In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-196V
Filed: October 21, 2021

ANGELIA R. ANDREWS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Special Master Katherine E. Oler Ruling on the Record; Entitlement; Systemic Lupus Erythematosus (SLE); Influenza Vaccine

Fred A. O'Neill, Perkins & O'Neill, LLC, Thayer, MO for Petitioner
Christine M. Becer, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

On February 28, 2016, Angelia Andrews ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program[2] alleging that she suffered connective tissue disease as a result of either the Pneumovax or the influenza ("flu") vaccinations she received on August 2, 2014.[3] Pet. at 2, ECF No. 1 at 2. For the reasons set forth below, I find that Petitioner

[1] Because this Decision contains a reasoned explanation for the action in this case, I intend to post this Decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2012)). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

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

[3] Although the Petition alleges that either the flu vaccine or the Pneumovax vaccine caused Petitioner's connective tissue disease, Pneumovax is not a covered vaccine. Additionally, Petitioner's expert reports

has not preponderantly demonstrated that she has SLE, that the flu vaccine can cause SLE, or that it did so in her particular case.

I. Procedural History

Petitioner filed her petition, along with medical records (Exs. 1-5, 7, 8) and an affidavit (Ex. 6) on February 28, 2016. ECF No. 1. She filed a statement of completion on March 1, 2016. ECF No. 9.

Respondent filed his Rule 4 Report on June 9, 2016, indicating that the case was not appropriate for compensation under the terms of the Vaccine Act. ECF No. 12.

On April 4, 2017, Petitioner filed an expert report from Dr. Thomas Zizic. Ex. 9. Respondent filed a responsive report from Dr. Robert Lightfoot on August 21, 2017. Ex. A. On that same date, Respondent also filed Dr. Lightfoot's CV (Ex. B) and one piece of medical literature (Ex. C).

On July 1, 2019, I ordered Dr. Zizic to respond to six specific questions that I had concerning the SLE diagnostic criteria. Order dated July 1, 2019; ECF No. 42.

Petitioner filed Dr. Zizic's second expert report on August 27, 2019. Ex. 10. Although this report addressed most of the questions I posed, it did not address one of them. Accordingly, I directed Petitioner to file a supplemental report from Dr. Zizic responding to this specific question. *See* Non-PDF Scheduling Order dated September 24, 2019. Petitioner filed a third report from Dr. Zizic on October 14, 2019. Ex. 11.

On February 6, 2020, Respondent filed a supplemental expert report from Dr. Lightfoot (Ex. D), as well as two pieces of medical literature (Exs. E, F).

On March 31, 2020, Petitioner expressed her willingness to have the case decided upon the record. ECF No. 48. Respondent also indicated he was amenable to a ruling on the record. ECF No. 49. On July 1, 2020, Petitioner filed her motion for a ruling on the record. ECF No. 50. Respondent filed a response on September 9, 2020. ECF No. 51. Petitioner did not file a reply.

On October 4, 2021, I directed Petitioner to file the medical literature referenced in Dr. Zizic's first expert report. *See* Non-PDF Scheduling Order dated Oct. 4, 2021. Petitioner filed this literature on October 13, 2021. ECF No. 57; Ex. 12. This case is ripe for an adjudication.

II. Medical History

On April 23, 2014, before her allegedly causal vaccination, Petitioner visited Burton Creek Rural Clinic. Ex. 3 at 51. During this visit, she reported decreased energy, poor sleep, and that she did not feel well. *Id.* at 52. She indicated that she was "tired all the time." *Id.* Her physical exam and laboratory results were normal. *Id.* at 54-55.

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and Petitioner's brief allege that she suffered from Systemic Lupus Erythematosus (SLE) caused by the flu vaccine. Accordingly, I have analyzed whether her flu vaccine caused Petitioner to develop SLE.

On August 2, 2014, Petitioner received both the flu vaccine and the pneumonia vaccine[4] at a Walgreen's Pharmacy. *See* Ex. 2. On August 3, 2014, Petitioner visited the Ozark Medical Center ER with complaints of fever, chills, sweats, "not feeling well", weakness, muscle aches, and "hurts all over". Ex. 4 at 6. She reported that she got her pneumonia and flu vaccines the previous day and thought she was having a "bad reaction". *Id.* She reported that her fever of 100.2, shortness of breath, and chest tightness and heart pounding began the previous night. *Id.* She took Aleve and Tylenol, which Petitioner indicated did not help much; she then took Benadryl that morning, which did help some. *Id.* The HPI further indicated that Petitioner "had a moderate, painful skin rash consisting of 'redness' located on the left arm." *Id.* She also reported nausea and joint pain. *Id.* Petitioner's physical exam noted tachycardia. *Id.* at 6. The record states, "Patient in mild distress (appears not feeling well and worried)." *Id.* The physical exam also noted "moderate erythema, tenderness, and swelling" of the left shoulder. *Id.* Her laboratory work-up showed an elevated WBC count. *Id.* at 9. The reason for exam was listed as "poss[ible] reaction to pneumonia shot." *Id.* at 10. Petitioner was discharged with a direction to visit her primary care provider. *Id.*

Petitioner visited Curtis Hortsman, DO (her primary care provider) the next day, on August 4, 2014. Ex. 3 at 58. The HPI indicates that Petitioner "went to the ER last night because I was hurting all over and my left arm was really hurting. They told me they think I had an adverse reaction to a pneumonia shot I got on Saturday." *Id.* During her visit with her PCP, Petitioner reported constant, moderate arm pain whose onset "has been sudden and has been occurring in a persistent pattern for 2 days." *Id.* Her physical exam was significant for "lateral L upper arm moderate swelling and induration. No sign[s] o[f] cellulitis, very mildly reddened." *Id.* at 59. Petitioner was assessed with a vaccination side effect and was given a Medrol dose-pack. *Id.* at 60.

On August 5, 2014, John Myers, the vaccine provider at Walgreen's Pharmacy, filed a VAERS report noting that Petitioner received the pneumonia and flu vaccines on August 2, 2014 in the left arm. *See* Ex. 2. The VAERS report indicates that Petitioner experienced arm swelling and was seen at the ER. *Id.* The record further states that "chest x-ray revealed immune reaction to pneumovax." *Id.* The description of the adverse event concludes by noting "[t]hat night, p[atien]t was discharged from ER to home with no further events." *Id.*

On August 5, 2014, Petitioner called her PCP and reported,

> that she went back to work today after her reaction to the pneumonia vaccine. … She said around noon she had what she thought was had acid reflux and she took 2 zantac and that seemed to pass. She states that now for the past 30 minutes her heart and felt like [sic] she had a "charlie horse." She said her chest has felt tight since the reaction but she just feels like she has a ton of bricks on her chest.

Ex. 3 at 33. Dr. Hortsman indicated that he thought Petitioner's reaction was from the steroids. *Id.* On August 6, 2014, Petitioner returned to her PCP and stated that "[y]esterday my heart started feeling weird. It's like it is spasming and sometimes it feels like it is gurgling. I am short of breath too." *Id.* at 61. Dr. Hortsman ordered an electrocardiogram, which was unremarkable. *Id.* at 62.

