In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 24, 2018

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MERYL BRAUN,	*	PUBLISHED
	*	
Petitioner,	*	No. 16-1098V
	*	
v.	*	Special Master Gowen
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision on Entitlement; Ruling on the Record; Influenza ("Flu") Vaccination; Guillain-Barré Syndrome ("GBS") Systemic Lupus Erythematosus ("SLE").
Respondent.	*	
* * * * * * * * * * * * * * *		

Martin J. Rubenstein, Law Office of Martin J. Rubenstein, Staten Island, NY, for petitioner.
Lisa A. Watts, United States Department of Justice, Washington, DC, for respondent.

ENTITLEMENT DECISION[1]

On September 2, 2016, Meryl Braun ("petitioner") filed a claim pursuant to the National Vaccine Injury Compensation Program (the "Vaccine Act" or the "Vaccine Program").[2] Petitioner initially alleged that as a result of receiving an influenza ("flu") vaccination on September 11, 2013, she developed Guillain-Barré Syndrome ("GBS"), with onset approximately 4 months later. Respondent filed a Rule 4(c) report recommending against compensation in part because the onset of GBS was too attenuated from the vaccination. Petitioner then submitted a rheumatologist's expert opinion that her GBS was one component of a systemic lupus erythematosus ("SLE") which began within 24 hours of the vaccination and was caused by the same. Respondent submitted another rheumatologist's opinion disputing both the assessment of SLE and causation. After I tentatively agreed with respondent, petitioner submitted her affidavit and her motion for a ruling on the record. After a full review of the entire record, I hereby **DENY** petitioner's motion for a ruling resolving entitlement in her favor. I

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this decision contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the decision is posted on the court's website, each party has 14 days to file a motion requesting 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). "An objecting party must provide the court with a proposed redacted version of the decision." Id. **If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website without any changes.** Id.

[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 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

hereby find that petitioner has not established that the flu vaccination caused the onset of her undisputed condition, GBS, approximately four months later. Moreover, petitioner has not submitted preponderant evidence to rebut the contemporaneous medical records and establish that her GBS was one part of a larger injury, SLE, which began within 24 hours of the vaccination. Therefore, petitioner is not entitled to compensation and her claim must be dismissed.[3]

I. LEGAL STANDARD[4]

A. Petitioner's Burden of Proof

The Vaccine Act was established to compensate vaccine-related injuries and deaths. Section 300aa-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 & Human 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).

A petitioner must prove that she is entitled to compensation under the Vaccine Program. Petitioner's burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). A petitioner may demonstrate entitlement in one of two ways. The first way is to show that she suffered an injury listed on the Vaccine Injury Table, beginning within the requisite time period set forth on the Table (a "Table injury"), in which case, causation is presumed. 42 C.F.R. § 100.3.

In the present case, petitioner does not allege a Table injury. Thus, petitioner bears the burden of demonstrating actual causation by a preponderance of the evidence. See Cedillo v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); § 300aa-13(a)(1). To do so, petitioner must provide: "(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 the vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The preponderance of the evidence standard requires a petitioner to demonstrate that it is "more likely than not" that the vaccine caused her injury. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n. 2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner

[3] Pursuant to Section 300aa-13(a)(1), in order to reach my decision, I have considered the entire record including all of the medical records, statements, expert reports, and medical literature submitted by the parties. This decision discusses the elements of the record I found most relevant to the outcome.

[4] Decisions of special masters (some of which I cite in this decision) constitute persuasive but not binding authority. Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998). Decisions from the Court of Federal Claims are only binding in the same case on remand. Id. Federal Circuit decisions concerning legal issues are binding on special masters. Guillory v. Sec'y of Health & Human Servs., 59 Fed. Cl. 121, 124 (2003), aff'd 104 Fed. App'x 712 (Fed. Cir. 2004); see also Spooner v. Sec'y of Health & Human Servs., No. 13-159V, 2014 WL 504278, at *7 n. 12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

must demonstrate 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 v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006).

B. Nature of Petitioner's Injury

The Federal Circuit has outlined certain instances in which "identifying [the petitioner's injury] is a prerequisite" to the Althen analysis. Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, n. 3 (Fed. Cir. 2012) (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010)). In Broekelschen, certain treating physicians and the petitioner's expert assessed the petitioner with transverse myelitis, which is inflammatory in nature. Petitioner's expert based his causation opinion on that injury. However, other treating physicians and respondent's expert contended that petitioner had anterior spinal cord artery syndrome, which involves a vascular infarction or other vascular event. Petitioner's expert did not offer an opinion as to whether the vaccination could have caused a vascular injury. The Federal Circuit affirmed the special master's approach of first determining the nature of the injury before turning to the Althen test. Broekelschen, 656 F.3d at 1343. Compare to Contreras v. Sec'y of Health & Human Servs., 107 Fed. Cl. 280, 288 (2012) (reversing a special master's ruling as to the nature of injury when "the parties were unified in their view that the analysis of causation did not require a precise diagnosis of TM [transverse myelitis], GBS, or TM combined with GBS").

C. Fact Evidence

The Vaccine Act requires a special master to consider the record as a whole. The Act also prohibits a special master from ruling in petitioner's favor solely based on her own allegation, "unsubstantiated by medical records or medical opinion." § 13(a)(1).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). Cucuras, 993 F.2d at 1528. This presumption is based on the linked propositions that (1) sick people visit medical professionals; (2) sick people honestly report their health problems to those professionals; and (3) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. Sanchez v. Sec'y of Health & Human Servs., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); Cucuras, 993 F.2d at 1525. Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. Lowrie v. Sec'y of Health & Human Servs., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

When contemporaneous medical records conflict with later accounts (i.e., affidavits or oral testimony), special masters generally give greater weight to the medical records. Murphy v. Sec'y of Health & Human Servs., No. 90-88V, 1991 WL 74931, at *4 (Fed. Cl. Spec. Mstr. April 25, 1991); see also Reusser v. Sec'y of Health & Human Servs., 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) ("written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later").

More recently, the Court of Federal Claims has recognized four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1335 (Fed. Cir. 2014). Later testimony "must be consistent, clear, cogent, and compelling to outweigh medical records prepared for the purpose of diagnosis and treatment." Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998)

In La Londe, the Court provided that the special master should consider all of these possibilities, as part of his or her responsibility to "consider all relevant and reliable evidence contained in the record." Id. at 204 (citing § 12(d)(3); Vaccine Rule 8). See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that a special master's rational determination about whether to afford greater weight to contemporaneous medical records than to later accounts, is reviewed only for an abuse of discretion).

D. Expert Opinions

In Vaccine Act cases, 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 also Cedillo, 617 F.3d at 1339 (citing Terran v. Sec'y of Health & Human 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). In Vaccine Program cases, these factors are used in the weighing of the scientific evidence actually proffered and heard. Davis v. Sec'y of Health & Human Servs., 94 Fed. Cl. 53, 66–67 (Fed. Cl. 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"), aff'd, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the Daubert factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. See, e.g., Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 742–45 (2009).

Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the ipse dixit of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." Snyder, 88 Fed. Cl. at 743 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 146 (1997)). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. Moberly, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

II. EVIDENCE SUBMITTED AND PROCEDURAL HISTORY[5]

A. Contemporaneous Medical Records

At the time in question – late 2013 to early 2014 - petitioner was about 30 years old. She lived in a third-floor walk-up apartment in Hoboken, New Jersey. She was working full-time as a clinical laboratory technologist at New York Presbyterian Hospital ("NYPH") in New York, New York. She was taking classes for a graduate degree at a college in Jersey City, New Jersey. See, e.g., Pet. Ex. 4 at 26. Petitioner's medical history included several minor surgeries to remove foreign bodies. Pet. Ex. 6 at 9, 107. In 2010, she received several acupuncture treatments for neck and shoulder pain and stiffness with radiation from a Dr. Wong. Pet. Ex. 7 at 1-5, 7. On June 18, 2012, she had a routine gynecologic exam, where a diagnosis of polycystic ovarian syndrome ("PCOS") was noted. Pet. Ex. 6 at 106-07. Petitioner received the flu vaccine at her workplace on September 11, 2013. Pet. Ex. 10 at 2. There are no medical records for the next two months.

On November 5, 2013 at approximately 11:30 p.m., petitioner went to the emergency room at Christ Hospital in Jersey City. A nurse recorded: "sudden onset of blurry vision on left eye around 11pm tonight, she had headache earlier today, with lightheadedness, pt took ibuprofen around 2pm today." Pet. Ex. 25 at 11. A doctor recorded that petitioner had seen "a flashing light in the left eye while driving," but her symptoms had resolved by the time she reached the emergency room. Petitioner had no trauma or history but had a history of "floaters." Pet. Ex. 25 at 14. The physical exam was normal. Her eyes were normal. Pupils were equal, round, and reactive to light. Extraocular muscles were intact. Id. at 15. A CAT scan without contrast was normal. Id. at 16. The clinical impression was "pain in eye, migraine with aura." Petitioner was discharged at approximately 1:00 a.m. The nurse recorded that petitioner was to

[5] The evidence submitted and procedural history are organized chronologically to reflect the progression of the case. Petitioner initially alleged that the flu vaccination caused GBS. She later amended her claim to say that the flu vaccination caused her to develop SLE, which included the uncontested diagnosis of GBS. There are also some differences between the contemporaneous medical records, the original petition, and petitioner's later submissions.

follow up with her primary care provider in 1-2 days. Id. at 13. The doctor directed petitioner to follow up with her ophthalmologist the next day. Id. at 15. However, there are no medical records for the next two and a half months.

In January 2014, petitioner reported worsening weakness, tenderness, and stiffness in her shoulders and lower back to Dr. Wong, who treated with acupuncture. Pet. Ex. 7 at 6.[6]

On January 24, 2014, petitioner had an initial evaluation with Dr. Bevelacqua, a sports medicine specialist at NYPH. Dr. Bevelacqua recorded:

> "Meryl Braun is a 30 year old female with no [prior medical history] who presents with 2 weeks of difficulty walking, weakness, numbness, and tingling. On Jan[uary] 12th she went for a 45 mile bike ride and the following day she ro[de] 25 miles. The next day she was sitting and study[ing] for over 10 h[ou]rs and began to feel pain and weakness in her lower extremities. Over the next week she noticed numbness and tingling in her arms and legs. She has been taking Naproxen[7] for the pain without relief. She was brought in by wheelchair today by a coworker. Symptoms are stable but not improving. She rates the pain as a 9/10 aching, crampy, stiff, tight pulling pain. She reports associated numbness or tingling. Last week, she did have some abdominal pain but does not recall any viral illness or respiratory symptoms. She denies shortness of breath. She denies any bowel or bladder changes/ incontinence. She does report feeling like she has the chills. She works in the lab here and took her own bloodwork which is significant for slightly elevated CK 150, LDH 289, AST and ALT in the 60s, and glucose 167. Her Chem 7 is wnl [within normal limits]."

Pet. Ex. 6 at 99-100. On physical exam, Dr. Bevelacqua noted diffuse weakness in both proximal and distal muscle groups and absence of deep tendon reflexes. Id. at 100. Her impression was GBS[8] versus a viral myositis. She referred petitioner to the emergency room at NYPH for admission and further evaluation. Id. at 100.

Petitioner went to the emergency room that same day, where she was evaluated by Dr. Brusen and Dr. Revzhankoo. They recorded that petitioner "was riding bike last fall and did a 45 mile bike ride Jan[uary] 1st and was in bed for a day afterwards. Jan[uary] 12th rode another 45

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[6] The handwritten date could be read as "01/28/2014." It is unlikely that petitioner saw Dr. Wong on the 28th, because she was hospitalized by that time. The record could also be read as January 20, 2014. However, petitioner's affidavit provides that the record is incorrectly dated and that in fact, she saw Dr. Wong on the 21st or 22nd. Pet. Ex. 28 at 6-7.

[7] Naproxen is a non-steroidal anti-inflammatory drug. Dorland's Illustrated Medical Dictionary ("Dorland's"), 32nd Ed. (2012) at 1232.

[8] GBS is described as a "rapidly progressive ascending motor neuron paralysis . . . . [for which] an autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs and face; other characteristics include slight fever, bulbar palsy, absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells." Dorland's at 1832.

miles, and then another 25 the next day. The next day studied 10 hours and gave [boyfriend] a massage, and the next day felt very unsteady on feet with cramps in legs and calves…" Pet. Ex. 4 at 4. Dr. Brusen and Dr. Revzhankoo recorded in their review of systems: "neuro: migraine in November." Pet. Ex. 4 at 5.

That day, January 24, 2014, bloodwork showed high lactate dehydrogenase ("LDH"); high direct and indirect bilirubin; a positive ANA with a titer of 1:160; normal platelets; low red blood cells; high mean corpuscular hemoglobin (MCH); high red cell distribution width (RDW); high CK; and high reticulocytes. Pet. Ex. 2 at 10-11. Haptoglobin was also low. Id. at 8. Cerebrospinal fluid (CSF) analysis showed high protein, lymphocytes, monocytes, and macrophages but a normal white blood cell count. Id. at 7-8.

On January 25, 2014, neurologists Dr. Weimer and Dr. Reilly evaluated petitioner for admission. They recorded:

> "[Petitioner] was in her usual state of health until 12 days prior to admission (Sunday, 1/12), when she went for a 45 mile bike ride with her boyfriend. The next day, she felt great and went for another 25 mile bike ride. The day after (Tuesday, 1/14) she woke up with severe cramping in her bilateral calves and a sensation of fatigue. One day later (1/15), she woke up in the morning and felt that both legs were weak. She tried to stand but had both legs give out from under her. She noted they felt 'wobbly.' At the same time she experienced a new onset the tingling sensation in the dorsa of both feet. As the day wore on she noted some pain and cramping in her calves bilaterally and by the next day noted pain between her shoulder blades she described as a cramping sensation. Over the next few days, her weakness progressed to involve first her distal muscles in her feet, then the proximal muscles in her legs and then distal and proximal muscles in her arms as well. During this period, she noted changes in sensation not only involving her feet but also involving her hands bilaterally which sh[e] characterized as a pins and needles sensation with subjective numbness."

Pet. Ex. 4 at 10-11. The neurologists recorded that "notably, prior to this event [petitioner] had not experienced any acute illness." Petitioner denied prior upper respiratory infection. Id. at 11. The physical examination noted "no rashes visible." Id. at 12. There was diffuse mild weakness in her upper and lower extremities, absent deep tendon reflexes, and decreased sensation to light touch and pin prick. Id. at 12.

As noted above, a lumbar puncture showed elevated CSF protein but a normal white blood count. Pet. Ex. 2 at 7-8. Dr. Weimer recorded that this "albuminocytologic dissociation" was consistent with GBS. Pet. Ex. 4 at 13. He concluded: "Presentation and findings consistent with GBS with moderate weakness. Exercise and mildly increased CK likely not contributory. She reports possibly a bit more strength though IVIG not yet started." Dr. Weimer started petitioner on a five-day course of intravenous immunoglobulin (IVIG) for treatment of her likely GBS. Id.

