. Ex. 51 at 1. Dr. Zizic's research, which requires training and experience in rheumatology, toxicology, pharmacology, and epidemiology, includes topics such as "polymyalgia rheumatica, fibromyalgia, post-traumatic arthropathy, environmentally induced autoimmune disease, rheumatoid arthritis, polymyositis, vasculitis[,] and a variety of other diseases that have an immunologic basis." Pet. Ex. 10 at 1; see also Pet. Ex. 51 at 18-25. Dr. Zizic has published over 100 articles and abstracts in peer-reviewed journals as well as several chapters in medicine textbooks. Id.; Pet. Ex. 51 at 6-18.

b. Opinion

i. Diagnosis

In his first expert report, Dr. Zizic noted that after Petitioner was transferred to UW, he was diagnosed with inflammatory myopathy. Pet. Ex. 10 at 34. He also noted that Petitioner's muscle biopsy was most consistent with dermatomyositis, and that Petitioner was diagnosed with "dermatomyositis sine dermatitis." Id. In his initial expert report, Dr. Zizic usually referenced Petitioner's diagnosis as "dermatomyositis." See id. at 32-34.

In his second expert report, Dr. Zizic stated that he and Respondent's expert, Dr. Matloubian, "appear to agree that [Petitioner] suffered from an autoimmune inflammatory process (polymyositis/dermatomyositis)." Pet. Ex. 32 at 1, 3. In his last expert report, Dr. Zizic does not offer any further opinions as to Petitioner's diagnosis. See Pet. Ex. 45.

In summary, while Dr. Zizic used the word dermatomyositis, he opined that Petitioner had "an autoimmune inflammatory process (polymyositis/dermatomyositis)." Pet. Ex. 32 at 1, 3. He also acknowledged that the muscle biopsy was most consistent with dermatomyositis, and that Petitioner was diagnosed with "dermatomyositis sine dermatitis." Pet. Ex. 10 at 34. In his reports, there is no indication that Dr. Zizic's opinions as to causation turn on a specific characterization of Petitioner's diagnosis, other than autoimmune inflammatory myopathy (polymyositis/dermatomyositis).

ii. Onset

Prior to setting forth his opinions, in his first expert report, Dr. Zizic provided a comprehensive summary of the medical records. Pet. Ex. 10 at 3-27. In the summary, Dr. Zizic acknowledged that on December 1, 2016, Petitioner presented to his health care provider complaining of "fatigue, sore muscles, and chills for [one] month." Id. at 7. Petitioner also complained of arm and leg tingling, that he was "mentally foggy," had occasional chest pain, and had lost "a lot of his muscle tone." Id. Labs were significant for an elevated AST and ALT (55 and 57). Id. By December 16, Petitioner reported "difficulty getting up out of a chair," "weakness below the hips," and "difficulty walking." Id. at 8. CK was elevated at 674, and AST and ALT were also elevated. Id.

Dr. Zizic opined that "Petitioner developed dermatomyositis symptoms within 24 hours after the [flu] vaccination." Pet. Ex. 10 at 34. Dr. Zizic did not identify what these symptoms were or explain why he believed they constituted the onset of Petitioner's dermatomyositis.

Dr. Zizic disagreed with Dr. Matloubian that before vaccination, Petitioner had "pre-existing subclinical muscle disease" as evidenced by elevated AST and ALT. Pet. Ex. 32 at 3. In his second and third expert reports, Dr. Zizic devoted considerable time opining that to the extent that Petitioner's AST and ALT were elevated prior to vaccination, those elevations were due to pre-existing liver damage. Id. at 2-3, 8; Pet. Ex. 45 at 1. He opined that Petitioner's liver injury also caused problems with synthesizing albumin and prothrombin. Pet. Ex. 32 at 3. Dr. Zizic asserted that AST and ALT are "markers of liver injury." Id. at 4. He discussed the elevation of these enzymes, along with Petitioner's liver ultrasound results on April 5, 2018, which showed "patchy fatty liver or 'hepatic steatosis.'" Id. Dr. Zizic discussed all the relevant lab values (AST, ALT, GGT, albumin, and prothrombin) and provided a detailed summary of his opinions. Id. at 4-8. He concluded that Petitioner "had an abnormal and fatty liver manifesting as abnormal liver function in the production of albumin and prothrombin and hepatocellular damage with elevation of transaminases." Id. at 8.

In summary, Dr. Zizic opined that Petitioner had pre-existing liver disease, but he disagreed that Petitioner had pre-existing muscle disease prior to vaccination. Pet. Ex. 32 at 2-3, 8; Pet. Ex. 45 at 1. Instead, Dr. Zizic averred that Petitioner had liver damage that "proceeded and coincided with the polymyositis dermatomyositis which developed subsequent to the vaccination." Pet. Ex. 32 at 8.

iii. Althen Prong One

Regarding his medical theory of causation, Dr. Zizic opined that the flu vaccine "triggered activation of B and/or T lymphocytes through molecular mimicry, cross-priming, immune complex formation[,] or a combination of these," due to "genetic susceptibility, result[ing] in autoimmunity and the development of dermatomyositis." Pet. Ex. 10 at 34.

Relying on a paper published by Schattner,[34] Dr. Zizic set forth three conditions which must be met to "establish a role for viral vaccines in the subsequent development of autoimmune diseases." Pet. Ex. 10 at 28. These conditions are (1) viral infections "should be linked to autoimmunity," (2) a "mechanism or mechanisms whereby exposure to viral antigens [in infection or vaccination] leads to autoimmunity must be established," and (3) "evidence must be obtained that patients who have been vaccinated against viruses developed an autoimmune disease, bearing in mind that association alone does not necessarily indicate causality." Id. (quoting Pet. Ex. 11 at 7).

[34] Ami Schattner, Consequence of Coincidence? The Occurrence, Pathogenesis and Significance of Autoimmune Manifestations After Viral Vaccines, 23 Vaccine 3876 (2005).

Of interest, Schattner discussed her review of literature from 1966 through June 2004 that discussed vaccination and autoimmune illnesses. Pet. Ex. 11 at 1. She explained that "[w]henever controlled studies of autoimmunity following viral vaccines were undertaken, no evidence of an association was found." Id. Regarding the flu vaccine, Schattner noted that GBS was the most commonly reported illness. Id. She did not discuss immune-mediated myositis, polymyositis, or dermatomyositis.[35] Id. at 1-9. Schattner concluded that "very few patients [] develop some autoimmune diseases following viral vaccination." Id. at 1, 9. Schattner did not conclude that the flu vaccine met her criteria for establishing a role for "viral vaccines in the subsequent development of autoimmunity," with regard to polymyositis and/or dermatomyositis.[36] See id.

Dr. Zizic generally discussed how various viral and bacterial infections trigger autoimmune diseases. Pet. Ex. 10 at 28-29. Then he described how vaccinations may stimulate the immune system with respect to rheumatoid arthritis. Id. at 29-30.[37] Next, Dr. Zizic described the mechanism of molecular mimicry. Id. at 30. He explained it happens "at times [when] the body's immune system produces antibodies to infectious agents or vaccines that cross-react with self-molecules." Id. The "foreign molecule, or piece of the molecule such as a peptide, mimics a self-antigen such that the antibody to the foreign molecule (e.g., infectious agent or vaccine) also reacts to a self-antigen producing an autoantibody." Id. He further explained that after "immunologic tolerance" is broken, "self-antigens replace the initial inciting foreign antigen . . . and an autoimmune disease develops." Id.

An example of a molecular mimicry induced illness described by Dr. Zizic is acute rheumatic fever caused by antigens from the bacteria *beta Streptococcus*. Pet. Ex. 10 at 30. He also provided two examples of an autoimmune illness associated with vaccines including vaccine-induced arthritis, caused by the Lyme vaccine, and autoimmune vasculitis, which he opined is associated with the hepatitis B vaccine. Id.

After providing examples of autoimmune illnesses that he contended are associated with infections and vaccines, Dr. Zizic discussed the role of individual responses to vaccines as well as genetic predisposition and its role in the development of autoimmunity. Pet. Ex. 10 at 31. He explained that humans have an "immune repertoire of B and T cells that can consist of over 10

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[35] While myositis is listed in a table relevant to autoimmune manifestations after the flu vaccine, the number of cases is not provided. Pet. Ex. 11 at 5 tbl.4.

[36] Schattner also discussed adjuvants, such as thiomersal and aluminum, in vaccines, and the potential roles of these substances. Pet. Ex. 11 at 7. However, there is no evidence that the flu vaccine here contained either of these ingredients. Petitioner filed a hepatitis B vaccine manufacture's package insert. Pet. Ex. 23. However, Petitioner did not receive the hepatitis B vaccine. The flu package insert relevant to the vaccination given to Petitioner was not filed. Regardless, there is no evidence that the flu vaccine at issue contained thiomersal or aluminum.

[37] Dr. Zizic discussed a number of theories relevant to rheumatoid arthritis, but these opinions do not seem relevant here since Petitioner did not have that illness, so for the sake of brevity, these opinions are not discussed.

billion different B and T cell receptors." Id. Some people have a unique repertoire that leads to an "effective response to a vaccine," conferring protection. Id. Others, however, do not have an effective response, and they do not receive protection from vaccination. Id. Dr. Zizic attributed these different responses to "genetic predisposition." Id. And some individuals "have naïve or memory cells in their repertoire that cross-react with antigens in the [] vaccine . . . leading to cross-reactivity and molecular mimicry to self-antigens that then break tolerance to self . . . caus[ing] autoimmune disease." Id. Dr. Zizic provided an overview of how molecular mimicry is thought to trigger autoimmunity in rheumatoid arthritis. Id.