[4] Pneumovax is not a vaccine set forth in the Vaccine Injury Table and thus is not a covered vaccine. 42 CFR § 100.3.

On August 11, 2014, Petitioner again visited Dr. Hortsman reporting that she was dizzy all day yesterday, that today her chest hurt and her blood pressure was elevated. Ex. 3 at 64. Her physical exam was significant for high blood pressure (170/100). *Id.* at 65. Petitioner was started on metoprolol and Lisinopril. *Id.* at 66.

On August 14, 2014, Petitioner returned to Burton Creek Rural Clinic for evaluation and management of her high blood pressure. Ex. 3 at 67. Her blood pressure was measured at 122/82 and her physical exam was normal. *Id.* at 68. She was wearing a Holter monitor to monitor her palpitations. *Id*. Dr. Aaron Mills added a note to the record: "I warned her estrogen which she takes can elevate the blood pressure." *Id.* Dr. Mills advised that she speak with Dr. Israel about hormone therapy and "consider her options." *Id.*

On August 21, 2014, Petitioner visited Dr. Hortsman and reported that her blood pressure had been running high. Ex. 3 at 69. Her blood pressure was measured at 114/68 and her physical exam was normal. *Id.* at 70.

On September 15, 2014, Petitioner visited Dr. Hortsman complaining that she feels forgetful and hesitant with her speech, and that she has had difficulty with word finding and enunciation. Ex. 3 at 74. Petitioner further indicated that she had been monitoring her blood pressure at home and that it was in the normal range. *Id.*

About six months later, on March 16, 2015, Petitioner again visited Dr. Hortsman. Ex. 3 at 79. During this visit, she complained of pain all over, dizziness, and nausea. *Id.* Petitioner's myalgias had been occurring intermittently for the past three days. *Id.* Her review of symptoms was significant for chills, fatigue, nausea, joint pain, muscle pain, and myalgia. *Id.* at 80. Her physical exam was normal. *Id.* at 80.

On March 17, 2015, Petitioner had bloodwork performed. Her C-reactive protein was high at 1.537 (normal range = 0-0.800). Ex. 3 at 1. Her rheumatoid factor was normal. *Id.* at 4. Her erythrocyte sedimentation rate was also within the normal range. *Id.* With respect to the elevated C-reactive protein, Dr. Hortsman noted, "labs are ok. The CRP is slightly elevated but so litt[le] and the rest are normal so it is not signific[ant]". *Id.* at 25.

On March 18, 2015, Petitioner visited John Smart, DO at SMCHC Medical. She reported that she has had body aches, high blood pressure, heart fluttering, dizziness, and lightheadedness since her pneumonia shot in August. Ex. 7 at 27. Her physical exam was normal except for a swollen right thumb. *Id.* at 29. Dr. Smart ordered blood tests. Petitioner's ESR and ANA were both negative. *Id.* at 31. Her CRP was high at 5.51 (reference range 0.00-3.00). *Id.* at 25.

On March 23, 2015, Petitioner presented to SMCHC Medical for "generalized ache from head to toes." Ex. 7 at 12. Her labs were noted as "satisfactory". *Id.* at 14. She was started on Neurontin and was referred to rheumatology. *Id.*

On June 24, 2015, Petitioner presented to Dr. Melinda Reed (a rheumatologist). Ex. 5 at 1. Petitioner reported that her symptoms began after her pneumonia vaccine in August. *Id.* Petitioner provided the following history to Dr. Reed:

> After [the pneumonia vaccine] her arm that she had the injection in swelled diffusely, she came down with body aches, and a red rash on her cheeks. Since that time, she has had diffuse body aches, which she describes in her joints and muscles. Her symptoms have been getting worse and worse over time. She has noted occasional swelling in her knees, ankles, and feet, which does go down with elevation overnight. She occasionally has muscle spasms in her leg and back. She feels weak in her hands. She does have fatigue.… She does have underlying anxiety and feels panicked at times.

Id. Petitioner reported that her bad days usually occur a few times per week, and cause her to develop fatigue and redness on her cheeks where they will feel sunburnt. *Id.* She also has occasional red bumps on her arms that itch. *Id.* She further reported dry mouth and occasional painful sores on her tongue. *Id.* Dr. Reed further noted that Petitioner has "questionable Reynaud's" due to Petitioner's description of white color change on her fingers due to cold exposure. *Id.* Petitioner reported that her mother had a history of lupus and fibromyalgia. *Id.* at 2. On physical exam, Petitioner had muscle tenderness in her upper extremities, and "soft-tissue tenderness with 8/18 tender points for fibromyalgia." *Id.* Her laboratory work-up showed an elevated CRP, normal ESR, and negative ANA. *Id.* Dr. Reed's impression was:

1. Arthralgias, myalgias and fatigue. She has 8/18 tender points today. Clinically she is improved on the gabapentin.
2. Possible symptoms of connective tissue disease including arthralgias, myalgias, fatigue, subjective fevers, reported malar rash, questionable Reynaud's, and dry mouth. We will evaluate further for autoimmune disease, underlying inflammatory arthropathy or myositis or metabolic abnormality.

Id. Dr. Reed further noted that she discussed the "probable diagnosis of fibromyalgia" with Petitioner. *Id.* Dr. Reed ordered labs for CK, rheumatoid factor, anti-SSA and SSB antibodies and 25-hydroxy vitamin D level. *Id.*

Petitioner returned to SMCHC on July 1, 2015 for a follow-up. Ex. 7 at 8. The HPI indicates that Petitioner was being followed by a rheumatologist and was noted to have fibromyalgia and a Vitamin D deficiency. *Id.* Under review of symptoms, her physician indicated that she had "good general[] health lately." *Id.* at 10.

On October 8, 2015, Petitioner returned to SMCHC for a follow-up on her labs. Ex. 7 at 2. During this visit, Petitioner reported "brief episodes of palpitations, dizziness, lightheadedness, and facial flushing and chest pain lasting a few seconds about 5 times a day and more if stressed. [H]ad 24 hour holter done and did not capture any abnormalities." *Id.* She received a referral to cardiology. *Id.*

Petitioner had an echocardiogram performed and underwent an exercise stress test on November 12, 2015. Ex. 8 at 7. She visited Dr. Achenkunju at Heart Care Services on December 2, 2015 to discuss her test results. *Id.* Her echo was unremarkable, and the stress test show "upsloping ST depressions" which was "suggestive of inferolateral wall ischemia." *Id.* at 7, 9.