On January 26, 2014, LDH and direct bilirubin had fallen within their normal ranges. Indirect bilirubin had decreased, but was still high. Platelets had fallen below the normal range. Red blood cells had fallen further below the reference range. MCH and RDW were normal. Pet. Ex. 2 at 4-5.

On January 27, 2014, LDH was slightly above the normal range. Direct bilirubin was normal. Indirect bilirubin had decreased, but was still above the normal range. Platelets and red blood cells had increased slightly, but were still below normal. MCH and RDW had increased to slightly above normal. Haptoglobin was unchanged, still below normal. Pet. Ex. 2 at 4.

On January 27, 2014, another neurologist, Dr. Lewis, recorded: "Relatively straight-forward GBS with history going back two weeks," and "likely demyelinating neuropathy of AIDP[9] variety." Id. at 31. An EMG/ NCS performed on January 27, 2014, further supported the diagnosis of GBS. Id. at 95-96; Pet. Ex. 6 at 94-95.

By January 29, 2014 - the end of the IVIG treatment – petitioner was feeling "much better," but "asking for disability forms to be filled out." Pet. Ex. 4 at 56. She could lift herself out of bed, but had continued weakness. She could take four to five steps without assistance, but her gait was wide and insecure. Id. at 57. On January 30, 2014, petitioner complained of a "mild right-sided headache." She was also "anxious to get out of the hospital." Id. at 58-59. She was transferred to NYPH inpatient rehabilitation with a diagnosis of GBS on February 1, 2014. Id. at 67-70.

On February 2, 2014, platelets and red blood cells had risen to normal ranges. Pet. Ex. 2 at 1-2. However, on the next day, both fell slightly, to below normal. Pet. Ex. 2 at 1. Petitioner received daily physical therapy and occupational therapy sessions until her discharge on February 6, 2014. Pet. Ex. 3.

On April 3, 2014, petitioner had her first neurology follow-up visit with another physician, Dr. Traub. Pet. Ex. 6 at 67-68. In June 2014, petitioner had two acupuncture treatments with Dr. Wong. Pet. Ex. 7 at 6. She also began a second round of outpatient physical therapy and occupational therapy. Pet. Ex. 5. After several months of leave from work, she was cleared to return to the job with modifications and regular breaks. Pet. Ex. 6 at 71.

On July 8, 2014, Dr. Traub recorded that she had resumed bicycling and was working with restrictions. Pet. Ex. 6 at 53-54. On July 21, 2014, she saw a cardiologist, Dr. Tolani, for chest tightness that "occurs randomly, midsternal, lasts a few minutes." Dr. Tolani recorded that petitioner had been "riding her bike up to 20 miles, also does stationary bike for an hour." Petitioner had "unlimited ET [exercise tolerance] and bikes without DOE [dyspnea/ shortness of breath on exertion] or symptoms." Dr. Tolani's assessment was "atypical" chest pain, unlikely

[9] AIDP is an abbreviation for "acute inflammatory demyelinating polyneuropathy." Neil M. Davis, Medical Abbreviations (15th Ed. 2011) ("Medical Abbreviations") at 82. Respondent's expert Dr. Matloubian explained: "There are several variants of GBS with [AIDP] being the most common form, accounting for 85-90% of the cases in the US." Resp. Ex. A at 5.

to be cardiac in origin. Pet. Ex. 6 at 35-38. In August 2014, petitioner was cleared to resume all aspects of her job without modifications. Pet. Ex. 6 at 22-27.

On September 16, 2014, petitioner saw Dr. Bevelacqua for neck pain "she reports began after she became sick" with GBS. Dr. Bevelacqua's impression was "myofascial neck pain." She prescribed a muscle relaxer and referred to physical therapy. Pet. Ex. 6 at 17-18.

On March 10, 2015, Dr. Bevelacqua noted petitioner's complaints of pain in her neck and shoulders. Dr. Bevelacqua recorded that petitioner's "strength was almost back at baseline. She continues to fatigue and has decreased endurance. She continues to have tingling in b/l upper and lower extremities." Dr. Bevelacqua's impression was AIDP with "almost complete recovery aside for decreased endurance and paresthesias[10] in upper and lower extremities." Id. at 11-12.

On November 2, 2015, petitioner called Dr. Traub's office because she "was scared that that she think[s] her symptoms are coming back" and wanted to speak with the doctor. Later that day, Dr. Traub edited the note to add: "increased tinglin[g] in the feet. New insurance. VC10 visit or ER if rapidly worsening." Pet. Ex. 6 at 8.[11]

B. Original Petition

On September 2, 2016, petitioner filed her claim that as a result of the flu vaccination received on September 11, 2013, she developed GBS. The petition provides that she "felt like she was in very good health before and after the flu shot until the symptoms of Guillain-Barré Syndrome developed." Petition at ¶ 6. It addresses petitioner's migraine-like headache and her emergency room visit for the same in November 2013. Id. at ¶ 7. The petition adds: "After the flu vaccine, petitioner became aware of feeling numbness in her feet which she attributed to the effects of riding her bike." Id. at ¶ 9. "On or about January 10, 2014, petitioner felt what she describes as dry heels, like her heels were cracking and felt that her heels couldn't warm up. This continued until about January 14-15, 2014, when she started to develop a sharp pain in the middle of both calves, painful cramping and tightness in the calves, which then gave way to tingling from feet up to calves." Id. at ¶ 10. "Around January 16th or 17th, 2014, petitioner couldn't raise her arms up above her head, her shoulders were weak, her legs felt weak and giving way on steps going down and her legs felt like they would collapse going upstairs and she needed her arms to help go upstairs." Id. at ¶ 11. Petitioner attributed these symptoms to her bike rides and her other commitments. Id. at ¶ 12. The remainder of the petition is consistent with the contemporaneous medical records.

[10] Paresthesia is defined as "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." Dorland's at 1383.

[11] No subsequent records from Dr. Traub have been filed. On April 13, 2017, petitioner filed a status report indicating that she had not seen Dr. Traub (or Dr. Bevelacqua) since November 2, 2015. Status Report (ECF No. 20).

C. Initial Proceedings on the Claim

An initial status conference was held on October 14, 2016, after which petitioner filed additional records and a Statement of Completion. Initial Order (ECF No. 7). On December 16, 2016, respondent filed a status report opposing compensation based on his contention that that the contemporaneous medical records documented that the "onset of GBS was on January 12, 2014, four months after the flu vaccin[ation], which is outside of a medically acceptable timeframe to ascribe causation to the vaccin[ation]." Status Report (ECF No. 10).

D. Petitioner's Expert Dr. Arthur Brawer's First Report

On January 31, 2017, petitioner filed Dr. Arthur Brawer's report (comprising both a medical evaluation and an expert opinion), curriculum vitae, and cited medical literature. Pet. Exs. 11-24. On April 13, 2017, petitioner filed Dr. Brawer's handwritten examination notes. Pet. Ex. 27. Dr. Brawer obtained his medical degree in 1972. He completed an internship followed by two fellowship/ residencies focusing on arthritis. Since 1976, Dr. Brawer has served as the director of rheumatology, director of the arthritis clinic, and an attending physician at the Monmouth Medical Center in Monmouth, New Jersey. He is also an assistant clinical professor of medicine and an author of approximately twenty medical articles. He holds board certifications in rheumatology, internal medicine, and medical examination. Pet. Ex. 12.