Dr. Zizic then turned to the topic of the association between vaccination and polymyositis/dermatomyositis. Pet. Ex. 10 at 32. Dr. Zizic asserted that there is "a large body of evidence including case reports and epidemiological evidence" supporting an association between these illnesses and vaccination. Id. He noted that these conditions are rare and the annual "incidence is approximately 2-7 cases per million." Id. He explained that the average age of onset is 50 years of age, and that the time frame between vaccination and disease onset is "24 hours to [two] months." Id. There are many mechanisms that he identified which may cause "post-vaccination autoimmunity against the skeletal muscle," including molecular mimicry.[38] Id.

In support of his opinions, Dr. Zizic cited several medical articles. The first is a literature review by Stübgen[39] about the "possible relationship between inflammatory myopathies and vaccines." Pet. Ex. 29 at 2. The review included publications from various databases as well as reports based on the Vaccine Adverse Event Reporting System ("VAERS")[40] database. Id. Stübgen identified case reports of polymyositis/dermatomyositis following vaccination, including cases that occurred following the flu vaccination. Id. at 2-3. Stübgen noted that case reports are anecdotal in nature, which "creates a potential for selection bias[] and provides only limited potential to establish casual effects. Therefore, these case reports . . . should not be interpreted as proof of cause[,] i.e., association does not equate to causation." Id. at 3. Stübgen also reviewed several retrospective studies, which showed that vaccinations "were not an important trigger for [dermatomyositis/polymyositis]." Id.

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[38] The other mechanisms identified by Dr. Zizic are "epitope[] spreading, bystander activation, release of cryptic epitopes, reactivation of memory T cells, activation of super antigens, direct inflammatory damage on the muscle, formation of immune complexes, expression of [major histocompatibility complex] antigens on non-immune cells[,] and patient genetic predisposition to autoimmunity." Pet. Ex. 10 at 32. He also referenced the role that adjuvants may play in causing autoimmune illnesses. Id. There is no evidence in this case, however, that the flu vaccine at issue contained an adjuvant.

[39] Joerg-Patrick Stübgen, A Review on the Association Between Inflammatory Myopathies and Vaccination, 13 Autoimmunity Rev. 31 (2014).

[40] VAERS is a "national early warning system to detect possible safety problems in [] vaccines." About VAERS, https://vaers.hhs.gov/about.html (last visited June 12, 2023). "VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events." Id.

Stübgen's review of VAERS reports did not show "evidence of an increase in the number of [dermatomyositis/polymyositis] cases observed and reported among the 43.3 million civilians immunized with the A/NJ/76 (swine flu) vaccine" administered in 1976 in the United States. Pet. Ex. 29 at 4. Additionally, there was "no increase in the incidence rate of [dermatomyositis/polymyositis]" in the "nearly [one] million vaccinated Army and Navy personnel" during that same period. Id. Further, "there was no indication of an increase in the number of [dermatomyositis/polymyositis] cases diagnosed at major medical institutions during or following the 1976 national immunization program." Id. at 4-5. Stübgen also searched the VAERS database through 2013, and while acknowledging the limitations of using VAERS data, concluded that it did "not establish epidemiological support for post-vaccination [dermatomyositis/polymyositis]." Id. at 6. Finally, Stübgen reviewed studies examining the effects of vaccination on patients with pre-existing dermatomyositis/polymyositis and concluded that flu vaccination was "safe and effective in adult patients with [dermatomyositis/polymyositis]."[41] Id.

Additionally, Dr. Zizic cited a paper by Ferri et al.,[42] presenting three case reports of inflammatory myopathies after the 2009-2010 seasonal flu vaccine season in Italy. Pet. Ex. 30 at 1. In two cases there was "interstitial lung disease." Id. at 2. In a third case, the patient had skin involvement, and initially a "good response" to treatment, but after 40 days, succumbed to EBV-related pneumonia. Id. The authors noted that the association between vaccination and illness "may be coincidental; however, it is supposable that vaccine-related viral antigens and/or adjuvants might play a triggering role . . . possibly in genetically predisposed subjects . . . in keeping with [] clinical observations suggesting a possible link between myopathies and infectious triggering agents." Id. at 2-3.

iv. Althen Prong Two

Dr. Zizic summarized Petitioner's clinical course prior to turning to his specific opinions as to Prong Two. Pet. Ex. 10 at 33-34. He acknowledged that Petitioner saw his physician on December 1, 2016 for "a viral syndrome with fatigue, sore muscles[,] and chills." Id. at 33. Petitioner also had some "tingling and numbness in his arms," however, Dr. Zizic noted that Petitioner's neurological exam was normal, and "his strength [was] intact." Id. Dr. Zizic also acknowledged that on December 12, 2016, Petitioner's lab studies "were notable for elevated

[41] In the concluding section in Stübgen, the author stated that "[t]he phenomenon of post-vaccination [inflammatory myopathies] likely exists, but the occurrence is rare." Pet. Ex. 29 at 7. The basis of this statement is unclear given the conclusions that Stübgen reached regarding each subsection of the article, as summarized in this paragraph, essentially finding no evidence of an increase in dermatomyositis/polymyositis cases following vaccination. Moreover, the undersigned notes that Respondent asserted that Table 3 in Stübgen is confusing, because it is not clear how many patients are included. See Resp. Response at 27-28; Pet. Ex. 39 at 8-10 tbl.3. The undersigned agrees.

[42] Clodoveo Ferri et al., Polymyositis Following Pandemic Influenza A (H1N1) and 2009-10 Seasonal Trivalent Vaccines, 2012 Case Reps. Rheumatology 836930.

AST and ALT at 63 and 73[,] respectively." Id. The flu vaccination at issue was administered to Petitioner at that visit. Id. On the evening of receiving the flu shot, Petitioner "developed some bilateral shoulder pain, and some weakness in his upper extremities." Id. Dr. Zizic summarized Petitioner's course over the subsequent weeks, describing his progressive weakness, paresthesias, difficulty getting out of bed, and walking. Id. He also noted Petitioner's progressively abnormal labs, including increasingly abnormal AST, ALT, and CK. Id. at 33. Dr. Zizic completed his summary by discussing Petitioner's muscle biopsy and transfer to UW, his diagnosis, and treatment for myositis. Id. at 33-34.

After summarizing Petitioner's clinical course, Dr. Zizic opined that Petitioner "did not have any persistent rheumatic symptoms prior to vaccination." Pet. Ex. 10 at 34. Dr. Zizic attributed Petitioner's "aches and pain" to "cervical spondylosis."[43] Id. Dr. Zizic concluded that "there is nothing in the medical records to support any pre-existing autoimmune disease, nor any inflammatory form of arthritis, nor anything to suggest inflammatory muscle disease." Id. He therefore concluded that "this is a logical sequence of cause (the [flu] vaccine was the only perturbation to his immune system around the time of illness onset) and the effect (the development of dermatomyositis). There is an absence of any other good explanation for a triggering event." Id.

In his second and third expert reports, Dr. Zizic opined that Petitioner's elevated AST and ALT enzymes pre-vaccination were not evidence of pre-existing myopathy, but instead evidence that Petitioner had "an abnormal and fatty liver manifesting as abnormal liver function in the production of albumin and prothrombin and hepatocellular damage with elevation of transaminases." Pet. Ex. 32 at 8. He agreed that AST, ALT, and CK are all "muscle enzymes that may be elevated in patients with inflammatory myopathy." Id. at 1. However, he maintained that ALT was a "relatively specific indicatory of liver cell damage." Id. at 2. Dr. Zizic also explained that CK is specific to muscle, and therefore, it is the "most useful serum enzyme for diagnosis" of patients with inflammatory myopathies. Id.

Dr. Zizic then explained that albumin levels can be affected by liver damage. Pet. Ex. 32 at 3. He opined that Petitioner's low albumin levels on December 25, 2016 indicated liver damage. Id. Additionally, on January 3, 2017, Petitioner had an abnormally prolonged prothrombin time, which Dr. Zizic also attributed to liver injury. Id. These abnormalities, and the finding of a fatty liver on sonogram suggested to Dr. Zizic that Petitioner had liver injury. Id. Dr. Zizic provided a thorough description of these blood tests and cited medical articles to support his opinions. Id. at 4-7. He also defined GGT, and cited literature noting GGT should be used to distinguish whether the liver was the cause for elevated enzyme levels (AST and ALT), particularly if there is a suspicion of alcohol abuse. Id. at 4, 6. After a discussion of liver disease, Dr. Zizic concluded that Petitioner's elevated AST and ALT before vaccine administration was "classic[] for liver disease." Id. at 7. And he opined that the specific values

[43] During his hospitalization, Petitioner had an MRI of his cervical spine due to his history of weakness. Pet. Ex. 5 at 184-85. The study showed "multilevel degenerative disc disease . . . [a]t most mild central canal stenosis at C5-6 . . . [and] [a]t most mild neural foraminal stenosis at multiple levels." Id. at 185. There is no indication in Petitioner's records that his physicians attributed his weakness to these findings.

and relationships between AST and ALT were also reflective of liver injury. Id. Dr. Zizic opined that the Petitioner's albumin and prothrombin abnormalities reflected abnormal liver function. Id. at 8.[44] In conclusion, Dr. Zizic averred that Petitioner had abnormal liver function which "proceeded and coincided with the polymyositis dermatomyositis which developed subsequent to the vaccination." Id.

v. Althen Prong Three

Dr. Zizic opined that Petitioner "developed dermatomyositis symptoms within 24 hours after the [flu] vaccination." Pet. Ex. 10 at 34. Dr. Zizic did not identify what these symptoms were or why he believed they constituted the onset of Petitioner's illness.

Dr. Zizic did not discuss or explain how his alleged causal mechanism of molecular mimicry can cause onset of immune-mediated myositis within 24 hours of vaccination. He only stated that development of dermatomyositis "within 24 hours after the [flu] vaccination . . . is in the timeline that was described . . . by Stübgen for an inflammatory myopathy after a vaccination." Pet. Ex. 10 at 34.