On January 21, 2016, Petitioner returned to Dr. Achenkunju. Ex. 8 at 1. She continued to have some chest pain and palpitations. *Id.* Her physical exam was normal. *Id.* at 4. Dr. Achenkunju assessed her with atypical chest pain, benign essential hypertension, and intermittent palpitations. *Id.* at 5. He instructed Petitioner to follow-up in six months or as needed. *Id.*

III. Expert Reports

A. Petitioner's Expert – Dr. Thomas Zizic - First Expert Report

In support of her claim, Petitioner offered the medical expert opinion of Dr. Thomas Zizic. Although Petitioner did not file Dr. Zizic's CV into the record, Dr. Zizic summarized his qualifications at the beginning of his first expert report. In addition, I am familiar with Dr. Zizic's qualifications due to his work on the case of *Moran v. Sec'y of Health & Hum. Servs.*, No. 16-538V, 2021 WL 4853544 (Fed. Cl. Spec. Mstr. Oct. 4, 2021). Dr. Zizic has been an Associate Professor of Medicine at Johns Hopkins University School of Medicine in Baltimore, Maryland for approximately thirty years. Ex. 9 at 1 (hereinafter "First Zizic Rep."). He was also the Associate Director of the Rheumatic Disease Unit for Johns Hopkins at the Good Samaritan Hospital from approximately 1973 to 1982. *Id.*

Dr. Zizic is a founding fellow of the American College of Rheumatology. First Zizic Rep. at 1. He received his medical degree from Johns Hopkins University School of Medicine in 1965 and completed an internship and residency in internal medicine at Johns Hopkins University Hospital Center from 1965 to 1967. *Id.* at 1-2. From 1967 through 1969, Dr. Zizic served as a flight surgeon at the School of Aerospace Medicine at Brooks Air Force Base in San Antonio, Texas and from 1969 to 1971, he served as Post-Doctoral Fellow in Rheumatology at Johns Hopkins. *Id.* at 2.

In 1971, Dr. Zizic became an Instructor of Medicine and has remained on the faculty at Johns Hopkins University School of Medicine. First Zizic Rep. at 2. For the first seventeen years, he was full-time faculty, after which he began serving part time upon entering into private practice in rheumatology. *Id.*

Dr. Zizic's research has included osteoarthritis, osteoporosis, osteonecrosis, the study of connective tissue diseases including damage to cartilage and tendons and such disorders as systemic lupus erythematosus, polymyalgia rheumatica, rheumatoid arthritis, polymyositis and a variety of other diseases that have an immunologic basis. First Zizic Rep. at 2. Dr. Zizic has published approximately 100 articles and abstracts as well as several dozen chapters in medical textbooks. *Id.*

In Dr. Zizic's first report filed on October 27, 2016, he began by summarizing Petitioner's medical history. First Zizic Rep. at 3-14. In his analysis of the case, Dr. Zizic began by opining

that Petitioner meets the American College of Rheumatology ("ACR") criteria for systemic lupus erythematosus. *Id.* at 14. Dr. Zizic specifically opined that Petitioner met criteria i, iii, iv, and v, which represent photosensitivity, arthritis, oral ulcers, and malar rash, respectively. *Id.* at 14-15.

Dr. Zizic provided an overview of the innate and adaptive immune systems. First Zizic Rep. at 15-16. He explained that humans have over ten billion B and T cell receptors, randomly developed and unique to each individual. *Id.* at 17. Some have an effective immune response to vaccinations while others have no or an inadequate response. *Id.* Dr. Zizic stated that because of this vast repertoire and genetic heterogeneity, it is unlikely that even large epidemiologic studies can capture the rare incidents of vaccine-induced autoimmunity. *Id.* He then opined that "in genetically susceptible individuals, vaccination can result in the unmasking of an autoimmune disease triggered by the immunization." *Id.* at 16.

Dr. Zizic noted that "the top four autoimmune diseases (AID) reported after vaccination are Guillain-Barre syndrome, rheumatoid arthritis, systemic lupus, or ITP." First Zizic Rep. at 16. He then noted that it is understandably improbable "that even large epidemiologic studies will not have sufficient power to capture these infrequent patient-specific events." *Id.* at 17. Dr. Zizic opined that the majority of people who are vaccinated do not go on to develop autoimmune disease, but among the subset that do, "only the unlucky subjects who have naive or memory cells in their repertoire that cross-react with antigens in the specific vaccine" develop disease. *Id.* He further stated that influenza antigens in the flu vaccine lead to cross reactivity and molecular mimicry to self-antigens that result in breaking tolerance. *Id.*

Dr. Zizic went on to describe research that demonstrates molecular mimicry between the influenza virus and a portion of the type II collagen ("CII") molecule as a mechanism by which the influenza vaccine can trigger autoimmunity. First Zizic Rep. at 17. An article by Sekine et al. highlights the importance of CII in RA pathogenesis. Sekine et al., *Type II collagen is a target antigen of clonally expanded T cells in the synovium of patients with rheumatoid arthritis*, 58 ANN RHEUM DIS 446-50 (1999). It has been shown that a CII peptide (256-271) contains epitopes that can trigger an RA-specific T cell response. Diab et al., *Human collagen II peptide 256-271 preferentially binds to HLA-DR molecules associated with susceptibility to rheumatoid arthritis*, 49 IMMUNOGENETICS 36-44 (1999). Dr. Zizic explained that influenza virus hemagglutinin 308-317 peptide shares a similar three-dimensional structure with CII 256-271 for purposes of molecular mimicry and can thus bind HLA-DR4/1 molecules with higher affinity. First Zizic Rep. at 18. Dr. Zizic stated that "[t]hus, it is logical that the influenza virus hemagglutinin peptide acts in a similar mean as the CII peptide, with respect to induction of rheumatoid arthritis." *Id*.

Dr. Zizic concluded that, with respect to the first prong of *Althen*, Petitioner's vaccination triggered activation of B and/or T lymphocytes through "molecular mimicry, cross-priming, immune complex formation or a combination of these, which because of Angelia Andrews' genetic susceptibility, resulted in autoimmunity and the development of SLE." First Zizic Rep. at 18. As to the second prong, Dr. Zizic explained that, (1) Petitioner did not have any symptoms prior to her vaccination, and (2) her diagnosis was contemporaneously documented. *Id*. Finally, with respect to prong three, Dr. Zizic opined that the petitioner developed symptoms within days after the influenza vaccination and "and developed the remainder of her SLE manifestations over the next 12 months." *Id*. He opined this demonstrated an evolving process initiated by the flu vaccine,

Id. It is Dr. Zizic's opinion, "that the facts of this case support the view that Ms. Angelia Andrews, more likely than not, developed new onset of SLE as a result of the influenza vaccination." *Id.*

B. Respondent's Expert – Dr. Robert W. Lightfoot, Jr. - First Expert Report

Dr. Lightfoot received both his undergraduate and medical degrees from Vanderbilt University. *See* Ex. B at 1 (hereinafter "Lightfoot CV"). He performed residencies at Columbia Presbyterian Medical Center and Vanderbilt University Hospital. Lightfoot CV at 1. He then completed a fellowship in rheumatology at Columbia University College of Physicians and Surgeons. *Id.* He is board certified in both internal medicine and rheumatology. *Id.* Dr. Lightfoot has authored or co-authored more than 70 articles and book chapters, which are listed on his CV. *See Id.* at 16-23.