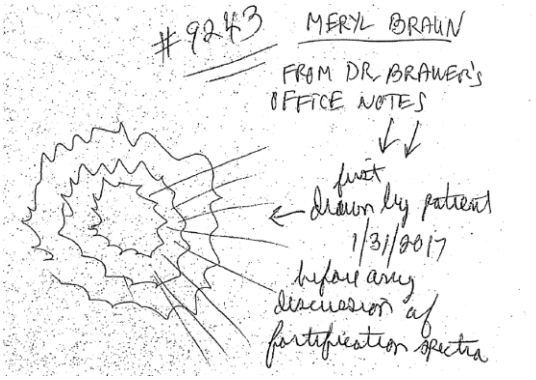
i. Dr. Brawer's Evaluation

Dr. Brawer provides that he met with petitioner at her counsel's request on January 31, 2017. He stated that he received copies of the medical records. However, he did not cite to specific medical records in his report. He obtained "an extensive history" from petitioner and performed a physical examination. Pet. Ex. 11 at 1.

Dr. Brawer did not address petitioner's original claim that the flu vaccination simply caused petitioner to develop GBS 4 months afterwards. Pet. Ex. 11 at 1. His handwritten notes seem to read: "interval from vaccination to onset of G-B too long, but tied together SLE 11/2013." Pet. Ex. 27 at 2.

Dr. Brawer recorded that "within 24 hours" of the flu vaccination on September 11, 2013, petitioner developed "generalized fatigue, which persisted unabated." Id. at 1. "Approximately seven to eight weeks after her vaccination, she developed classical fortification spectra[12], characterized by overlapping irregular and jagged 'rings' permeated by a diversity of different colors." Dr. Brawer's handwritten notes contain the following illustration:

[12] Fortification spectra are defined as "a form of migraine aura characterized by scintillating or zig zag bands of colored light forming the edge of an area of teichopsia [a luminous appearance before the eyes]." Dorland's at 1743, 1878.



Pet. Ex. 27 at 1. Petitioner also told Dr. Brawer: "The fortification spectra [were] accompanied by an intense headache, the latter of which subsided in two to three days, followed by resolution of the fortification spectra itself in approximately six days." Pet. Ex. 11 at 1.[13]

> Dr. Brawer recorded petitioner's account that:
>
> "A few weeks [after the fortification spectra,] prior to the first week in December 2013, [petitioner] developed tingling and numbness in her feet, myalgias[14] and tightness in her calf muscles, and a sensation that the skin on her heels was 'cracked' without any physical abnormality present on her heels to the naked eye. These symptoms persisted on a daily basis, along with her fatigue. By the early part of January the numbness had progressed to her hands and other parts of her extremities, which then in turn became accompanied by a progressive generalized weakness in her muscles and unsteadiness of gait. All of these symptoms were corroborated on physical examination by the third week in January, at which time it was also noted that tendon reflexes were absent diffusely. She was admitted to Columbia Presbyterian Hospital on January 24, 2014, where she was ultimately diagnosed with [GBS]."

Id. at 1-2. Dr. Brawer opined that the NYPH lab findings showed pleocytosis[15], elevated CSF protein, elevated muscle enzymes (with a CPK[16] at approximately 300), hemolytic anemia[17] with

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[13] Compare to Pet. Ex. 10 at 11 (November 5, 2013, nurse's notation that petitioner experienced a headache, followed by "sudden onset of blurry vision on left eye" that same day); and Pet. Ex. 25 at 14 (November 5, 2013, doctor's notation that petitioner "saw a flashing light in the left eye while driving," but her symptoms resolved by the time she reached the emergency room).

[14] Myalgia is defined as a pain in a muscle or muscles. Dorland's at 1214.

[15] Dorland's at 1460 defines pleocytosis as "presence of a greater than normal number of cells in the CSF."

[16] CPK is an abbreviation for "creatine phosphokinase." Medical Abbreviations at 90.

[17] Anemia is "a reduction below normal in the concentration of erythrocytes [red blood cells] or hemoglobin in the blood, measured per mm^3 or by volume of packed red blood cells per 100 mL of blood." Dorland's at 78, 644. Hemolytic anemia can be "either acute or chronic," and is "characterized by excessive hemolysis (shortened survival of mature erythrocytes) and inability of bone marrow to compensate with new erythrocytes. Id. at 79.

increased indirect bilirubin,[18] decreased haptoglobin,[19] elevated reticulocytes[20], decreased platelets, elevated LDH, and a positive ANA test in a titer of 1:160 in a speckled pattern. Pet. Id. at 1-2.

Dr. Brawer wrote that after receiving IVIG and being discharged, petitioner experienced "profound weakness" prompting extensive rehabilitation, continuing fatigue, continuing weakness, and intermittent tingling and numbness in her extremities. Id. at 2. He recorded that petitioner also developed "polyarthralgias[21] with stiffness, tightness, and soreness in multiple joints, including her cervical spine, shoulders, hands, wrists hips, and feet, accompanied by similar symptoms in the scapula areas." Id. He also referred to this as "joint inflammation." Id.

Dr. Brawer recorded that petitioner "has not been able to resume prior physical activities that [she] enjoyed prior to September 11, 2013, such as gym workouts and bicycling, and she even has trouble doing routine housecleaning." Dr. Brawer recorded petitioner's statement that her muscle strength "was not normal." Id. Upon physical examination, Dr. Brawer recorded that upper extremity tendon reflexes were 2 to 3+ and symmetrical. Left knee reflex was 1 to 2+ and the right knee reflex was trace. Proximal muscle strength on single testing was normal in all four extremities. In both hands, grasp was diminished at 50%. Petitioner had some discomfort in the cervical spine, both shoulders, and both wrists. Her hands, in the MCP joints,[22] were tender to palpation without swelling. The hips, knees, and ankles were normal. Id. at 2-3.

Dr. Brawer also recorded that petitioner had noticed "intermittent malar erythema on her face" over the past year. On physical examination, he noted "faint malar erythema." Id. at 2. He also recorded that in January 2017, "a pregnancy ended in death in utero at approximately nine or ten weeks gestation (despite taking progesterone supplements)." Id.

ii. Dr. Brawer's Opinion

Dr. Brawer opined that "the development of Guillain-Barré Syndrome in Ms. Braun was merely part of an overall vaccination-induced systemic autoimmune disease, namely systemic lupus erythematosus [SLE]."[23] Pet. Ex. 11 at 3.

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[18] Bilirubin is a yellow bile pigment, often produced by the breakdown of erythrocyte hemoglobin in reticuloendothelial cells. Dorland's at 215.

[19] Haptoglobin is a plasma glycoprotein that binds to free hemoglobin, but is removed by the liver. Haptoglobin levels are decreased by hemolysis (the breakdown of erythrocytes). Dorland's at 821, 841.

[20] Reticulocytes are immature erythrocytes. Dorland's at 1631.

[21] Polyarthralgia is defined as pain in many joints. Dorland's at 150, 1487.

[22] MCP is an abbreviation for "metacarpophalangeal." Medical Abbreviations at 203. The metacarpophalangeal joints connect the metacarpus (i.e., the palm of the hand) to the phalanges (the fingers). Dorland's at 1142.

[23] Dorland's at 1080 defines SLE as: "A chronic, inflammatory, often febrile multi-systemic disorder of connective tissue that proceeds through remissions and relapses; it may be either acute or insidious in onset and is characterized principally by involvement of the skin, joints, kidneys, and serosal membranes. The etiology is unknown, but it may be a failure of regulatory mechanisms of the autoimmune system, since there are high levels of numerous

He opined: "Although rare, it is well-known that neuropsychiatric manifestations may encompass the initial symptoms and signs of [SLE]. When this happens, this type of presentation differs significantly from the 'classical' systemic manifestations of symptoms and signs displayed by a 'typical' case of SLE." Id.