2. Respondent's Expert, Dr. Mehrdad Matloubian[45]

a. Background and Qualifications

Dr. Matloubian is a "physician-scientist with basic science training in virology and immunology and clinical training in adult rheumatology." Resp. Ex. A at 1. He is board-certified in rheumatology and internal medicine. Id.; Resp. Ex. B at 1-2. He received his M.D. as well as a Ph.D in virology/immunology from University of California, Los Angeles. Resp. Ex. A at 1; Resp. Ex. B at 1. He is currently an Associate Adjunct Professor at the University of California, San Francisco, School of Medicine. Resp. Ex. B at 1. Dr. Matloubian's research for the past 20 years has been focused on "innate and adaptive immune responses, including those of T and B cells, to acute and chronic viral infections." Res. Ex. A at 1. He has published numerous peer-reviewed articles in these areas. Id.; Resp. Ex. B at 10-13. As an immunologist and board-certified rheumatologist who actively evaluates and treats patients, Dr. Matloubian is qualified to address both diagnostic and immunological issues regarding "complex autoimmune" diseases. Resp. Ex. A at 1.

b. Opinion

i. Diagnosis

Regarding diagnosis, Dr. Matloubian opined that Petitioner's presentation of "progressive muscle weakness affecting proximal muscle groups more than distal ones," along with "elevated

[44] For Dr. Zizic's specific enumerated points regarding the lab values and his opinions about them, see Pet. Ex. 32 at 7-8.

[45] Respondent submitted two expert reports by Dr. Matloubian. Resp. Exs. A, C.

muscle enzymes (CK, AST, and ALT)," were "consistent with a myopathy but not necessarily a myositis (inflammatory muscle disease)." Resp. Ex. A at 10. Petitioner's MRI, however, was "consistent with myositis involving diffuse muscle groups." Id. Muscle biopsy pathology showed "non-specific inflammatory changes consistent with a myositis rather than myopathy." Id. And the pathologists who interpreted the biopsy "opined that the observed changes could be due to an 'autoimmune (dermatomyositis . . .) viral or other infectious process.'" Id. (quoting Pet. Ex. 4 at 1059). Thus, Petitioner's treating physicians concluded that he had an "immune-mediated myopathy" that was "difficult to further classify." Id. (quoting Pet. Ex. 4 at 74).

Dr. Matloubian opined that Petitioner's response to "immunosuppressive therapy with normalization of his muscle enzymes and improvement of his muscle strength confirm[ed] an immune mediated pathologic process." Resp. Ex. A at 10. However, Dr. Matloubian explained that Petitioner's response to treatment "does not distinguish between an autoimmune response and an immune-mediated response directed against an infectious agent, such as a virus."[46] Id.

Dr. Matloubian agreed with Petitioner's physicians, that Petitioner had an "immune mediated myopathy" that was "difficult to classify." Resp. Ex. A at 10 (citing Pet. Ex. 4 at 74). More specifically, Dr. Matloubian opined that Petitioner "most likely had either dermatomyositis sine dermatitis or an infection-associated immune mediated myopathy." Id. "Dermatomyositis is an autoimmune disease that typically affects the muscles and the skin with a characteristic rash. However, as the term 'sine dermatitis' indicates, in some cases the muscle disease can exit without any skin disease." Id.

ii. Onset

Dr. Matloubian opined that Petitioner's muscle disease began before his vaccination on December 12, 2016. Resp. Ex. C at 1. He based this opinion on his review of the medical records, including Petitioner's pre-vaccination elevated AST and ALT, and the fact that Petitioner's treating physicians did not attribute his elevated enzymes to liver disease, or diagnose him with or treat him for liver disease. Id.

First, Dr. Matloubian reviewed the relevant entries in the medical records that formed the basis of his opinions as to onset. Resp. Ex. A at 10-13. The records establish that Petitioner presented to his physician on December 1, 2016, about two weeks before his flu vaccination,

[46] An autoimmune response is "an immune response against an autoantigen." Autoimmune Response, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=103673 (last visited June 14, 2023). An immune response is "any response of the immune system to an antigenic stimulus, including antibody production, cell-mediated immunity, and immunologic tolerance." Immune Response, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=103684 (last visited June 14, 2023). "Immune response may follow simulation by a wide variety of agents." Illustrated Dictionary of Immunology at 358.

complaining of "fatigue, sore muscles, [and] chills" for about one month.[47] Id. at 10 (quoting Pet. Ex. 2 at 50). At that visit, Petitioner also complained of "numbness/tingling" and that "he [was] losing a lot of his muscle tone." Id. (quoting Pet. Ex. 2 at 50).

Next, Dr. Matloubian cited record entries documenting instances where Petitioner related the onset of his illness back in time, prior to vaccination on December 12, 2016. Resp. Ex. A at 10-11. For example, after Petitioner was hospitalized, an assessment note written by Helen Ward, LICSW, on December 19, 2016, stated that "[Petitioner] pointed out that although he doesn't think he was sick when he got his flu shot, he thinks he was 'fighting something off' that could have contributed to the symptoms he experienced after the shot and has been 'losing some muscle strength for a while.'" Id. at 10 (quoting Pet. Ex. 5 at 268).

Moving forward, on December 25, 2016, Dr. Feller documented that Petitioner reported being "in his usual state of health until roughly [three] weeks ago when he began feeling 'crummy' with no specific symptoms he could pinpoint." Resp. Ex. A at 10 (quoting Pet. Ex. 4 at 263). Dr. Matloubian opined that this note places onset on approximately December 4, 2016, eight days prior to vaccination. Id.

Then, on January 8, 2017, it was documented that Petitioner "was feeling well until a few weeks before his initial presentation to Good Sam[aritan], when he developed generalized malaise ('feeling crumby')."[48] Resp. Ex. A at 10 (quoting Pet. Ex. at 431). Dr. Matloubian opined that based on this note, Petitioner's symptoms preceded the flu shot he received on December 12 "and were progressive." Id.

Dr. Matloubian explained that this history from Petitioner, reported to his physicians and other health care providers, shows that Petitioner reported "muscle aches and progressive loss of muscle tone" as early as December 1, 2016 and admitted that he was "losing muscle strength" before his flu vaccine on December 12, 2016, "consistent with the expected clinical course for inflammatory myopathies, where muscle weakness as the presenting symptom evolves over weeks to months." Resp. Ex. A at 10-11. Thus, Dr. Matloubian opined that Petitioner's symptoms "most likely" began before December 1, 2016, and progressed to "clinically apparent weakness that led to his hospitalization" on December 16, 2016. Id. at 11.

In support of his opinion, Dr. Matloubian cited a book chapter by Mammen about dermatomyositis and polymyositis, which provides that "[s]ymmetric proximal muscle weakness evolving over weeks to months is the presenting symptom in most patients." Resp. Ex. A, Tab 2 at 2. According to Dr. Matloubian, it was not surprising that Petitioner did not have "difficulty with tasks, such as getting up or going up stairs until around [December 14, 2016] . . . since a great amount of muscle mass needs to be damaged and lost before the affected individual becomes overtly symptomatic and debilitated." Resp. Ex. A at 10. Further, he explained that "subtle loss of strength" may not be observed by an examining physician, particularly where weakness evolves "over weeks to months." Id. at 10-11.

[47] This note would place onset on November 1, 2016.

[48] Petitioner was admitted to Good Samaritan on December 16, 2016.

In addition to muscle weakness, Dr. Matloubian opined that there was "objective evidence" in the form of lab results which also provide evidence that onset preceded vaccination. Resp. Ex. A at 11. In his report, Dr. Matloubian provided the following table:

Date	AST (10-35)	ALT (9-46)	CK (0-200)	GGT (8-78)	Citation
9/12/2014	22	16	Not Done	Not Done	Ex. 2 at 147
12/4/2015	22	21	Not Done	Not Done	Ex. 2 at 143
12/1/2016	55	57	Not Done	Not Done	Ex. 2 at 140
12/12/2016	63	73	Not Done	Not Done	Ex. 2 at 138
12/16/2016	76	73	674	Not Done	Ex. 5 at 111
12/24/2016	493	114	11678	60	Ex. 5 at 211-213
1/27/2017	33	47	81	Not Done	Ex. 5 at 1175

Id. at 11 tbl.1.

The table above shows that Petitioner's AST and ALT were elevated on December 1 and December 12, prior to administration of the flu vaccination. Resp. Ex. A at 11 tbl.1. Since Petitioner's AST and ALT were abnormal before vaccination, Dr. Matloubian opined that Petitioner's "muscle disease began before [his] immunization and was not caused by it." Id. at 12.

According to Dr. Matloubian, AST and ALT are traditionally considered to be "liver enzymes," but they are also "muscle enzymes" since they are "released from damaged muscle and elevated levels are often, but not always, found in patients with autoimmune myopathy." Resp. Ex. A at 11. He further stated that "this may lead to confusion in some clinical situations" and trigger a workup for a possible underlying liver etiology, like it did in Petitioner's situation. Id. Dr. Matloubian again cited Mammen who wrote that "[n]ot infrequently, elevated AST and ALT levels are misinterpreted as evidence of liver disease in patients with myopathy." Resp. Ex. A, Tab 2 at 4. To determine whether elevation of these enzymes is due to muscle or liver damage, a serum GGT level can be measured; "GGT is usually released along with AST and ALT in liver disease but not from damaged muscle." Id.

Petitioner's GGT was normal on December 24, 2016 (60; normal range of 8-78), indicating that his elevated enzymes were due to muscle injury and not liver disease. Resp. Ex. A at 11 (citing Pet. Ex. 5 at 211-13). Dr. Matloubian also referenced a note by gastroenterologist Dr. Agarwal, who wrote that Petitioner's "[l]iver enzyme elevations [were] likely secondary to muscle injury. They should start improving when ongoing muscle injury stops." Id. (quoting Pet. Ex. 5 at 101). This note appears to indicate that Dr. Agarwal believed that Petitioner's elevated AST and ALT were caused by muscle injury and not liver damage.