Dr. Lightfoot noted that Petitioner had an immediate local reaction to her vaccinations that he described as an "Arthus-type reaction." Ex. A at 6 (hereinafter "First Lightfoot Rep."). Dr. Lightfoot noted that "Arthus reactions occur when antigens are injected into tissue already containing antibody to those antigens." *Id.* at 7. Because it is likely that Petitioner had prior flu vaccines, he stated that the antigens met with pre-existing antibodies which in turn induces inflammation. *Id.* This can be expressed as fever, elevated WBC, malaise, local swelling and erythema. *Id.* Dr. Lightfoot noted that Arthus symptoms are short lived and noted that "petitioner's symptoms of local pain, swelling and redness shortly subsided, not to return." *Id.*

Dr. Lightfoot remarked that none of Petitioner's medical providers noted malar rash during their examinations of her. First Lightfoot Rep. at 7. He further noted that her rashes were described as "transient". *Id.* He opined that "Lupus rashes are lasting (at times permanent, indurated, scaly or scarred) they do not occur transiently off and on during the day." *Id.*

Similarly, Dr. Lightfoot noted that while Petitioner complained of tongue ulcers, none were ever noted during a medical examination. First Lightfoot Rep. at 7.

Dr. Lightfoot noted that all of Petitioner's autoantibody testing was negative. First Lightfoot Rep. at 8. Specifically, her rheumatoid factor and ANA were negative. *Id.* Dr. Lightfoot stated that her anti-SSA and anti-SSB were presumably negative, as he could not find those results in Petitioner's medical records. *Id.* Importantly, Dr. Lightfoot stated, "Ninety-five percent of SLE patients have a positive ANA, and of the remaining 5%, approximately 60% have anti-SSA antibodies. So only 3% of the SLE population would have both a negative ANA and anti-SSA, and have their SLE diagnosed on non-serological grounds alone." *Id.*

Dr. Lightfoot made the point that none of Petitioner's treating physicians diagnosed her with SLE. First Lightfoot Rep. at 8. Although Dr. Reed mentioned the possibility of a connective tissue disease, she also discussed the probable diagnosis of fibromyalgia. *Id.*

Dr. Lightfoot further noted that there was only one medical encounter where objective evidence of swelling was noted on exam. First Lightfoot Rep. at 8. Dr. Reed documented that Petitioner experienced "swelling in the knees ankles and feet which goes down with elevation overnight." *Id.* Dr. Lightfoot noted that swelling in SLE does not go down with elevation, but he

remarked that edema does. *Id.*

Fibromyalgia is often accompanied by chronic fatigue syndrome. First Lightfoot Rep. at 8. Petitioner experienced symptoms of fatigue prior to her vaccination. *Id.* Additionally, Petitioner's "difficulty with forgetfulness, word-finding and enunciation are classical features in fibromyalgia, often called 'fibrofog." *Id.*

In responding to Dr. Zizic's report, Dr. Lightfoot evaluated Dr. Zizic's application of the American College of Rheumatology's Classification Criteria for SLE to Petitioner's case. First Lightfoot Rep. at 9. He opined as follows:

> The **first** is Malar rash, requiring "Fixed erythema…" not fleeting redness sometimes noticed by others, but by none of the clinicians in petitioner's case.
> The **second** is "Discoid rash," raised patches with keratotic scaling, which has not been seen in petitioner.
> The **third** is "Photosensitivity" with rash observed either by the patient or by physician. (Petitioner may meet this criterion.)
> The **fourth** is "Oral ulcers"… "observed by a physician." Petitioner's alleged ulcers have never been recorded as seen by her examiners.
> The **fifth** is "Non-erosive arthritis" in two or more peripheral joints. Petitioner once had a swollen 1st MTP joint observed once by a clinician. Her occasional swelling in the lower extremities relieved by elevation do not count, for reasons I have mentioned above. On one occasion petitioner has been said to have tenderness across the MTP rows, but "no synovitis (i.e., swelling) in the same exam. Petitioner in my view does not meet this criterion.
> The **sixth** is pleuritis or pericarditis. On the multiple physical exams, the chest x-ray and the extensive cardiology tests, no evidence for either of these has been found.
> The **seventh through ninth** include: "Renal Disorder" manifested by heavy proteinuria or cellular casts in the urine, which petitioner lacks; "Neurologic Disorder" including seizures or psychosis, neither of which petitioner has; "Hematologic Disorder" with low red blood cells, white blood cells or platelets, none of which petitioner has had.
> The **tenth** is "Immunologic Disorder," including positive tests for anti-DNA, anti-Smith or anti-phospholipid antibodies, for none of which has petitioner been tested, probably because none of the clinicians, including the Rheumatologist, thought there was any likely chance petitioner's disease was lupus.
> The **eleventh**, and final criterion is "Positive antinuclear antibody," about which I have already commented.

First Lightfoot Rep. at 9-10. Dr. Lightfoot opined that Petitioner "may" meet one of these strict criteria (photosensitivity). *Id.* at 10.

With respect to Petitioner's molecular mimicry theory, Dr. Lightfoot noted that "apparently there exists no evidence to date that such mimicry exists for vaccines and lupus." First Lightfoot Rep. at 10.

Dr. Lightfoot concluded his report by stating he believes that "petitioner's primary (and pre-existing) symptomatic disorder all along was fibromyalgia, and that she fails to meet the criteria for SLE, as apparently did her rheumatologist and all her primary and other specialist providers." First Lightfoot Rep. at 11.

C. Dr. Zizic's Second Expert Report

In his second report filed on August 27, 2019, Dr. Zizic responded to Dr. Lightfoot's first report. Ex. 10 (hereinafter "Second Zizic Rep."). He also responded to questions that I posed. First, he made clear that he disagrees with Dr. Lightfoot that Petitioner had fibromyalgia, pre-existing or otherwise. Second Zizic Rep. at 1. Dr. Zizic discussed the Multi-center Criteria Committee of the American College of Rheumatology that developed the classification criteria for fibromyalgia. *See* Wolfe F, Smythe HA, Yunus MB, et al. *The American College of Rheumatology 1990 criteria for the classification of fibromyalgia. Report of the multicenter criteria committee*, 33 ARTHRITIS & RHEUMATISM, 2, 160-72, 1990 (filed as Ex. 10, Reference 1).