He stated that in petitioner's case, her SLE "began with fatigue and 'cerebritis' symptoms encompassing the fortification spectra and headaches." Id. He stated that the SLE progressed to include GBS, "myositis, hemolytic anemia, and probable transverse myelitis (implying that systemic vasculitis was also present), and also at least one episode of low platelets." He stated that following her discharge from the hospital, petitioner's SLE has continued as represented by joint inflammation, malar erythema, continuing fatigue, continuing weakness, and one miscarriage. Id. at 3-4. Dr. Brawer advised petitioner to pursue additional workup, by way of additional rheumatologic investigations. Id. at 4.

With regard to causation, Dr. Brawer opined that the flu vaccination can cause SLE through the mechanism of molecular mimicry. Pet. Ex. 11 at 3-4. He mentioned other possible "deleterious mechanisms" including, but not limited, to polyclonal B-cell activation. Pet. Ex. 11 at 5. Dr. Brawer opined that there was a logical sequence of cause and effect showing that the flu vaccination did in fact cause petitioner to develop SLE, because she "did not suffer from any inflammatory arthritis condition" prior to the flu vaccination. Additionally, her "chronic rheumatologic inflammatory condition" began within reasonable proximity to the flu vaccination and continued indefinitely after. Finally, there was no other identified infection or other cause for her injury. Pet. Ex. 11 at 5. Dr. Braun opined that there was a temporal relationship between the flu vaccination and the development of SLE because there was no manifestation of that injury before the vaccination, only after. Pet. Ex. 11 at 5-6.

Dr. Brawer did not cite to particular pieces of medical literature in support of particular propositions in his reports. He did write: "Appropriate references from the medical literature will be supplied to you [petitioner's counsel] regarding the onset of SLE caused by vaccinations, as well as the heterogeneity of the disease when neuropsychiatric manifestations represent the presenting complaints." Pet. Ex. 11 at 4. He also wrote: "[T]here is ample documentation in the medical literature that various vaccinations and immunizations can causally initiate [SLE]." Pet. Ex. 11 at 3-4. Dr. Brawer's medical literature is cited in the following footnote.[24]

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autoantibodies against nuclear and cytoplasmic cellular components. The condition is marked by a wide variety of abnormalities including arthritis, arthralgias, nephritis, central nervous system manifestations, pleurisy, pericarditis, leukopenia or thrombocytopenia, hemolytic anemia, an elevated erythrocyte sedimentation rate, and the presence in the blood of distinctive cells called LE cells."

[24] Older S.A. et al., Can Immunization Precipitate Connective Tissue Disease? Reports of Five Cases of Systemic Lupus Erythematosus (SLE) and Review of the Literature, 29 Seminars in Arthritis and Rheumatism 131 (1999) [Pet. Ex. 13]; Scofield R. and J. James, Immunization as a Model for Systemic Lupus Erythematosus, 29 Seminars in Arthritis and Rheumatism 140 (1999) [Pet. Ex. 14]; Agmon-Levin N. et al., Ten Cases of Systemic Lupus Erythematosus Related to Hepatitis B Vaccine, 18 Lupus 1192 (2009) [Pet. Ex. 15]; Srivastava A. et al., Concomitant Guillain-Barré Syndrome and Transverse Myelitis as Initial Neuropsychiatric Manifestation in a Case of Lupus: A Diagnostic Quandary, Case Reports in Rheumatol. (2016), available at http://dx.doi.org/10.1155/2016/5827860 [Pet. Ex. 16]; Birck R. et al., ANCA-Associated Vasculitis Following Influenza Vaccination: Causal Association or Mere Coincidence?, 15 J. Clin. Rheumatol. 289 (2009) [Pet. Ex. 17]; Zafrir Y. et al., Editorial: Post-Influenza Vaccination Vasculitides: A Possible New Entity, 15 J. Clin. Rheumatol .

E. Amended Petition

On April 6, 2017, petitioner filed an amended petition (ECF No. 17). This amended her injury from simply GBS to all of the signs and symptoms posited by Dr. Brawer: "[GBS], systemic lupus erythematosus, vaccination-induced lupus, fatigue, myositis, hemolytic anemia, probably transverse myelitis (implying that some vasculitis was also present), polyarthralgias, joint inflammation, [and] malar [e]rythema." Amended Petition at Preamble.

The amended petition also included different and new factual allegations. It added the account of generalized fatigue beginning within 24 hours of the flu vaccination. Id at ¶ 4. It adds additional detail of petitioner's symptoms on November 5, 2013, including the term "fortification spectra," introduced by Dr. Brawer. Id. The amended petition provided: "A few weeks later, prior to the first week in December of 2013, [petitioner] developed tingling and numbness in her feet, myalgias and tightness in her calf muscles, and a sensation that her skin was 'cracked' without any physical abnormality present on her heels to the naked eye. These symptoms persisted on a daily basis, along with her fatigue, and by the early part of January the numbness had progressed to her hands and other parts of her extremities, which then in turn became accompanied by a progressive generalized weakness in her muscles and unsteadiness of gait. All of these symptoms were corroborated on a physical examination by the third week in January, at which time it was also noted that tendon reflexes were absent diffusely." Id. The rest of the amended petition mirrors Dr. Brawer's report. Id. at ¶¶ 5-27.

F. Petitioner's Updated Medical Records

On April 13, 2017, petitioner filed updated medical records. An ultrasound report dated January 5, 2017, and a surgical pathology report dated January 10, 2017, both indicate that petitioner had a first trimester miscarriage. Pet. Ex. 28 at 22-34.[25] Subsequently, both nephrologist Dr. Elena Froleva and obstetrician-gynecologist Dr. Leonid Sorkin referred petitioner for high-risk preconception counseling for possible lupus. Id. at 3-4.[26] On March 20, 2017, bloodwork showed a positive ANA titer of 1:320 but all other tests were normal. Further testing for lupus anticoagulant and related antibodies were also negative. Id. at 10-11.

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269 (2009) [Pet. Ex. 18]; Lorenzoni P. et al., Vasculitic Neuropathy Following Influenza Seasonal Vaccination, 70 Arq. Neuro-Psiquiatr. (2012) [Pet. Ex. 19]; Hull J. et al., Severe Vasculitic Neuropathy Following Influenza Vaccination, 75 J. Neurol. Neurosurg. Psychiatr. 1507 (2004) [Pet. Ex. 20]; Vial T. & J. Descotes, Autoimmune Diseases and Vaccinations, 14 Eur. J. Dermatol. 86 (2004) [Pet. Ex. 21]; Brown M.A. and J.V. Bertouch, Brief Communications: Rheumatic Complications of Influenza Vaccination, 24 Aust. NW. J. Med. 572 (1994) [Pet. Ex. 22]; Stonjanovic M. et al., Role of Molecular Mimicry and Polyclonal Cell Activation in the Induction of Pathogenic β2-Glycoprotein I-Directed Immune Response in Balb/c Mice upon Hyperimmunization with Tetanus Toxoid, 56 Immunol. Res. 20 (2013) [Pet. Ex. 23].

[25] The medical records about the miscarriage were filed together with a letter dated January 31, 2017, from Dr. Arthur Brawer, who provides that petitioner is under his care for treatment of SLE. Id. at 5

[26] It is likely that petitioner herself or Dr. Brawer – who diagnosed petitioner and directed her to seek follow-up treatment for SLE – provided this diagnosis to these providers. Neither one of these providers takes an independent history or comes to an independent conclusion as to whether petitioner has SLE.