Dr. Matloubian disagreed with Dr. Zizic that Petitioner's elevated AST and ALT indicated liver disease. Resp. Ex. C at 2. While Dr. Matloubian agreed generally that ALT is "more liver-specific than AST," he cited medical literature in support of the proposition that

"ALT should not be considered as liver specific, as elevation of serum values can also be seen in other clinical conditions, mainly, skeletal muscle injury due to inflammatory . . . conditions." Id. (citing Pet. Ex. 37 at 2).[49]

In response to Dr. Zizic's assertions that Petitioner's increase in AST and ALT levels prior to vaccination reflected liver disease and was not attributable to his myositis or muscle injury, Dr. Matloubian provided a thorough explanation of the relevant lab studies, including albumin and prothrombin time, and detailed opinions. Resp. Ex. C at 2-4. He concluded that based on the medical records, lab results, and clinical course, Petitioner's low albumin level, "which coincided with the peak of his muscle disease and normalized as his muscle disease resolved, was most likely due to his inflammatory condition rather than a liver injury as alleged by Dr. Zizic." Id. at 3-4. Moreover, Dr. Matloubian emphasized that Dr. Agarwal did not diagnose Petitioner with any illness that caused liver damage. See id. at 3; Resp. Ex. A at 4, 11.

Dr. Zizic opined that Petitioner's prothrombin was decreased on January 3, 2017, due to liver injury. Resp. Ex. C at 4 (citing Pet. Ex. 32 at 8). Dr. Matloubian took issue with this opinion because "prolonged prothrombin time is not specific for liver disease," but can occur for many different reasons, including as a side effect from medications, gastrointestinal bleeding, or problems with clotting factors. Id. Dr. Matloubian explained that when Petitioner's prothrombin time was drawn and reported on January 3, he had a retroperitoneal hematoma due to bleeding. Id. After treatment with vitamin K, repeat testing on January 4 and 5, showed a normal prothrombin time. Id. (citing Pet. Ex. 4 at 1031-33). Further, Petitioner's previous prothrombin times from December 25 through December 28 were normal. Id. (citing Pet. Ex. 4 at 1046-54). Additionally, Petitioner did not have cirrhosis which can cause an abnormal prothrombin time and a low albumin level. Id. at 5. Dr. Matloubian concluded that Petitioner's "transiently elevated prothrombin [level] . . . in the setting of acute retroperitoneal bleeding . . . corrected with vitamin K," was not a reflection of liver disease, as asserted by Dr. Zizic. Id. at 4.

In support, Dr. Matloubian cited an article by Friedman,[50] which stated that a "prolonged prothrombin time is not specific for liver disease," since it may occur due to "consumption of clotting factors" caused by severe bleeding. Resp. Ex. C, Tab 1 at 4. Prolonged prothrombin time can also reflect vitamin K deficiency. Id. When bleeding is the cause, once treated, "the prothrombin time typically returns to normal within 24 hours." Id.

Dr. Matloubian also disagreed with Dr. Zizic's assertion that Petitioner's elevated AST and ALT levels were caused by "nonalcoholic fatty liver disease suggested by steatosis on

[49] Hamed A. Shabaneh Al-Tamimi & Rebecca McDonald, Elevated Alanine Aminotransferase Levels Associated With Polymyositis: Can This Be Due to Muscle Injury?, 14 J. Clinical Rheumatology 363 (2008).

[50] Lawrence S. Friedman, Tests of the Liver's Biosynthetic Capacity (eg, Albumin, Coagulation Factors, Prothrombin Time), UpToDate, https://www.uptodate.com/contents/tests-of-the-livers-biosynthetic-capacity-eg-albumin-coagulation-factors-prothrombin-time (last updated Sept. 4, 2018).

imaging."[51] Resp. Ex. C at 4 (citing Pet. Ex. 32 at 5). Dr. Matloubian cited medical literature which explained that patients with fatty liver disease may have normal AST and ALT levels, but if elevated, these enzymes are "typically two to five times the upper limit of normal." Id. (quoting Resp. Ex. C, Tab 2 at 5).[52] Because Petitioner's levels did not meet this standard, Dr. Matloubian opined that they were not characteristic of nonalcoholic fatty liver disease. Id. In addition, Petitioner was not treated for nonalcoholic fatty liver disease. Id. at 5.

Lastly, Dr. Matloubian observed that during Petitioner's month-long hospitalization, he was seen by different specialists, including gastroenterologists and hematologists, but was never diagnosed with liver disease. Resp. Ex. C at 5. Instead, his physicians attributed his abnormal AST and ALT to muscle injury. Id. And several health care providers documented that Petitioner reported symptoms prior to vaccination. Id. Petitioner's elevated enzymes, which were abnormal before vaccination, "normalized when his muscle disease was treated, indicating that they were due to his muscle disease and not an underlying liver disease." Id. Petitioner's decreased albumin level was not inconsistent with his inflammatory muscle disease, and his elevated prothrombin level occurred "in the context of severe bleeding" and normalized after "administration of vitamin K." Id. Thus, Dr. Matloubian opined that Petitioner's elevated AST and ALT were "most likely due to muscle inflammation since they completely resolved when his muscle disease was treated." Id. at 1.

In summary, Dr. Matloubian concluded that Petitioner had abnormally elevated muscle enzymes and weakness consistent with pre-existing subclinical dermatomyositis on December 1, 2016, prior to his vaccination. Resp. Ex. C at 5.

iii. Althen Prong One

The three criteria described by Schattner, and cited by Dr. Zizic, were used by Dr. Matloubian as a framework for discussing whether the flu vaccine can cause an immune-mediated myositis/dermatomyositis. Resp. Ex. A at 17.

Addressing the first criteria, that viral infections should be linked to autoimmunity, Dr. Matloubian acknowledged that flu infections have been associated viral myositis, but the pathogenesis is not attributed to an autoimmune mechanism. Resp. Ex. A at 17. Instead, viral myositis is thought to be caused by "direct infection and destruction of muscle cells by the [flu]

[51] "Nonalcoholic fatty liver disease . . . is the most common liver disorder in Western industrialized countries, where the major risk factors" include "obesity, type 2 diabetes mellitus, dyslipidemia, and metabolic syndrome." Resp. Ex. C, Tab 2 at 2. For additional information, see Resp. Ex. C, Tab 3.

[52] Sunil G. Sheth & Sanjiv Chopra, Epidemiology, Clinical Features, and Diagnosis of Nonalcoholic Fatty Liver Disease in Adults, UpToDate, https://www.uptodate.com/contents/epidemiology-clinical-features-and-diagnosis-of-nonalcoholic-fatty-liver-disease-in-adults (last updated Apr. 3, 2018).

virus." Id. In support of this opinion, Dr. Matloubian cited a paper by Desdouits et al.,[53] a study finding evidence that the etiology is due to direct infection of the muscles by the virus. Resp. Ex. A, Tab 11 at 1.[54] Also, Dr. Matloubian posited that in contrast to autoimmune myositis, viral myositis is "a self-limited disease that resolves on its own and does not require immunosuppressive therapy." Resp. Ex. A at 17.

Regarding autoimmune mechanisms, Dr Matloubian was not aware of any form of "autoimmune myositis occurring after a[] [flu] virus infection," and to his knowledge, it "has not been described in the medical literature." Resp. Ex. A at 17. "Since the [flu] vaccine . . . [is] an inactivated [] [flu] vaccine, it is biologically impossible for it to . . . infect and cause muscle damage in a manner analogous to [flu] virus infection." Id. Dr. Matloubian opined that "[s]ince an autoimmune inflammatory myositis is not known to occur after a[] [flu] infection, it is unlikely that a[] [flu] vaccine containing the same antigens would lead to [the disease] through the proposed mechanisms, such as molecular mimicry." Id. at 15. Thus, Dr. Matloubian concluded that because the flu virus is not known to cause an autoimmune myositis/dermatomyositis, the first Schattner criteria was not met here. Id. at 15-18.

The second Schattner criteria is a "mechanism or mechanisms whereby exposure to viral antigens (be it during infection or vaccination) leads to autoimmunity must be established." Pet. Ex. 11 at 7. Dr. Matloubian provided a brief overview of molecular mimicry and described it as "either sequence or structural similarity between a pathogen and self-molecule. When this occurs, T or B cell responses directed at the pathogen will then cross-react with similar self-antigens and cause damage to the host's tissues." Resp. Ex. A at 18. He explained that B cells "make antibodies specific for one molecular pattern, either linear or three-dimensional," and that "[i]n contrast, T cells only detect small linear pieces of proteins in the context of [human leukocyte antigens ("HLA")][55] molecules." Id. "Each HLA molecule follows specific rules based on its structure for what peptides (linear pieces of protein) it can present to T cells. Many autoimmune diseases are associated with a specific HLA molecule." Id. As an example, Dr. Matloubian noted that the autoimmune illness ankylosing spondylitis is associated with HLA-B27. Id.

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[53] Marion Desdouits et al., Productive Infection of Human Skeletal Muscle Cells by Pandemic and Seasonal Influenza A(H1N1) Viruses, 8 PLoS ONE e79628 (2013).

[54] In another paper cited by Dr. Matloubian, however, the "possibility" of "autoimmune myositis resulting from a viral infection" was briefly discussed, albeit as a "possibility." Resp. Ex. A, Tab 9 at 2 (Michael D. Nauss et al., Viral Myositis Leading to Rhabdomyolysis: A Case Report and Literature Review, 27 Am. J. Emergency Med. 372.e5 (2009)).