Dr. Zizic quoted from the report, noting "When the criterion of widespread pain was combined with that of 11 of 18 tender points (defined as mild or greater tenderness), which was the variable that had the best overall sensitivity, specificity, and accuracy, the best diagnostic criteria were identified." Second Zizic Rep. at 1. He further noted that in Dr. Reed's June 24, 2015 consultation, Petitioner only had 8/18 tender points for fibromyalgia present on examination. *Id.* at 2. Dr. Zizic opined that "[t]his does not meet the most discriminating criteria for the diagnosis/classification of fibromyalgia namely pain in 11 or more of 18 tender points sites on digital palpation." *Id.*

Dr. Zizic stated that Petitioner in this case did not undergo immunopathological testing for SLE, with the exception of fluorescence antinuclear antibody (FANA) testing, which was negative. Second Zizic Rep. at 3. He agreed with Dr. Lightfoot that 90-95% of patients with SLE will have a positive ANA, however, he caveated this statement, noting that this positive result would only need to occur at some point during the course of their illness. *Id.* He noted that "[t]he autoantibodies as well as the clinical manifestations of SLE consist of a dynamic process such that both antibodies and clinical course wax or wain and vary with time and/or treatment." *Id.* Dr. Zizic also took issue with Dr. Lightfoot's assumption that the anti-SSA and anti-SSB tests ordered by Dr. Reed were negative. *Id.* Dr. Zizic opined it was more likely these tests were not run, due to the fact that they are essentially diagnostic for SLE and no results were reported in the medical records. *Id.*

Dr. Zizic also disputed Dr. Lightfoot's assessment of the SLE diagnostic criteria as applied to Petitioner's case. He opined as follows:

> 1) *Photosensitivity. Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation.*
> As noted by Dr. Melinda Reed on June 24, 2015: "besides the rash on her face, she has occasional red bumps on her arms that is. [sic] She thinks this may be brought on by sun exposure."

> 2) *Arthritis. Non-erosive arthritis involving two or more peripheral joints, characterized by* ***tenderness, swelling****, or effusion*. (Emphasis added).
> On 3/22/15, Dr. Smart noted **swelling** of the right first MCP joint. On 6/24/15, Dr. Reed noted **tenderness** of the MTP joints. (Emphasis added)
> *3) Malar rash. Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds.*
> On 3/22/15, Dr. Smart notes "Once cheeks became very red with family history of lupus." The duration of this episode is not noted therefore is not possible to determine whether it was "fixed" for a period of time or not. On 4/3/15, Dr. Smart notes "Swelling of the right first MCP joint, very red cheeks with a family history of lupus." Along with the swelling in the thumb joint, the red cheeks could be observational, although, it is not entirely clear. On 4/22/15 Dr. Smart records indicate "malar rash noted". On 6/24/15, Dr. Melinda Reed, fever." In Dr Read's Impression: "Symptoms of connective tissue disease: arthralgias, myalgia, fatigue, subjective fever, reported malar rash, questionable Raynaud's and dry mouth." Although it is not definitely established that a fixed rash was present, the repeated mention of malar rash over time, strongly suggest it was not a transient phenomenon.
> *4) Oral ulcers. Oral or nasopharyngeal ulceration, usually painless, observed by a physician.*
> On 6/24/15, Dr. Melinda Reed rheumatologist noted: "She has occasional painful sores on her tongue." Technically, this doesn't qualify since it wasn't observed by a physician. However, she was only seen once by a rheumatologist who would be looking for oral or nasopharyngeal ulcers. When in doubt, most physicians would believe the patient.

Second Zizic Rep. at 3-4. Based on this, Dr. Zizic opined that Petitioner met 4/11 of the SLE diagnostic criteria. *Id.* at 4. In addition to this, Dr. Zizic noted that Petitioner had other symptoms consistent with SLE, such as "fatigue, myalgias, headache, hesitancy with speech, difficulty with word finding, memory difficulty, problems with concentration, slurring of speech, possible Raynaud's phenomenon." *Id.* He also noted that Petitioner's C-reactive protein was elevated, which is "characteristic" of the inflammation seen in SLE but is not seen in fibromyalgia. *Id.*

D. Dr. Zizic's Third Expert Report

Dr. Zizic filed his third expert report in response to my order that he answer one of my questions that was not addressed in his second report. Specifically: "Do you agree that the swelling of inflammatory arthritis (such as SLE) does not go down with elevation overnight?" Ex. 11 (hereinafter "Third Zizic Rep."). In response to this question, Dr. Zizic stated that if the inflamed joints include the knees, ankles, or feet, then they may improve with elevation of the legs. Third Zizic Rep. at 1. Dr. Zizic contrasted the arthritis in SLE with the arthritis in rheumatoid arthritis (RA), noting that "[i]n SLE, the arthritis is much more transient and migratory." *Id.* He ultimately concluded that "[t]he combination of elevation and rest of the joints at night, along with fluctuating inflammation can cause the swelling of lupus arthritis to go down with elevation overnight." *Id.*

E. Dr. Lightfoot's Second Expert Report

In his second expert report, Dr. Lightfoot responded to Dr. Zizic's second and third reports. Ex. D (hereinafter "Second Lightfoot Rep."). Dr. Lightfoot first addressed Dr. Zizic's position that joints swollen from inflammation could go down to normal with overnight elevation. Second Lightfoot Rep. at 1. He opined that all swelling decreases overnight, even in individuals who do not have rheumatologic disease. *Id.* In the vast majority of patients who experience swelling that goes down in the morning, "no arthritis of the lower extremity joints is ultimately found." *Id.*

Dr. Lightfoot noted that "arthralgia" is defined as a painful, non-swollen joint and can result from many different conditions. Second Lightfoot Rep. at 2. He further stated that a painful, enlarged joint is more likely to have some form of arthritis. *Id.* Dr. Lightfoot remarked that Dr. Reed (a rheumatologist) found that Petitioner had one swollen metacarpal-phalangeal (MCP) joint, but no additional joint abnormalities. *Id.*

Dr. Lightfoot found it significant that Dr. Reed indicated "*Possible* symptoms of connective tissue disease, including *reported* malar rash, *questionable* Raynaud's and dry mouth." [italic emphasis mine] "Discussed probable diagnosis of fibromyalgia with the patient." Second Lightfoot Rep. at 2. Dr. Reed also stated that she "Discussed importance of proper sleep hygiene, controlling psychiatric issues and regular exercise regimen." *Id.* Dr. Lightfoot noted that all of these are classic treatments for fibromyalgia and not for SLE. *Id.*

Dr. Lightfoot stated that since his last report, the European League Against Rheumatism/ American College of Rheumatology Classification Criteria for Systemic Lupus Erythematosus were published in 2019. Second Lightfoot Rep. at 2.

Dr. Lightfoot noted that 0.05% of the U.S. population (1 in 2,000) has SLE. Second Lightfoot Rep. at 2. Of those with SLE, 95% of them have a positive antinuclear antibody (ANA) test. *Id.* DR. Lightfoot stated that ".048% of the general population have SLE with a positive ANA (1 in 2,083). Therefore, 0.002% have SLE with a negative ANA, or 1 in 50,000)." *Id.* Additionally, of the 5% of SLE patients who have a negative ANA, 60% have a positive anti-SSA. *Id.* Dr. Lightfoot noted that this is the likely reason Dr. Reed ordered the anti-SSA testing in Petitioner's case. *Id.*

The 2019 EULAR/ACR Criteria for the Classification of SLE resulted from the collaboration of two international rheumatology organizations. Second Lightfoot Rep. at 2. This cohort determined that arthralgias and fatigue "were less common in SLE patients than in controls." *Id.* at 3. They also determined that ANA positivity was present in 97.8% of SLE patients. *Id.* Based on this finding, these experts determined that ANA positivity should be included as a criterion in the diagnosis of SLE. *Id. See* Aringer et al., *2019 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Systemic Lupus Erythematosus,* 71 ARTHRITIS & RHEUMATOLOGY 9, 1400-12, 2019, (filed as Ex. E) (hereinafter "2019 EULAR/ACR Criteria").