G. Respondent's Expert Dr. Mehrdad Matloubian's Report

On July 21, 2017, respondent filed a responsive expert report from Dr. Mehrdad Matloubian. Respondent's ("Resp.") Ex. A. Dr. Matloubian graduated from medical school in 1996. Like Dr. Brawer, Dr. Matloubian completed a fellowship in rheumatology and is board-certified in rheumatology and internal medicine. He also has a PhD in virology/ immunology. He has been engaged in research in this area for more than 20 years. He is an associate adjunct professor in medicine at the University of California, San Francisco ("UCSF"). With regard to clinical practice, he acts as an attending physician for one month each year at UCSF's Rheumatology Inpatient Consult Service. He also acts as an attending physician one afternoon per week, two to three times per month, at UCSF's Outpatient Arthritis Clinic. Resp. Ex. B.

Dr. Matloubian did not personally examine petitioner. However, he questioned Dr. Brawer's history that petitioner experienced persistent fatigue beginning within 24 hours of the vaccination; developed tingling and numbness in her feet, myalgias and tightness in her calf muscles, and a sensation that the skin on her heels was cracked in the first week of December 2013; and then developed a progressive generalized weakness in her muscles and unsteady gait beginning in early January 2014.

Dr. Matloubian contended that the contemporaneous medical records did not reflect any specific neuromuscular symptoms prior to early January 2014. The medical records do provide that petitioner biked 45 miles on January 12, 2014; 25 miles on January 13, 2014; and then experienced rapidly progressing weakness and paresthesias that led to her hospitalization on January 24, 2014. She was hospitalized and eventually diagnosed with GBS/ AIDP. She received a five-day course of IVIG. She was recovering some of her strength by the time she was discharged to inpatient rehabilitation on February 1, 2014. She was back to work full-time and had resumed taking long bike rides by September 2014. He noted that petitioner had some residual paresthesias for which she did not want to take any medications. She also had some neck and shoulder symptoms, which were attributed to myofascial pain by Dr. Bevelacqua. Finally, Dr. Matloubian noted that there was no further documentation of her neurologic symptoms beyond March 2015. Dr. Matloubian stated that the available contemporaneous medical records reflect a course that was consistent with GBS, which is a monophasic disease which starts with symptoms progressing over a period of one to two weeks. Resp. Ex. A at 7-8.

Dr. Matloubian rejected Dr. Brawer's assessment that petitioner's GBS was a rare neurological manifestation of SLE. Resp. Ex. A at 6. Dr. Matloubian stated that SLE is a complex autoimmune disease affecting multiple organs. Dr. Matloubian allowed that SLE can affect any organ system, the presentation is variable, and the symptoms or organs affected can be separated by time and do not need to occur simultaneously. Resp. Ex. A at 8. Dr. Matloubian submitted the American College of Rheumatology ("ACR")'s diagnostic criteria for SLE. The criteria are cumulative and "need not be present concurrently." They include: rash; hemolytic anemia; thrombocytopenia (<100,000/ mm^3 at least once); and immunologic criteria (including an ANA level above laboratory range and positive tests for specific antibodies). Resp. Ex. A at 8-9.[27]

[27] Citing Petri M. et al., Derivation and Validation of the Systemic Lupus International Collaborating Clinics Classification Criteria for Systemic Lupus Erythematosus, 64 Arthritis Rheum. 2677 (2012).

Dr. Matloubian summarized and responded to Dr. Brawer's assessment of SLE based on persistent fatigue and weakness, sensory symptoms, one episode of migraine headache with aura, hemolytic anemia, thrombocytopenia, a positive ANA test, myositis/ joint inflammation, transverse myelitis and/ or systemic vasculitis, malar erythema, and the January 2017 miscarriage. Resp. Ex. A at 9.

Dr. Matloubian opined that fatigue is a non-specific complaint and is not a diagnostic characteristic of SLE. In petitioner's case, the contemporaneous medical records do not reflect that she had been experiencing persistent fatigue for four months prior to her hospitalization. The medical records provide that petitioner biked 45 miles on January 12 and 25 miles on January 13, just 10 days before the hospitalization.[28]

Dr. Matloubian also stated that individuals that are assessed with and appropriately treated for GBS may experience residual fatigue. This may explain petitioner's account of fatigue after the vaccination. But again, the records provide that after being treated for GBS, petitioner resumed bike rides of up to 20 miles. These suggest that "chronic fatigue may not have been a major medical issue." Resp. Ex. 9-10.

Dr. Matloubian stated that the ACR criteria for SLE does not include headaches. They are not a specific symptom of SLE. Rather, they are quite common and have a variety of causes. Petitioner experienced one episode of migraine with visual aura (fortification spectra), which is the most common type of headache. It also resolved spontaneously. Moreover, Dr. Brawer did not "provide any biological mechanism by which the influenza vaccin[ation] could have allegedly caused this single episode of migraine with aura" about 8 weeks later. Dr. Matloubian concluded that petitioner's headache episode did not suggest SLE and was not caused by the flu vaccination. Resp. Ex. A at 7, 10.

Dr. Matloubian continued that the ACR criteria does not include myositis. He opined that myositis is usually associated with other entities, such as dermatomyositis or mixed connective tissues disease. Either way, he opined that petitioner did not have myositis because (1) her muscle enzyme (CK) was only mildly elevated at 305, compared to a reference range going up to 221 and (2) the supposed myositis subsided even though she didn't receive any treatment specific for that condition. He opined that the mildly elevated CK level could simply be consistent with petitioner's accepted diagnosis of GBS. Resp. Ex. A at 10.

Dr. Matloubian disagreed with Dr. Brawer's opinion that in addition to GBS, petitioner had "probable transverse myelitis (implying that systemic vasculitis was also present)." Dr. Matloubian opined that petitioner's symptoms, autonomic dysfunction, EMG/ NCS findings, absence of CSF pleocytosis, testing negative for antibodies that are usually associated with systemic vasculitis (ANCAs, anti-PR3, anti-MPO), and positive response to IVIG were all consistent with GBS rather than TM or any form of systemic vasculitis. Additionally, the

[28] The medical records also reflect that petitioner reported that her weakness, cramping and tingling began around January 15, 2014. See, e.g., Pet. Ex 4 at 10-11.

treating physicians did not suspect TM/ vasculitis, as shown by the fact that they did not perform further studies such as MRI of her spinal cord. Resp. Ex. A at 10-11.

Dr. Matloubian wrote that Dr. Brawer said that petitioner "has manifested joint inflammation," but Dr. Brawer personally noted "absence of any joint swelling, especially in her hands" on January 30, 2017. Dr. Matloubian also mentioned that petitioner had "normal inflammatory markers on 12/06/2016." He also mentioned that petitioner had pre-vaccination musculoskeletal complaints and he opined those were probably related to her job and/ or carpal tunnel syndrome. Resp. Ex. A at 12.

The ACR criteria for SLE include hemolytic anemia. Dr. Matloubian stated that during her January – February 2014 hospitalization, petitioner was "mildly anemic" and displayed "a degree of hemolysis or destruction of red blood cells." Resp. Ex. A at 11-12. She was not tested for direct Coombs, which would have distinguished between autoimmune hemolytic anemia and other causes. However, she had a negative indirect Coombs, which supported the absence of alloantibodies to direct Coombs. Resp. Ex. A at 11-12.