[55] HLAs are "histocompatibility antigens governed by genes of the HLA complex (the human major histocompatibility complex), a region on the short arm of chromosome 6 containing several genetic loci, each having multiple alleles. . . . The A, B, C, and DR antigens are defined and typed by serologic reactions. The D antigens are defined and typed by one-way mixed lymphocyte culture (MLC) using panels of HLA-D-homozygous typing cells." Human Leukocyte Antigens, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com /dorland/definition?id=56923 (last visited June 13, 2023).

For the mechanism of molecular mimicry to occur with B cells, "specific antibodies produced by that cell against a pathogen-associated structure must also detect a similar structure on [] cells and tissues." Resp. Ex. A at 18. For a T cell immune-mediated illness, "the same T cells that are generated against a specific pathogen-drive peptide seen in the context of an HLA molecule also have to see peptides derived from a self-protein in the context of that same HLA." Id.

Given this background, Dr. Matloubian opined that Dr. Zizic did "not provide[] any evidence to suggest the existence of molecular mimicry between antigenic components of the [flu] vaccine and those of muscles as the basis for how the vaccine could cause muscle injury." Resp. Ex. A at 18. According to Dr. Matloubian, the references by Dr. Zizic to support molecular mimicry are not relevant to either rheumatoid arthritis or myositis. Id. at 19.

Dr. Matloubian also discussed Dr. Zizic's references to the hepatitis B infection and its association with vasculitis, which was referenced as an autoimmune illness. Resp. Ex. A at 19; (citing Pet. Ex. 10 at 29-30). Dr. Matloubian opined that the mechanism by which hepatitis B infections cause vasculitis is not molecular mimicry, but instead is "thought to be due to deposition of immune complexes containing the hepatitis B viral antigens and antibodies against them in vessel walls leading to inflammation and destruction." Id.

In summary, regarding the second Schattner criteria, Dr. Matloubian opined that Dr. Zizic failed to provide "any scientific evidence to support molecular mimicry between the [flu] virus or vaccine and development of an immune mediated myositis, such as dermatomyositis." Resp. Ex. A at 16.

The third Schattner criteria is that "evidence must be obtained that patients who have been vaccinated against viruses developed an autoimmune disease, bearing in mind that association alone does not necessarily indicate causality." Pet. Ex. 11 at 7. To analyze this criteria, Dr. Matloubian reviewed the two articles cited by Dr. Zizic to support an association between vaccination and autoimmune myositis, specifically the articles by Stübgen and Ferri et al. Resp. Ex. A at 17-18; Pet. Exs. 29-30. Regarding Stübgen, Dr. Matloubian observed that the article summarized case reports of different vaccines that were temporally associated with myopathies but failed to provide "details of the cases, such as the possibility of a recent infection or pre-existing subclinical diseases." Resp. Ex. A at 17. Further, Stübgen concluded that "retrospective and epidemiologic studies failed to ascertain an association between [dermatomyositis/polymyositis] and vaccines; no significant increase in the incidence . . . was reported after large vaccination campaigns." Id. (quoting Pet. Ex. 29 at 1).

As for Ferri et al., Dr. Matloubian noted the authors conceded that they could not "definitely exclude that the systemic manifestations following [flu] vaccination in [their] three patients [may be] coincidental." Resp. Ex. A at 18 (quoting Pet. Ex. 30 at 2). Dr. Matloubian concluded that these articles did not support the third Schattner criteria. See id. at 15-18. Moreover, Dr. Matloubian opined that these articles did not provide support for any mechanism supporting flu vaccine associated autoimmune myositis. See id.

In addition to analyzing causation using the Schattner framework suggested by Dr. Zizic, Dr. Matloubian filed medical literature which illustrated that Petitioner's theory of molecular mimicry has not been acknowledged as a causal mechanism for dermatomyositis/polymyositis. See Resp. Ex. A at 13-14, 18-19. For example, Dr. Matloubian cited the book chapter by Mammen discussing the "pathogenic mechanisms underlying the autoimmune myopathies." Resp. Ex. A, Tab 4 at 12. Mammen explained that these mechanisms are "still poorly understood." Id. Regarding dermatomyositis, for instance, some studies show "damage to intermediate-sized" blood vessels that "may cause ischemia" and muscle fiber atrophy. Id. Other studies suggest that interferon[56] induced gene expression may play a role in disease causation. Id. Yet another explanation is that dermatomyositis is a "complement-mediated microangiopathy."[57] Resp. Ex. A, Tab 7 at 5 fig.1. Further, the "factors that trigger inflammatory muscle diseases remain unknown." Id. at 9. Genetic risk factors have been suggested. Id. Viruses have also been suggested as playing a causal role, but to date, "attempts to amplify viruses . . . from the muscles have failed." Id. The increased risk between dermatomyositis and cancers, along with studies that have shown that cancer treatment can positively affect prognosis in myositis, "suggests a possible mechanistic relationship." Resp. Ex. A, Tab 8 at 2.[58] In summary, these references support Dr. Matloubian's opinion that "the cause of immune myopathies, such as dermatomyositis and polymyositis is not known." Resp. Ex. A at 13.

In conclusion, Dr. Matloubian opined that Petitioner has "not provided any scientific evidence to support molecular mimicry between the [flu] [] vaccine and the development of an immune mediated myositis, such as dermatomyositis." Resp. Ex. A at 16.

iv. Althen Prong Two

Regarding the question of whether the evidence supports a logical sequence of cause and effect, Dr. Matloubian opined that because Petitioner's myositis began before his vaccination, it was not caused by it. Resp. Ex. A at 12. In addition, because the flu vaccine did not have "any significant effect" on Petitioner's AST and ALT between December 12 and December 16, 2016, when he was symptomatic and required hospitalization, Dr. Matloubian thought it was unlikely that the vaccine played a role in causing or worsening the illness. Id. at 15.

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[56] Interferons refer to any "family of glycoproteins that exert virus-nonspecific but host-specific antiviral activity by inducing the transcription of cellular genes coding for antiviral proteins that selectively inhibit the synthesis of viral RNA and proteins. Interferons also have immunoregulatory functions . . . [and] [p]roduction of interferon can be stimulated by viral infection." Interferon, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25558 (last visited June 13, 2023).

[57] For a description of this theory, see Resp. Ex. A, Tab 7 at 5.

[58] Ami A. Shah et al., Cancer-Induced Autoimmunity in the Rheumatic Diseases, 67 Arthritis & Rheumatology 317 (2015).

Next, Dr. Matloubian addressed alternative causes for Petitioner's alleged vaccine-related illness. He noted that Petitioner's muscle biopsy findings were "non-specific," suggesting the cause "could be due to an autoimmune etiology or an infectious one." Resp. Ex. A at 13. Dr. Matloubian explained that while dermatomyositis is not necessarily considered to be post-infectious, Petitioner had positive test results of "coxsackie and CMV, with evidence of ongoing infection for [CMV]." Id. at 14. Further, both viruses were referenced by the pathologists in Petitioner's biopsy report "as potential causes of a viral myositis that could not be ruled out based on the pathologic findings." Id. (citing Pet. Ex. 4 at 1059). While Dr. Matloubian opined that it was "unlikely that [P]etitioner's CMV [was] the cause of his condition," such "an association ha[d] been described in a few case reports." Id. He cited the study referenced by the pathologist, authored by Fasth et al., reporting that CMV might play a role in triggering dermatomyositis/polymyositis in some patients. Id. (citing Resp. Ex. A, Tab 10). Further, on December 1, 2016, Petitioner was seen for illness, described as a "viral syndrome with fatigue, sore muscles[,] and chills." Id. at 16 (quoting Pet. Ex. 10 at 33) (citing Pet. Ex. 2 at 50). Dr. Matloubian concluded that Petitioner had a "recent and active infection with CMV, a virus that has been associated with development of an inflammatory myositis." Id.

In addition to raising the question of whether a viral infection played a role in causing Petitioner's illness, Dr. Matloubian also described the association between dermatomyositis and cancer. Resp. Ex. A at 13. Petitioner's biopsy findings were more consistent with dermatomyositis than polymyositis, however, Petitioner did not have the rash characteristic of dermatomyositis. Id. Due to the absence of the classic rash, Petitioner's physicians diagnosed him with "dermatomyositis sine dermatitis" or "autoimmune myopathy." Id. Dr. Matloubian explained that the cause of dermatomyositis is not known, but he noted that there is "a strong association between dermatomyositis and cancer" which "has been observed in multiple studies." Id. Cancers most commonly seen in association with dermatomyositis include colon cancer, non-Hodgkin's lymphoma, and melanoma. Id. The risk of cancer occurs in nine to 32% of patients with dermatomyositis, and the risk window last up to at least five years after diagnosis. Id. In addition to describing the increased risk of cancer in patients with dermatomyositis, Dr. Matloubian described the mechanism by which autoimmunity is thought to occur as part of the immune response that targets cancer cells.[59] Id.

v. Althen Prong Three

Regarding prong three—whether there is a temporal association between vaccination and the onset of Petitioner's myopathy—Dr. Matloubian opined that onset preceded vaccination, and therefore, there is "a lack of relationship between [Petitioner's] immunization and progression of his pre-existing symptoms." Resp. Ex. A at 15.

Dr. Matloubian also refuted Dr. Zizic's opinion that an onset of 24 hours was appropriate. Dr. Matloubian averred that Petitioner "associated his disease with his immunization because of symptoms he experienced the night of his vaccination." Resp. Ex A at 15. Dr. Matloubian opined that the onset of symptoms in "less than a day after vaccination does not fit with the kinetics of T and B cell immune responses." Id. at 15-16. Instead, the medically appropriate

[59] For an explanation of this mechanism, see Resp. Ex. A at 14.

time for onset of an immune response (molecular mimicry) dependent on T and B cells responses would be seven to 14 days. Id. at 15. Thus, Dr. Matloubian opined it would be "biologically impossible" for the flu vaccine to have triggered an immune response within one day. Id.