Dr. Lightfoot highlighted that Petitioner's ANA was negative. Second Lightfoot Rep. at 3. Although Dr. Zizic opined that an additional test may have been positive, Dr. Lightfoot noted that Dr. Zizic's assertion is speculative. *Id.*

With respect to cutaneous lesions, Dr. Lightfoot opined that they must be observed by a clinician. Second Lightfoot Rep. at 3. He further noted that "subjunctive characteristics required specific qualities of the rash, either clinical or histological, to distinguish SLE rashes from those that might occur in anyone." *Id.* Dr Lightfoot stated that Dr. Reed did not note a rash on exam. *Id.* Dr. Lightfoot further stated that "'Transient flushing' of the cheeks in sunlight is so common a false positive in my non-lupus patients, that neither I nor the EULAR/ACR committee count it toward the diagnosis of SLE." *Id.*

Dr. Lightfoot stated that oral lesions must be observed by a clinician. Second Lightfoot Rep. at 3. Petitioner's oral lesions were not observed on exam. *Id.*

Finally, Dr. Lightfoot discussed Petitioner's joint involvement. Second Lightfoot Rep. at 3. The criterion requires "Either synovitis involving 2 or more joints…" or "tenderness in 2 or more joints and at least 30 minutes of morning stiffness." *Id.* Petitioner did not experience synovitis. *Id.* Further, although she did have tenderness across both MTP rows in the feet, there is no indication in the medical records that Petitioner suffered from 30 minutes of morning stiffness. *Id.*

The 2019 SLE criteria require a score of 10 or more. Second Lightfoot Rep. at 4. According to Dr. Lightfoot, "Petitioner does not meet the entry criterion of a positive ANA and scores at most 6 for her musculoskeletal complaints." *Id.* Dr. Lightfoot concluded by opining, consistent with the opinion of Dr. Reed, that Petitioner's likely diagnosis is fibromyalgia. Second Lightfoot Rep. at 4.

III. Applicable Law

A. Petitioner's Burden

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873* (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health*

& Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records of by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*. *Althen* requires that petitioner establish by preponderant evidence that the vaccinations he received caused her injury "by providing: (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." *Id.* at 1278.

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be

considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V 2011 WL 1935813 at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013). *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate

diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See,* e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

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

V. Analysis

Petitioner alleges that her flu vaccination caused her to develop SLE. The first step in analyzing a claim is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1341,1353 (Fed. Cir. 2011). The Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury," and "[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached." *Id.*; *see Broekelschen*, 618 F.3d at 1346 (explaining that "identifying the injury is a prerequisite to the [causation] analysis"). In this case, Petitioner has not demonstrated that she suffered from SLE.

A. Petitioner has not Established that SLE is her Correct Diagnosis

Dr. Zizic references the American College of Rheumatology's Classification Criteria for SLE to opine that Petitioner has SLE. *See* First Zizic Rep. at 15-16; Tan et al., *The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus*, 25 ARTHRITIS AND RHEUMATISM 11, 1271-77 (1982) (filed as Ex. 10 Reference 1) (hereinafter "Tan"). These criteria have been revised since their initial publication. The most current version available at the time Petitioner presented to her rheumatologist was from 1997. *See* First Lightfoot Rep. at 9, 12; reference 1: https://www.rheumatology.org/Portals/0/Files/1997%20Update%20of%201982%20Revised.pdf. (filed as Court Ex. 1001) (hereinafter "1997 ACR Criteria"). In order to be diagnosed with SLE, a person must meet four of the 11 criteria.[5] Tan at 1274; Second Zizic Rep. at 4. Dr. Zizic contends that Petitioner meets the following four criteria:[6]

[5] The 1982 ACR Criteria contain the following statement: "The proposed classification is based on 11 criteria. For the purpose of identifying patients in clinical studies, a person shall be said to have systemic lupus erythematosus if any 4 or more of the 11 criteria are present, serially or simultaneously, during any interval or observation." Tan at 1274. Although the 1997 ACR Criteria do not contain the same statement, I have presumed it is also true for this revision based on the representations of the experts.

[6] Because Dr. Zizic does not assert (nor does the record support) that Petitioner has met any of the other seven criteria, I have not analyzed them.

Criterion	Definition
Malar Rash	Fixed erythema, flat or raised, over the malar eminences, tending to spare the nasolabial folds
Photosensitivity	Skin rash as a result of unusual reaction to sunlight, by patient history or physician observation
Oral ulcers	Oral or nasopharyngeal ulceration, usually painless, observed by physician
Nonerosive arthritis	Involving 2 or more peripheral joints, characterized by tenderness, swelling, or effusion

1997 ACR Criteria at 1. I have discussed these criteria in the order of their significance to this decision.

1. Oral Ulcers

With respect to Petitioner's purported oral ulcers, Dr. Zizic stated "Technically, this doesn't qualify since it wasn't observed by a physician. However, she was only seen once by a rheumatologist who would be looking for oral or nasopharyngeal ulcers. When in doubt, most physicians would believe the patient." Second Zizic Rep. at 4. Although Petitioner did not meet this criterion based on its plain language (the oral ulcers must be observed by a physician), Dr. Zizic nevertheless went on to state, "Angelia Andrews fulfills the requisite 4 of 11 criteria for the classification of SLE." *Id.* I find the opinion of Dr. Lightfoot that Petitioner does not have SLE to be persuasive. Because a clinician did not observe Petitioner to have oral ulcers, in accordance with Dr. Lightfoot's opinion, I find she has not satisfied four of the 11 criteria. For the sake of completeness, I will briefly address the remaining three criteria.

2. Malar Rash

The 1997 ACR Criteria require that a malar rash be fixed. Petitioner's medical records do not indicate that she had a fixed malar rash; instead they suggest transient redness. (*See* Ex. 7 at 16; medical visit on March 18, 2015 noting, "once cheeks became very red"; Ex. 7 at 10; medical visit from April 22, 2015 noting that Petitioner's "face will turn red alot [sic] since last visit with others commenting on it."; Ex. 5 at 1; medical visit from June 24, 2015 indicating Petitioner described "redness on her cheeks where they will feel sunburnt," and "she will feel like she has a fever although she has not checked it."). No treating physician ever documented that Petitioner had a rash. Dr. Lightfoot stated that "Lupus rashes are lasting (at times permanent, indurated, scaly or scarred) they do not occur transiently off and on during the day." First Lightfoot Rep. at 7. Dr. Zizic also acknowledged this issue. He stated: "Although it is not definitely established that a fixed rash was present, the repeated mention of malar rash over time, strongly suggest it was not a transient phenomenon." Second Zizic Rep. at 4. I do not find this argument to be persuasive. It is Petitioner's burden to establish her diagnosis by preponderant evidence. There is not preponderant evidence that Petitioner had a malar rash that was fixed.