The ACR criteria for SLE also list thrombocytopenia (the latter needing platelets to be under 100,000/ mm^3 at least once). Petitioner's medical records provide a reference range of 165,000 - 415,000. During petitioner's hospitalization, her platelet count was 185,000; 153,000; 154,000; 168,000; and 157,000. See generally Pet. Ex. 2. While some of these counts were slightly below the reference range, they did not meet the ACR's definition of thrombocytopenia. Furthermore, on March 30, 2017, petitioner's platelet count was well within normal, at 206,000. Resp. Ex. A at 11-12 (citing Pet. Ex. 28 at 18).

Dr. Matloubian opined that in SLE, hemolytic anemia and thrombocytopenia tend to be chronic and need specific treatment, such as prednisone. However, petitioner did not receive this treatment. On March 30, 2017, bloodwork showed red blood cells and platelets within normal ranges. Resp. Ex. A at 11-12 (citing Pet. Ex. 28 at 18). Dr. Matloubian added that low blood counts can be caused by multiple other mechanisms, including infections. He suggested that petitioner had an asymptomatic infection which caused her low counts (and possibly the onset of her GBS). Resp. Ex. A at 12.

Dr. Matloubian stated that the first-line screening test for SLE is for anti-nuclear antibodies (ANAs). However, healthy individuals and first-degree relatives of those with autoimmune diseases can test positive for ANAs. If the ANA test is positive, it is followed by testing for specific antibodies such as anti-double-stranded DNA (dsDNA), anti-Smith, anti-RNP, SSA, or SSB. He stated that the anti-Smith test is less sensitive than the ANA test, but more specific for SLE. If the specific antibody tests are negative, it is less likely than the individual has SLE. Dr. Matloubian stated that petitioner met this description. She had a low titer positive ANA test, but was not positive for any specific antibodies. Resp. Ex. A at 8 (citing Pet. Ex. 28 at 11, labwork performed on March 20, 2017).

Dr. Matloubian questioned Dr. Brawer's assessment of a "malar erythema." He noted Dr. Brawer described it as "faint." Dr. Matloubian stated that a "faint" rash suggested rosacea, in comparison to the lupus malar rash "also known as acute cutaneous LE [which] tends to be present for weeks and is characterized by itching and burning of skin lesions" and "raised with scaling and crusts." Dr. Matloubian wrote that he was not convinced by Dr. Brawer's brief description alone that petitioner had a true malar rash. He recommended evaluation by an experienced dermatologist if this recurred. Resp. Ex. A at 13.

Dr. Matloubian stated that petitioner's first-trimester miscarriage in January 2017 was unfortunate. However, miscarriage is not uncommon (estimated to occur in about 8-20% of pregnancies). It is not a feature of SLE unless it is associated with positive anti-SSA antibodies or antiphospholipid syndrome. The criteria for antiphospholipid syndrome requires three or more consecutive miscarriages before 10 weeks of gestation. In this case, Dr. Matloubian did not receive copies of petitioner's prenatal records. However, the miscarriage was in the first trimester, at approximately 9 or 10 weeks. Additionally, Dr. Brawer provided that petitioner had been taking progesterone. Dr. Matloubian suggested that this was likely based on maternal factors such as petitioner's prior diagnosis of polycystic ovarian syndrome. Additionally, on March 30, 2017, petitioner tested negative for anti-SSA antibodies and lupus coagulant. This also appears to be her first miscarriage. Dr. Matloubian concluded that this one miscarriage was not "sufficient to diagnose an SLE-related event." Resp. Ex. A at 13.

Dr. Matloubian agreed with Dr. Brawer that "rarely, patients with SLE can present with a neurologic disease that can be classified as GBS/ AIDP." Resp. Ex. A at 13. However, the available case reports reveal two important features that were absent from petitioner's case. First, in the case reports, the affected individuals had unequivocal severe organ involvement and laboratory findings, including multiple autoantibodies characteristic of SLE. But in this case, there is no evidence of severe organ involvement. Second, in the case reports, the affected individuals required glucocorticoids in addition to another immunosuppressive medication. But in this case, petitioner did not require aggressive immunosuppressive therapy. Resp. Ex. A at 13.

Finally, Dr. Matloubian disagreed that the flu vaccination can cause SLE. He opined that even if petitioner is found to have SLE, the flu vaccination did not cause that condition. Resp. Ex. A at 14-17.

H. Petitioner's Expert Dr. Brawer's Second Report

On October 20, 2017, petitioner filed Dr. Brawer's second report. He first critiques respondent's expert Dr. Matloubian as "first and foremost a researcher with a sound background in immunology. His clinical expertise, however, is a small fraction of what is traditionally acquired by primary practicing rheumatologists who see legions of patients on the front lines every day in hospitals and offices, transpiring over many decades. As such . . . Dr. Matloubian has a cookie cutter, one size fits all approach to [SLE] that is untampered by clinical reality." Pet. Ex. 29 at 1.

Dr. Brawer contended that Dr. Matloubian only discussed the "typical" form of SLE, which is caused by genetic predisposition or HLA susceptibility and involves a "classical spontaneous development" and a "self-sustaining immunological response." Id.

Dr. Brawer contended that SLE caused instead by an environmental factor by a vaccination, would involve "quite different" "initial inflammatory events in the first few days and weeks." Id. He did not elaborate on how this atypical form of SLE would present or cite to any criteria.

He also contended that SLE was a "clinical diagnosis at the bedside, supported or refuted by subsequent laboratory tests." Id. He added that "not all criteria need to be present at a single point in time." "[S]ome aspects . . . may become dormant for an indefinite period of time, but this does not negate their contribution to an appropriate diagnosis in the first place." Id. at 1-2.

He acknowledged that fatigue is not part of the recognized diagnostic criteria for SLE. He opined that fatigue is a symptom of (1) malignancy; (2) infection; or (3) chronic inflammation. He did not identify any malignancy or recognizable infection. Thus, he concluded that petitioner's fatigue was due to chronic inflammation which would be consistent with SLE. Id. at 2. He opined that petitioner's fortification spectra were consistent with central nervous system involvement in SLE, which is well-recognized in the medical literature. Id.

He maintained - based on their January 31, 2017, evaluation - that petitioner's paresthesias, myalgias, and other sensory phenomena began "prior to the first week of December 2013." Id. He stated that the examining physicians "inadvertently and erroneously comingled the paresthesias and other symptoms that clearly began prior to the first week in December 2013" with "the complaints of weakness and difficulty walking [which] did occur for the first time in January of 2014." Id.

He contended that Dr. Matloubian purposely ignored "the multiple of her components of [petitioner's] multisystem systemic illness and the chronological evolution that began within 24 hours of her influenza vaccination." He stated that Dr. Matloubian also disregarded petitioner's miscarriage. He stated that the miscarriage "clearly did not occur in a vacuum" and "there are many patients with [SLE] who have recurrent episodes of fetal wastage in the absence of predictive lab tests for this event." Id. at 2-3.

Dr. Brawer maintained, consistent with his first report, that petitioner had SLE. He also responded to Dr. Matloubian's comments regarding possible causation between the flu vaccination and SLE. Id. at 3.

I. Rule 5 Status Conference

After holding a status conference with both parties represented by their counsel pursuant to Vaccine Rule 5, on October 23, 2017, I issued an order summarizing my review of the medical records, expert reports, and literature filed to date.[29] I noted that the diagnosis of GBS was

[29] I held the Rule 5 status conference on October 19, 2017. During the status conference, petitioner's counsel indicated that he possessed, but had not filed, Dr. Brawer's second expert report (summarized in section II.H,

undisputed, but the onset was well outside the medically accepted timeframe for that alleged vaccine injury. I was inclined to agree with Dr. Matloubian, who was highly doubtful of the assessment of SLE. I concurred that Dr. Brawer's assessment of SLE relied on a history which was not consistent with the contemporaneous medical records. Moreover, Dr. Brawer relied on several symptoms that were non-specific and could have various explanations. I directed petitioner to file a motion for dismissal of her claim, a motion for a decision on the record, or a status report proposing another cause of action by November 13, 2017. Order (ECF No. 26).