In conclusion, Dr. Matloubian opined that the Petitioner's "development of an immune mediated inflammatory myositis was more likely than not completely unrelated to his [flu] immunization on [December 12, 2016]." Resp. Ex. A at 16.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair, and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

Petitioner must prove 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 & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors

unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling 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 & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike 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 v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports,

diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them.").

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege that he suffered a Table Injury, he must prove a vaccine he received caused his injury. To do so, Petitioner must establish, by preponderant evidence: "(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.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

V. ANALYSIS

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury," determining facts relating to the claimed injury can be significant in a case where diagnosis is not clear. Id.

Here, Petitioner alleges that he suffered "an auto[]immune myopathy, more likely than not dermatomyositis." Am. Petition at Preamble. In their joint submission, the parties stipulate that Petitioner most likely suffered from an "immune mediated myopathy." Joint Submission at 1. The parties suggest, however, that the experts disagree on whether a more specifical diagnosis is more appropriate. Id. Thus, the question is whether a ruling as to a diagnosis more specific than "immune mediated myopathy," is appropriate in order to resolve each of the Althen prongs of causation.

The experts address diagnosis in their expert reports. Dr. Zizic opines that Petitioner's muscle biopsy was most consistent with dermatomyositis, and he also notes that Petitioner was diagnosed with "dermatomyositis sine dermatitis." Pet. Ex. 10 at 34. Dr. Matloubian opines that while Petitioner's myopathy was "difficult to [] classify," he "most likely had [] dermatomyositis sine dermatitis or an infection-associated immune mediated myopathy." Resp. Ex. A at 10. According to Dr. Matloubian, Petitioner's diagnosis can be further characterized based on his response to treatment. Petitioner had a positive response to immunosuppressive treatment. His muscle enzyme levels returned to normal, and his muscle weakness improved. Based on these facts, Dr. Matloubian opines that Petitioner had an immune-mediated condition. However, Dr. Matloubian states that these facts do not allow one to distinguish between an autoimmune response and an immune-mediated response directed against a particular trigger, like a viral illness. Id.

The treating physicians address diagnosis throughout Petitioner's clinical course. After the muscle biopsy was performed on December 27, 2016, the pathologists' assessment that "the muscle demonstrate[d] non-specific myopathic changes which may be related to inflammatory myopathy with possible etiologies including autoimmune[], viral[,] or other infectious processes" was often referenced when describing diagnosis. Pet. Ex. 4 at 1059. When Petitioner was discharged from UW, his discharge diagnosis was autoimmune myositis, possibly dermatomyositis sine dermatitis. Dr. Balderia, the rheumatologist who saw Petitioner after his hospitalization, used the diagnosis, "acute myositis complicated by rhabdomyolysis, likely autoimmune, biopsy consistent with dermatomyositis without associated typical skin findings." Id. at 95. Dr. Sacksen's diagnosis was "autoimmune myopathy, most likely [dermatomyositis]" and "inflammatory autoimmune myopathy." Id. at 37; Pet. Ex. 48 at 18. While a number of different phrases were used to characterize Petitioner's myopathy, on the whole, the diagnosis of dermatomyositis without associated skin changes (dermatomyositis sine dermatitis) was the most often referenced diagnosis, and was the diagnosis given to Petitioner by Dr. Balderia. Thus, the

weight of the evidence suggests that more likely than not, Petitioner's diagnosis is immune-mediated myopathy (dermatomyositis without skin changes).

This finding is consistent with case law. The Federal Circuit has made clear that "identifying [the Petitioner's] injury is a prerequisite" to the Althen analysis. Broekelschen, 618 F.3d at 1346. However, it is not necessary to diagnose an exact condition. Astle v. Sec'y of Health & Hum. Servs., No. 14-369V, 2018 WL 2682974, at *19 (Fed. Cl. Spec. Mstr. May 15, 2018). In Lombardi, the Federal Circuit explained that "[t]he function of a special master is not to diagnose vaccine-related injuries, but instead to determine based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [P]etitioner's injury." Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1351 (Fed. Cir. 2011) (internal quotation marks omitted) (quoting Andreu, 569 F.3d at 1382).

The diagnosis of immune-mediated myopathy, "more likely than not dermatomyositis," is consistent with the diagnosis plead by the Petitioner in his petition, it was referenced by both experts, and Respondent agrees that the subtype is dermatomyositis, not polymyositis, and more specifically dermatomyositis without skin changes is the most likely diagnosis. Therefore, the undersigned finds that the appropriate diagnosis is immune-mediated myopathy, dermatomyositis sine dermatitis.[60]

B. Onset

The medical literature filed by the parties establishes that immune-mediated myopathy is characterized by proximal skeletal muscle weakness and evidence of muscle inflammation. Patients usually report a history of subtle development of muscular weakness, with gradual worsening over a period of several months before they seek medical care. Characteristic lab findings include elevated AST, ALT, and CK. Petitioner's medical records, both prior to and after vaccination by several different health care providers, independently document that Petitioner reported his symptoms began prior to vaccination on December 12, 2016.

The following records provide examples:

1) On December 1, 2016, Petitioner was seen by Mr. Cichon, PA-C, whose records document that Petitioner reported a one-month history of fatigue, sore muscles, chills, increased arm and leg weakness, and loss of muscle tone. Pet. Ex. 2 at 50-52. This note places onset of symptoms on approximately November 1, 2016.

2) Labs drawn on December 1, 2016, revealed elevated AST and ALT (55 and 57). Pet. Ex. 2 at 140. Petitioner saw Dr. Dinh on December 12 and labs drawn on this date revealed continuously elevated AST and ALT (63 and 73). Id. at 125.

[60] Throughout this analysis, the undersigned uses the words immune-mediated myopathy or dermatomyositis when referencing Petitioner's diagnosis.

3) Four days later, December 16, 2016, Petitioner was admitted to Good Samaritan Hospital where he was seen by Dr. Yang. Dr. Yang documented that Petitioner reported a history of a "viral flu-like illness" about two weeks before admission, and prior to receipt of the flu shot. Pet. Ex. 5 at 93. This note places onset on approximately December 2, 2016.

4) On December 19, 2016, Helen Ward, LICSW, documented that Petitioner reported he had been "fighting something off" and been "losing some muscle strength for a while." Pet. Ex. 5 at 268.

5) Petitioner was transferred to UW on December 25, 2016 where he was seen by Dr. Feller, whose note indicates that Petitioner was in his "usual state of health until roughly [three] weeks ago when he began feeling 'crummy' with no specific symptoms." Pet. Ex. 4 at 136. This note places onset on approximately December 4, 2016.

Petitioner also related his symptoms to his vaccinations. In those instances, however, he did not negate the history in the reports noted above. Moreover, the histories provided by Petitioner to his health care providers, as documented above, are not inconsistent with Petitioner's or his wife's declarations, which do not speak to the onset of his muscle soreness, weakness, loss of muscle, or his flu-like illness prior to vaccination. To the extent that they are inconsistent with and/or contradict the health care providers' histories documented in the contemporaneous medical records and objective physical examinations or diagnostic testing, the undersigned defers to the contemporaneous records as the most reliable source of information. See Cucuras, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); Doe/70 v. Sec'y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010); Stevens v. Sec'y of Health & Hum. Servs., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that "clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"); Vergara v. Sec'y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.").

This finding also extends to lay witness affidavits and testimony. Other special masters faced with similar situations have found contemporaneous medical records more persuasive than the affidavits and testimonies of lay witnesses. See, e.g., Rote v. Sec'y of Health & Hum. Servs., No. 90-036V, 1992 WL 165970, at *5 (Cl. Ct. Spec. Mstr. July 1, 1992) (finding the lay witness testimony insufficient to overcome the weight of the contemporaneous medical records); Bergman v. Sec'y of Health & Hum. Servs., No. 90-1252V, 1992 WL 78671, at *4 (Cl. Ct. Spec. Mstr. Mar. 31, 1992) (same); Daiza v. Sec'y of Health & Hum. Servs., No. 90-1188V, 1992 WL 59709, at *4 (Cl. Ct. Spec. Mstr. Mar. 5, 1992) (same).

In summary, the medical records from different health care providers over the period of Petitioner's initial presentation and extending to his hospital admission document that Petitioner reported that his symptoms began as early as November 1, 2016 and by December 4, 2016. The

fact that at least four records place onset prior to vaccination is compelling evidence because they are consistent even though they are written by different providers. In their totality, these records provide persuasive evidence of onset. Thus, the undersigned finds that the initial manifestation of Petitioner's immune-mediated myopathy was as early as November 1, 2016 and by December 4, 2016. Regardless of whether onset was November 1, 2016 or December 4, 2016, onset predated vaccination.

Moreover, there is objective evidence that Petitioner had elevated AST and ALT enzymes prior to vaccination. Dr. Zizic's position is that the elevated enzymes reflect liver disease, not muscle damage, and therefore, they do not support a finding of onset prior to vaccination. The undersigned, however, finds Dr. Matloubian's explanation—that the pre-vaccination elevations of AST and ALT were due to Petitioner's muscle disease—more persuasive and consistent with the treating physician opinions and diagnoses, medical literature, and Petitioner's overall clinical picture. Further, as explained by Dr. Matloubian, once Petitioner received treatment for his muscle disease, his enzyme levels normalized. Lastly, again as noted by Dr. Matloubian, Petitioner was not diagnosed with or treated for liver disease.

C. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds Petitioner has failed to provide preponderant evidence that the flu vaccine can cause immune-mediated myopathy for the following reasons.