3. Photosensitivity

When Petitioner visited Dr. Reed, she reported experiencing "occasional red bumps on her arms …[that] [s]he thinks … may be brought on by sun exposure." Ex. 5 at 1. Although no physician observed these red bumps, this particular criterion only requires support by "patient history *or* physician observation" (emphasis added). 1997 ACR Criteria at 1. Accordingly, Petitioner has satisfied this criterion based on the history she provided to Dr. Reed.

4. Nonerosive Arthritis

Dr. Lightfoot contends that Petitioner does not meet this criterion. He stated:

> Petitioner once had a swollen 1st MTP joint observed once by a clinician. Her occasional swelling in the lower extremities relieved by elevation do[es] not count, for reasons I have mentioned above. On one occasion petitioner has been said to have tenderness across the MTP rows, but "no synovitis["] (i.e., swelling) in the same exam.

First Lightfoot Rep. at 9. This criterion does not require tenderness, swelling, *and* effusion, but instead indicates that tenderness, swelling, *or* effusion is sufficient. In her physical examination, Dr. Reed noted "[b]ilateral feet with tenderness throughout the MTP joints." Ex. 5 at 2. Dr. Zizic has opined that this finding is sufficient to allow Petitioner to satisfy this criterion. I agree with this assessment.

Because she has only met two of the 11 1997 ACR criteria, Petitioner has not provided preponderant evidence in support of an SLE diagnosis. This finding is consistent with the opinion of Petitioner's treating rheumatologist, Dr. Melinda Reed. Dr. Reed did not diagnose Petitioner with SLE, but instead noted that she "discussed probable diagnosis of fibromyalgia with the patient." Ex. 5 at 2. Dr. Reed further noted "[p]ossible symptoms of connective tissue disease." *Id.* She indicated that she would "evaluate further for autoimmune disease." *Id.* She ordered labs, which included CK, rheumatoid factor, and anti-SSA and SSB antibodies, and noted "[w]e will notify the patient of lab results and if any concerns or need to follow up in our clinic." *Id.* The results of these labs are not included in the medical records. Dr. Lightfoot assumed that Petitioner's results were negative, because Dr. Reed did not follow up on these results. First Lightfoot Rep. at 8. Dr. Zizic contended that this assumption was "not justifiable." First Zizic Rep. at 3. It is not necessary for me to resolve this particular question, as there is no evidence in the record that Petitioner tested positive for anti-SSA or anti-SSB antibodies.

This significance of this lack of evidence for anti-SSA or SSB antibodies is due to the fact that Petitioner's ANA results were negative. Ex. 7 at 31. 95% of people with SLE have a positive ANA. Second Lightfoot Rep. at 2. Further, of the 5 percent of people who have SLE and a negative ANA, 60% of that subset has a positive SSA antibody result. *Id.*

The importance of the positive ANA in diagnosing SLE is highlighted by the 2019 EULAR/ACR Criteria, which represent updated classification criteria for SLE "jointly supported by the European League Against Rheumatism (EULAR) and the American College of

Rheumatology (ACR)." 2019 EULAR/ACR Criteria at 1400. Although not applicable to this case, the 2019 EULAR/ACR Criteria require "ANA at a titer of ≥1:80 on HEp-2 cells or an equivalent positive test (ever)" as an *entry criterion*. *Id.* at 1409 (emphasis added). These criteria go on to note that if ANA is not positive at this level, "do not classify as SLE". *Id.*

The fact that Petitioner's ANA test was negative coupled with the fact that there is no evidence she had a positive anti-SSA result constitutes persuasive evidence that Petitioner does not have SLE. Dr. Lightfoot's analysis of the 1997 Criteria is also strong evidence that SLE is not Petitioner's correct diagnosis, as is the opinion of Petitioner's treating rheumatologist. Because Petitioner has not preponderantly established that she had SLE, further analysis is unnecessary. However, for the sake of completeness, I will briefly analyze the *Althen* prongs.

B. *Althen* Prong One

In the context of the Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Hum. Servs.*, 109 Fed. Cl. 421, 441 (Fed Cir. 2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359. For the reasons discussed in detail below, I find that Petitioner has not provided a sound and reliable medical theory causally connecting her flu vaccination to SLE.

Petitioner presented very thin evidence with respect to the first *Althen* prong. In his first expert report, Dr. Zizic generally discussed research that he states "demonstrates molecular mimicry occurring with respect to a portion of the influenza virus molecule and a portion of type II collagen…" First Zizic Rep. at 17. Dr. Zizic went on to cite several articles concerning type II collagen and rheumatoid arthritis ("RA"). *See* Sekine et al., *Type II collagen is a target antigen of clonally expanded T cells in the synovium of patients with rheumatoid arthritis*, 58 ANN RHEUM DIS 446-50 (1999); Diab et al., *Human collagen II peptide 256-271 preferentially binds to HLA-DR molecules associated with susceptibility to rheumatoid arthritis*, 49 IMMUNOGENETICS 36-44 (1999); Dessan et al., *X-Ray Crystal Structure of HLA-DR4 (DRA*0101, DRB1*0401) Complexed with a Peptide from Human Collagen II*, 7 IMMUNITY 473-81 (1997); Sun et al., *Superior Molecularly Altered Influenza Virus Hemagglutinin Peptide 308-317 Inhibits Collagen-Induced Arthritis by Inducing CD4+ Treg Cell Expansion*, 64 ARTHRITIS & RHEUMATISM 7, 2158-68, 2012 (hereinafter "Sun"); Skinner et al., *Lymphocyte responses to DRl/4 restricted peptides in rheumatoid arthritis, 53* ANN RHEUM DIS, 171-77, 1994 (hereinafter "Skinner").

I note that Dr. Zizic did not present a reasoned explanation as to how these articles support his theory. After citing Sun, he stated: "Thus, it is logical that the influenza virus hamagglutinin [sic] peptide acts in a similar manner as the type II collagen peptide, with respect to the induction of rheumatoid arthritis." First Zizic Rep. at 18.

I have addressed Dr. Zizic's theory (with respect to RA) in another Vaccine Program case. *See Moran*, 2021 WL 4853544. In that case, where Petitioner alleged that the flu vaccine caused him to develop RA, Dr. Zizic opined that influenza virus hemagglutinin 308-317 peptide shares a similar three-dimensional structure with CII 256-271 and can thus bind HLA-DR4/1 molecules,

resulting in molecular mimicry. *Id.* at *8. In *Moran*, I also considered much of the medical literature filed in this case and concluded that it did not support Petitioner's prong one theory.[7] I reach the same result in the present case.