Dr. Zizic embraces molecular mimicry as the causal theory that explains how the flu vaccination can cause an immune-mediated myopathy. He cited articles by Schattner, Stübgen, and Ferri et al. to support his opinions. None of the articles cited, however, establish that molecular mimicry has been posited as a causal mechanism for how the flu vaccine can cause immune-mediated myopathy.

Schattner explains that "[d]espite significant recent advances in our understanding of the pathogenesis of autoimmunity, many basic questions remain." Pet. Ex. 11 at 2. While the triggering infectious agent is defined in some "discrete illnesses such as reactive arthritis,

rheumatic fever[,] or vasculitis associated with hepatitis B virus," in "most [] autoimmune diseases, no exogenous infectious agent could be identified." Id. Schattner concluded that "[v]ery few patients may develop some autoimmune diseases following viral vaccination (in particular—arthropathy, vasculitis, neurological dysfunction[,] and thrombocytopenia)." Id. at 1. Although myositis was listed as an autoimmune condition reported after flu vaccination in Table 4 of her article, Schattner did not otherwise reference it. See id. at 5 tbl.4. Schattner did not identify myopathy as an autoimmune disease that follows vaccination. And she did not discuss immune-mediated myopathy, dermatomyositis, or polymyositis. Schattner generally discussed molecular mimicry; however, she did not discuss the mechanism in the context of the flu vaccine and myopathy.

The three criteria Schattner required to "establish a role for viral vaccine in the subsequent development of [] autoimmune diseases" were not discussed with respect to the flu vaccine and immune-mediated myopathy. Pet. Ex. 11 at 7. However, application of the Schattner criteria[61] to the evidence here does not support a role for the flu vaccine in the development of immune-mediated myopathy.

First, Petitioner has not established that flu infections lead to immune-mediated myopathy. As explained by Dr. Matloubian, flu infections have been associated with viral myositis. Although the pathogenesis of viral myositis is not known, direct infection of muscle has been acknowledged as a potential cause. See Resp. Ex. A, Tab 1 at 2. Dr. Matloubian cites Desdouits et al., which described a study that found evidence supporting a direct infectious etiology. See Resp. Ex. A, Tab 11 at 1. Dr. Matloubian further opines that autoimmune myopathy has not been reported following the flu vaccine. And Petitioner did not file evidence rebutting Dr. Matloubian's opinion in this regard.

Second, while Dr. Zizic posits the mechanism of molecular mimicry, he does not provide preponderant evidence showing that molecular mimicry due to antigens or molecules in the vaccine leads to immune-mediated myopathy. While Dr. Zizic discusses mimics relevant to other illnesses, like rheumatoid arthritis, he did not identify any common antigenic components between the vaccine and muscle tissue that could implicate molecular mimicry here. Dr. Matloubian effectively and persuasively shows the weaknesses of Petitioner's theory and failure to demonstrate any evidence to support homology or other indices of molecular mimicry.

Third, there must be evidence that patients who have received the flu vaccine have developed immune-mediated myopathy. While Dr. Zizic asserts that there is "a large body of

[61] The undersigned analyzes the evidence using the Schattner criteria here because Petitioner's expert, Dr. Zizic, did so, and because the criteria provide a useful framework to discuss Althen Prong One. However, the undersigned's decision does not turn on these criteria, but is based on the evidence, the case law relevant to the Althen Prongs, and on the requisite burden of proof—preponderance of the evidence. While the criteria outlined by Schattner is a way to organize the Althen Prong One analysis, the undersigned understands that petitioners are not required to demonstrate a specific biologic mechanism which caused their disease, nor are they required to present medical literature or epidemiological studies in support of their theory. See Knudsen, 35 F.3d at 549; Andreu, 569 F.3d at 1378-79.

evidence" supporting an association between the flu vaccine and immune-mediated myopathies, the undersigned finds the evidence lacking. Pet. Ex. 10 at 32. Stübgen concluded there was "a possible causal link between immunizations and inflammatory myopathies." Pet. Ex. 29 at 1. Possibilities, however, are not sufficient to establish causation. See, e.g., Waterman, 123 Fed. Cl. at 573-74; Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence). Retrospective studies showed that vaccinations were not thought to be a trigger for dermatomyositis/polymyositis. And VAERS reports did not show any increase in dermatomyositis/polymyositis cases following the swine flu vaccination campaign in 1976 in military personnel or at several large clinics and hospitals. Similarly, Stübgen's search of the VAERS database through 2013 did not support vaccination was associated with any increase in dermatomyositis/polymyositis. Finally, Ferri et al. presented three case reports of inflammatory myopathies after the 2009-2010 seasonal flu vaccine in Italy, but the authors reached no conclusions as to causation.

Moreover, opining that molecular mimicry is a causal theory, without more, is insufficient. See, e.g., McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (explaining that "merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question" (emphasis omitted)); Johnson v. Sec'y of Health & Hum. Servs., No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) ("Petitioners cannot simply invoke the concept of molecular mimicry and call it a day. Rather, they need to offer reliable and persuasive medical or scientific evidence of some kind (whether expert testimony or literature) . . . ." (internal citations omitted) (emphasis omitted)); Mattus-Long v. Sec'y of Health & Hum. Servs., No. 15-113V, 2022 WL 4242140, at *27 (Fed. Cl. Spec. Mstr. Aug. 31, 2022) (noting "the mere mention of molecular mimicry is not a 'get out of jail free card' in the Program, entitling claimants to compensation, merely because it has scientific reliability as a general matter"); Sheets v. Sec'y of Health & Hum. Servs., No. 16-1173V, 2019 WL 2296212, at *17 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (determining Petitioner had not satisfied Althen Prong One when he did not relate molecular mimicry "to either the vaccines in question or Petitioner's own specific condition").

Further, Dr. Zizic references other mechanisms by which the flu vaccine activated B or T lymphocytes, including "cross-priming, immune complex formation[,] or a combination of these." Pet. Ex. 10 at 34. While some of these words or phrases may be related to the mechanism of molecular mimicry, Dr. Zizic does not define or describe them. Instead, he mentions these concepts in a conclusory manner without development or explanation of how they could cause or contribute to disease. As such, Dr. Zizic's references to these concepts are conclusory in nature.

When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. denied, decision aff'd, 141 Fed. Cl. 138 (2018), aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on

"opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315).

Lastly, there appear to be only two reasoned decisions in the Program where a petitioner alleged immune-mediated myopathy (dermatomyositis type) following the flu vaccine, with one granting and one denying entitlement to compensation.[62] Whelan v. Sec'y of Health & Hum. Servs., No. 16-1174V, 2019 WL 1061473 (Fed. Cl. Spec. Mstr. Jan. 28, 2019); Ulysse v. Sec'y of Health & Hum. Servs., No. 15-451V, 2022 WL 2115248 (Fed. Cl. Spec. Mstr. May 19, 2022).

In Whelan, the Petitioner alleged that a flu vaccine caused her dermatomyositis. Whelan, 2019 WL 1061473, at * 1. The Petitioner did not develop symptoms until over two months following vaccination; the flu shot was administered on October 4, 2013, and the Petitioner presented to her physician in March 2014 complaining that in late January, she developed a rash and weakness in her legs. Id. Molecular mimicry was the posited causal mechanism, although Petitioner's expert also alluded to other mechanisms. Id. at *3, *15. Respondent's expert was Dr. Matloubian, and like here, he effectively rebutted the opinions of Petitioner's expert, opining that the wild type of flu virus has not been shown to cause dermatomyositis. Id. at *5, *15. Petitioner's expert, Dr. Brawer, offered no opinion about what the expected onset time frame should be (Althen prong three), whereas Dr. Matloubian opined that onset greater than eight weeks was outside the expected range given the theory of molecular mimicry. Id. at *15. Now-Chief Special Master Corcoran denied entitlement, finding Dr. Matloubian's testimony persuasive as to the lengthy onset and the Petitioner's failure to show that the flu vaccine has been associated with dermatomyositis. Id.

A different theory was advanced in Ulysse, with a favorable outcome for the Petitioner. Ulysse, 2022 WL 2115248, at *1. There, the Petitioner primarily had skin manifestations, with some muscle involvement, and the diagnosis was amyotrophic dermatomyositis versus mixed connective tissue disease. Id. at *3-5. Several causal mechanisms were advanced, including molecular mimicry. Id. at *6-8, *18-19. However, Chief Special Master Corcoran found that Petitioner's most compelling theory was related to the upregulation of cytokines, based on the well-developed opinions of Petitioner's expert, supported by reliable literature. Id. at *6-8, *18-19. Moreover, Respondent's expert failed to offer an effective rebuttal or even one medical article in support of his opinions. Id. at *11, *18-19.

[62] There are also three somewhat similar cases, distinguishable by virtue of the vaccines administered and/or diagnosis. Durden v. Sec'y of Health & Hum. Servs., No. 05-163V, 2007 WL 4962000 (Fed. Cl. Spec. Mstr. Sept. 26, 2007) (analyzing overlap syndrome and sclerodermatomyositis following diphtheria-tetanus vaccination); Rodd v. Sec'y of Health & Hum. Servs., No. 13-122V, 2015 WL 8489035 (Fed. Cl. Spec. Mstr. Nov. 13, 2015) (analyzing overlap syndrome, Sjogren's syndrome, polymyositis, or anti-synthase syndrome following flu vaccination); Rodriguez v. Sec'y of Health & Hum. Servs., No. 13-253V, 2017 WL 5563419 (Fed. Cl. Spec. Mstr. Oct. 26, 2017) (examining juvenile dermatomyositis following diphtheria-tetanus-acellular pertussis, measles-mumps-rubella, polio, and Varicella vaccinations).

Although decisions of other special masters are not binding, the undersigned generally agrees with the special master's reasoning in Whelan—that is, rejecting molecular mimicry and finding that Dr. Matloubian effectively rebutted the causation opinions asserted. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999). Also, both Whelan and the case at bar have an onset issue. Here, onset predates vaccination, and in Whelan, it was too long after vaccination. Moreover, the outcome in Ulysse does not conflict with the outcome here, as there was a different theory advanced, supported by medical literature, and effectively unrebutted by Respondent's expert.

For all of the reasons discussed above, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the first Althen prong.

D. Althen Prong Two

Under Althen Prong Two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

Because Petitioner failed to prove Althen Prong One, it follows that he cannot prove Althen Prong Two. However, even if Petitioner had proven Althen Prong One, the undersigned finds Petitioner has failed to prove Althen Prong Two by preponderant evidence for the following reasons.

First, because the undersigned finds that onset of Petitioner's immune-mediated myopathy occurred before vaccination, his flu vaccination could not have caused his illness. Therefore, the question would turn to whether there is a logical sequence of cause and effect to show that Petitioner's vaccination caused a significant aggravation of his condition, however, Petitioner did not allege a significant aggravation claim.[63]

Second, in evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). However, statements in a patient's history referencing a vaccination that is temporally associated with a condition, without more, does not meet the level

[63] While one statement in Petitioner's brief suggested Petitioner was pursuing a claim for significant aggravation, Petitioner's expert reports did not address the Loving prongs relevant to such a claim. Pet. Br. at 3. Moreover, Petitioner later confirmed that he was not pursuing a significant aggravation claim. Joint Status Rept., filed Mar. 23, 2023. Even if Petitioner had pursued a significant aggravation claim, the outcome would be the same, as he failed to prove by preponderant evidence all three Althen prongs, which constitute Loving prongs four, five, and six. See Loving, 86 Fed. Cl. at 142-44.

of preponderant evidence. See § 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009) ("[T]here 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."); Robertson v. Sec'y of Health & Hum. Servs., No. 18-554V, 2022 WL 17484980, at *17 (Fed. Cl. Spec. Mstr. Dec. 7, 2022) (explaining "the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases"); Hibbard v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 742, 749 (2011) (finding it neither arbitrary nor capricious for a special master to weigh competing treating physicians' conclusions against each other), aff'd, 698 F.3d 1355 (Fed. Cir. 2012); Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 136 (2011), aff'd, 463 F. App'x 932 (Fed. Cir. 2012).

There are two issues arising from opinions by Petitioner's physicians evidenced in the medical records—opinions regarding differential diagnoses and opinions related to alternative causes.

The first issue concerns statements made by Petitioner to his health care providers relating a temporal association of some of his symptoms back to the receipt of his flu vaccination. In several instances, physicians considered the question of a causal association. For example, after Petitioner was admitted to the hospital on December 16, 2016, Dr. Yang considered two differential diagnoses, "post-vaccine syndrome" or a "delayed autoimmune-immune neuropathy" due to the viral-like illness Petitioner had two weeks before admission. Pet. Ex. 5 at 95. These differential diagnoses were contemplated before the muscle biopsy and before Petitioner was diagnosed with immune-mediated myopathy. Later, neurologist Dr. Weiss wrote that he considered two differential causes of Petitioner's autoimmune myopathy, (1) the flu vaccine, "though rare case reports found," and (2) a "[p]ost-viral process." Pet. Ex. 4 at 70.

The undersigned finds that physician statements expressing differential diagnoses, which include a reference to the flu vaccine, without more, do not meet the level of preponderant evidence. See § 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"). "A treating physician's recognition of a temporal relationship does not advance the analysis of causation." Isaac v. Sec'y of Health & Hum. Servs., No. 08-601V, 2012 WL 3609993, at *26 (Fed. Cl. Spec. Mstr. July 30, 2012); see also A.T. v. Sec'y of Health & Hum. Servs., No. 16-393V, 2021 WL 6495241, at *28 (Fed. Cl. Spec. Mstr. Dec. 17, 2021) (finding that Petitioner's treating physicians "considered, though did not conclude," that Petitioner's vaccine significantly aggravated her condition); Robertson, 2022 WL 17484980 at *17 (finding treating physicians' statements of mere suspicion fall short of an opinion supporting vaccine causation); Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1347 (Fed. Cir. 2010) (concluding the special master did not err in affording little weight to the opinions of Petitioner's treating physicians where "none of the treating physicians concluded that the [] vaccine caused [Petitioner's] [condition]").

Next, it is appropriate to consider alternative causes in evaluating whether prong two is satisfied, and as described above, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326.

The physicians who cared for Petitioner raised the question of whether his immune-mediated myopathy had a viral etiology. As described above, Dr. Yang questioned whether Petitioner's preceding viral-like illness played a causal role. Dr. Alton and Dr. Ryan likewise documented their suspicion of a viral etiology, noting that Petitioner had tested positive for CMV. And Dr. Weiss also considered a post-viral process.

As such, Dr. Matloubian discusses alternative causes for Petitioner's alleged vaccine-related illness. He notes that Petitioner's muscle biopsy findings were non-specific, suggesting the cause could be infectious. Dr. Matloubian explains that while dermatomyositis is not usually thought of as being post-infectious, Petitioner had positive coxsackie and CMV test results, and evidence of an ongoing infection with CMV. These were references by the pathologists in Petitioner's biopsy report of "potential causes of a viral myositis[] that could not be ruled out based on the pathologic findings." Resp. Ex. A at 14 (quoting Pet. Ex. 4 at 1059). The pathologists cited Fasth et al., who reported that CMV might play a role in triggering dermatomyositis/polymyositis in some patients. Id. (citing Resp. Ex. A, Tab 10). Further, on December 1, 2016, prior to vaccination, Petitioner had a "viral syndrome with fatigue, sore muscles[,] and chills." Id. (quoting Pet. Ex. 10 at 33). Thus, Dr. Matloubian concludes that Petitioner had a "recent and active infection with CMV, a virus that has been associated with development of an inflammatory myositis." Id. at 16.

The undersigned acknowledges that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation. See Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1149-52 (Fed. Cir. 2007) (finding a petitioner does not bear the burden of eliminating alternative independent potential causes). However, she finds it reasonable to consider "evidence of other possible sources of injury"—here, Petitioner's antecedent viral-illness and CMV infection—to determine "whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." Stone, 676 F.3d at 1379.

The fact that Petitioner had a preceding viral-like illness and a CMV infection, "makes it difficult to attribute 'but for' causation to the vaccination." Pafford, 451 F.3d at 1358-59; see also Walther, 485 F.3d at 1151 n.4 ("Where multiple causes act in concert to cause the injury, proof that a particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine."). As such, the undersigned finds this to be an additional reason why Petitioner has failed to prove that the flu vaccine was the "but for" cause of his immune-mediated myopathy.

For the reasons described above, the undersigned finds that Petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect required under Althen prong two.

E. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." Id. The Petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that [P]etitioner must posit a medical theory causally connecting the vaccine and injury"), aff'd, 475 F. App'x 765 (Fed. Cir. 2012).

Based on the case law cited above, this Althen prong consists of two parts. Petitioner must first establish the time frame within which it is medically acceptable to infer causation. Secondly, he must show that the onset of his illness occurred during this time frame.

Petitioner's expert, Dr. Zizic, opines that Petitioner's symptoms began within 24 hours after vaccination, however, he does not identify what these symptoms were or why he believes they constitute the onset of Petitioner's illness. Other than a cursory reference to the Stübgen article, Dr. Zizic does not explain how an onset of 24 hours could occur given his posited theory of molecular mimicry. In contrast, Respondent's expert, Dr. Matloubian, opines that onset preceded vaccination, and therefore, the vaccine did not cause Petitioner's illness.

Petitioner's reliance on Stübgen as to whether there is an appropriate temporal association here is misplaced. Stübgen suggests several mechanisms relevant to dermatomyositis including "completement-mediated microangiopathy" that destroys blood vessels, leading to "hypoperfusion and inflammatory cell stress within the perifascicular regions," not molecular mimicry. Pet. Ex. 29 at 2. Further, while Stübgen includes tables listing several case reports with an onset of 24 hours or one day, the facts of the cases are not included, so it is impossible to verify the diagnosis or clinical course of those patients.

Because the undersigned finds that onset of Petitioner's myopathy occurred before vaccination, she agrees with Dr. Matloubian, that the flu vaccine could not have caused Petitioner's illness. Moreover, Petitioner has failed to explain how molecular mimicry could cause the onset of immune-mediated myopathy within 24 hours of vaccination. And Program cases do not support a 24-hour onset with molecular mimicry as the causation theory. See, e.g., Burgess v. Sec'y of Health & Hum. Servs., No. 17-688V, 2022 WL 17410582, at *35 (Fed. Cl. Spec. Mstr. Nov. 7, 2022); Hock v. Sec'y of Health & Hum. Servs., No. 17-168V, 2020 WL 6392770, at *28-29 (Fed. Cl. Spec. Mstr. Sept. 30, 2020); O.M.V. v. Sec'y of Health & Hum. Servs., No. 16-1505V, 2021 WL 3183719, at *48 (Fed. Cl. Spec. Mstr. June 16, 2021), mot. for rev. denied, 157 Fed. Cl. 376 (2021).

Therefore, the undersigned finds there is not preponderant evidence of a temporal association between Petitioner's receipt of his flu vaccination and the onset of his myopathy. Even if he had proven Althen prong three, a temporal association, without more, is insufficient. Moberly, 592 F.3d at 1323; Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury."). Thus, Petitioner is not entitled to compensation.

VI. CONCLUSION

The undersigned extends her sympathy to Petitioner for the illness that he has suffered. This Decision, however, cannot be based on sympathy, but rather on the evidence and the law.

For the reasons discussed above, the undersigned finds that Petitioner has not established by preponderant evidence that his flu vaccination caused his condition. Therefore, Petitioner is not entitled to compensation and his petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master