First, I note that Dr. Zizic has not explained how the cited medical literature supports his theory that Petitioner's flu vaccine caused her to develop SLE. Second, and relatedly, although Dr. Zizic concluded that Petitioner's vaccination triggered activation of B and/or T lymphocytes through "molecular mimicry, cross-priming, immune complex formation or a combination of these, which because of Angelia Andrews' genetic susceptibility, resulted in autoimmunity and the development of SLE" (First Zizic Rep. at 18), it is unclear how the articles he referenced, which concern RA, apply to Petitioner's alleged injury of SLE. *See Moberly*, 592 F.3d at 1322 (holding that a petitioner "must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Special masters are not required to accept the *ipse dixit* of program experts. Dr. Zizic's conclusions in the present case amount to little more than that.

I find that Petitioner's has not presented preponderant evidence demonstrating that her proffered prong one theory, molecular mimicry, is a sound and reliable theory showing the flu vaccine can cause SLE.

C. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong.

1. Petitioner's Evidence

The majority of Dr. Zizic's analysis with respect to the second *Althen* prong is contained in the following paragraph:

[7] In *Moran*, Dr. Zizic described a specific viral antigen (influenza virus hemagglutinin 308-317 peptide) and how it can bind to HLA-DR4. He also identified the collagen II autoantigen (CII 256-271) which can also bind to HLA-DR4. The influenza virus hemagglutinin 308-317 peptide shares a similar structure with CII 256-271 and both can bind to HLA-DR4 molecules. Based on this, Dr. Zizic opined that "it is logical that the influenza virus hemagglutinin peptide acts in a similar manner as the type II collagen peptide, with respect to the induction of rheumatoid arthritis." Ultimately, I found that the articles cited by Petitioner did not demonstrate that the same T cells can recognize both type II collagen peptide and influenza HA peptide bound to HLA-DR4. Thus, these articles did not support Petitioner's molecular mimicry theory. *Moran*, 2021 WL 4853544, at *24-26.

> With respect to the second requirement, the petitioner did not have any persistent rheumatic symptoms prior to vaccination. There is nothing in the medical records to support any pre-existing autoimmune disease, nor any inflammatory form of arthritis, nor anything to suggest SLE. The history subsequent to immunization was contemporaneously documented as manifestations compatible with SLE. Thus, it is my opinion that this is a logical sequence of cause (the influenza vaccine was the only perturbation to her immune system around the time of illness onset) and the effect (the development of SLE). There is an absence of any other good explanation for a triggering event.

First Zizic Rep. at 18. In essence, Dr. Zizic has opined that Petitioner did not have SLE before her flu vaccine, she developed SLE after her flu vaccine, and there is no explanation for Petitioner's condition, so the influenza vaccine *did cause* Petitioner's SLE. The Federal Circuit in *Capizzano* noted that "[t]he second prong of the *Althen* ... test is not without meaning." *Capizzano*, 440 F.3d at 1327. Indeed, in *Althen*, the Court stated: "Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278.

2. Petitioner's Post-Vaccine Reaction

Petitioner contends that she experienced an immediate reaction to one or both of her vaccines administered on August 2, 2014. This contention is supported by the medical records and by the opinions of Petitioner's treating physicians.

On August 3, 2014, Petitioner visited the Ozark Medical Center ER with complaints of fever, chills, sweats, "not feeling well", weakness, muscle aches, and "hurts all over". Ex. 4 at 6. She reported that she had received pneumonia and flu vaccines the previous day and thought she was having a "bad reaction". *Id.* The HPI further indicated that Petitioner "had a moderate, painful skin rash consisting of 'redness' located on the left arm." *Id.* The physical exam also noted "moderate erythema, tenderness, and swelling" of the left shoulder. *Id.* Her laboratory work-up showed an elevated WBC count. *Id.* at 9. The reason for exam was listed as "poss[ible] reaction to pneumonia shot." *Id.* at 10. Petitioner was discharged with a direction to visit her primary care provider. *Id.*

Petitioner visited Dr. Hortsman on August 4, 2014. Ex. 3 at 58. During this visit, Petitioner reported constant, moderate arm pain whose onset "has been sudden and has been occurring in a persistent pattern for 2 days." *Id.* Her physical exam was significant for "lateral L upper arm moderate swelling and induration. No sign[s] o[f] cellulitis, very mildly reddened." *Id.* at 59. Petitioner was assessed with a vaccination side effect and was given a Medrol dose-pack. *Id.* at 60.

Dr. Lightfoot opined that Petitioner experienced "an immediate local reaction to her vaccinations, that was almost certainly an Arthus-type reaction." First Lightfoot Rep. at 6. He further noted that "Arthus reactions are transient, and, indeed, petitioner's symptoms of local pain, swelling and redness shortly subsided, not to return." *Id.* at 7. Indeed, the medical records support this conclusion; the records do not reference this reaction after the VAERS report was filed on

August 5, 2014. Additionally, Dr. Zizic did not discuss Petitioner's local reaction to one or more of the vaccines she received and how that that reaction demonstrated her flu vaccine did cause her condition.

Ultimately, Petitioner appears to have experienced a local reaction to one or both of the vaccines she received on August 2, 2014 that resolved shortly thereafter. A diagnosis of SLE requires specific criteria to be met. The existing records show that Petitioner did not meet these criteria. Therefore, the records filed in this case do not support Petitioner's contention that the flu vaccine caused her to develop SLE.

3. Treating Physicians

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

In this case, none of Petitioner's treating physicians diagnosed her with SLE. This is for good reason; as discussed by Dr. Lightfoot, she did not meet the diagnostic criteria for that disease. In fact, her rheumatologist, Dr. Reed, told Petitioner she likely had fibromyalgia and treated her for that condition. Further, Petitioner's treating physicians did not link her condition to her vaccination.[8] The opinion of Petitioner's treating rheumatologist is significant and persuasive. For all these reasons, I conclude that Petitioner has not presented preponderant evidence in support of *Althen's* second prong.

D. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

Although Petitioner developed a local reaction to the vaccine or vaccines she received on approximately August 3, 2014, it is not clear when she developed symptoms associated with what she claims to be SLE. Dr. Zizic opined that "the petitioner developed symptoms within several days after the influenza vaccination, and developed the remainder of her SLE manifestations over the next 12 months. In my opinion, this further suggests an evolving process initiated by the influenza vaccination." First Zizic Rep. at 18. Dr. Zizic did not explain how a local reaction within 24 hours led to the initiation of an adaptive immune response, inherent in his molecular mimicry theory. Further, he did not explain how onset of symptoms in this timeframe was appropriate given

[8] Although several of Petitioner's treating physicians ascribed her signs and symptoms on August 3, 2014 to a vaccine reaction, this reaction was short lived and did not recur.

his theory of causation. Petitioner therefore has not established either element of the timing prong, and thus cannot meet *Althen* prong three.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[9]

IT IS SO ORDERED.

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

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.