J. Petitioner's Affidavit

On November 13, 2017, petitioner filed an affidavit. Pet. Affidavit (ECF No. 27). She recalls that during the time in question, she lived in a third-floor apartment in Jersey City, New Jersey. She had been living there since approximately March 2013. Id. at 1. Since April 2009, petitioner had been employed as a clinical laboratory technologist at New York Presbyterian Hospital in New York, New York. She was employed full time (approximately eight to ten hours each day, five days each week). She was commuting to work by bus and subway, which took about an hour each way. Pet. Affidavit at 2.

She recalls in her affidavit that she had started bike riding sometime "in the summer of 2013, after not riding for many years." Petitioner recalls that she "started increasing mileage from about 1 mile, in about 2-5 mile increments to about 25 miles and then 45 miles. 25 mile distance was about the most I went until I went as far as 45 miles." Pet. Affidavit at 2-3. Other than saying she began bike riding in "summer 2013," she does not provide any specific dates for her rides. It is not clear how frequent the rides were. It is not clear when she first rode for 25 miles or 45 miles. She does not relate bike rides to any specific dates in summer or fall 2013. Id. at 2.

She recalls being in good health upon receiving the flu vaccination on September 11, 2013. Upon vaccination, she felt like she was "punched in the arm." That day, she began to feel very tired. "The fatigue lasted. [She] felt lethargic but [she] continued to work, and continued to ride [her] bike but more slowly. [She] did everything with low energy." Id. at 2. Petitioner had "never felt fatigue like this before," but attributed it to her work, commute, personal responsibilities, and the new activity of bike riding. She also believed that she needed to continue bike riding to build strength and endurance. Id. at 2-3.

She recalls that on November 5, 2013, when she went to the emergency room, she was only concerned about her sudden headache and visual symptoms. She did not think her fatigue was from any health problem. Id. at 3.

She recalls that her fatigue persisted. Then, "around December 2013," she started sensing that her heels were dry and cracked, but they were not. "Also in December 2013," her feet felt as cold as ice, even when she was inside her house for hours and was under warm bedcovers. She had never experienced these symptoms before, but she thought they were from

above). I directed petitioner's counsel to file the same. Once petitioner's counsel filed Dr. Brawer's second expert report, I reviewed it and incorporated it into my order.

the cold. They continued until around January 14, 2014, when she lost sensation and experienced numbness and tingling in her feet and hands. Id. at 4.

Petitioner does not address whether she rode her bike for 45 miles on January 12, 2014, "felt great and went for another 25 mile bike ride" on January 13, 2014" as provided in the medical records. See Pet. Ex. 4 at 10-11.

She recalls that in early January 2014, she couldn't lift her arms and hands; began needing to grip a railing in order to climb stairs in her apartment building and in the subway; she developed a knot in the back of her calf; and her legs began to feel weak. Pet. Affidavit at 4-5. As January 2014 progressed, she felt even more tired. She tried to sleep as much as possible. "Then on Martin Luther King Day… January 20, 2014, [she] tried to ride her bicycle." Her boyfriend told her that the only way to recover from muscle fatigue was to get back on the bike and ride. However, she was going so slowly that her boyfriend left her and rode on. She could not continue. She rode approximately one mile home. Her boyfriend's mother, who was home at the time, had to carry petitioner and then her bike up the stairs. The next day, January 21, petitioner went to work. Id. at 5-6. The following day, January 22, she went to work but left early for acupuncture with Dr. Wong. Id. at 7. She continued to experience weakness and tingling on January 23. She went to Dr. Bevelacqua on January 24 and was hospitalized on January 25. Id. at 8.

She recalls that her fatigue began immediately after the vaccination in September 2013, but she attributed it to her increased exhaustion. The migraine with aura in November 2013 resolved. The sensory symptoms began in December 2013, but seemed to resolve. She then developed weakness and difficulty walking around January 14, 2014. When she was hospitalized later in January 2014, she did not connect all of the symptoms and explain them to the physicians. However, looking back, she believes they were all related and stemmed from the flu vaccination. Id. at 9-14. She stated that she continues to have fatigue and diminished strength. She does not ride a bicycle anymore. If she does even limited housework, she has body pain. Id. at 11-12.

K. Petitioner's Motion for a Ruling on the Record

On November 13, 2017, petitioner also filed a concise motion requesting for entitlement to be resolved in her favor. Pet. Motion (ECF No. 28). She also filed a status report to the same effect. Status Report (ECF No. 29). On November 27, 2017, respondent filed a brief response that was consistent with his Rule 4(c) report, and Dr. Matloubian's opinion, and my tentative view of the case. Resp. Response (ECF No. 30). This matter is now ripe for adjudication.

III. ANALYSIS

A. GBS

As noted during the Rule 5 status conference, the first challenge to petitioner's claim is that the contemporaneous medical records (and the original petition) reflect that petitioner suffered the onset of GBS approximately four months after the flu vaccination. The diagnosis of

GBS is undisputed. The timing in relationship to the vaccination, however, is quite remote in time. As a point of reference, the Vaccine Injury Table creates a presumption of causation for the onset of GBS within 3 – 42 days after a seasonal flu vaccination. 42 C.F.R. § 100.3.

Petitioner never alleged a Table GBS injury, nor would she have been able to demonstrate one given that the onset of her GBS was well beyond 42 days post-vaccination. Thus, she has the burden of demonstrating actual causation by a preponderance of the evidence. This would be supported by expert opinion and/ or medical literature supporting causation with a later onset. During the Rule 5 status conference, I indicated that timing somewhat outside of the Table window might support a finding of causation in fact, but the timing in this case is not likely. I am not aware of any medical literature or other cases in the Vaccine Program accepting anything close to the timing of this case for the onset of GBS after a seasonal flu vaccination. Moreover, petitioner has not attempted to overcome this challenge. Her expert, Dr. Brawer, does not address whether the timing between the flu vaccine and the onset of GBS alone (not as one component of another injury) would be acceptable. Moreover, petitioner has amended her claim and no longer alleges that the flu vaccination caused GBS alone. Thus, I find that petitioner has not established causation in fact for the originally alleged injury.

B. Factual Determinations

Petitioner and her expert Dr. Brawer now allege that the flu vaccination caused a more extensive set of injuries under the overarching assessment of SLE. The preliminary difficulty is that petitioner's and Dr. Brawer's later accounts diverge from the contemporaneous medical records and the original petition.

To summarize briefly, the contemporaneous medical records reflect that in early November 2013, petitioner had a migraine with aura. Pet. Ex. 25. On January 20 or 21, 2013, her acupuncturist noted worsening weakness, tenderness, and stiffness in her shoulders and lower back. Pet. Ex. 7 at 6. On January 24, 2014, the sports medicine specialist Dr. Bevelacqua recorded that petitioner "present[ed] with a two-week history of difficulty walking, weakness, numbness, and tingling." Petitioner had gone on a 45 mile bike ride on January 12; she went on a 25 mile bike ride on January 13; then she sat and studied for over 10 hours on January 14. Petitioner then began to feel pain, weakness, numbness, and tingling in her upper and lower extremities. Petitioner also "report[ed] feeling like she ha[d] the chills." Dr. Bevelacqua did not record any symptoms prior to early January 2014. Pet. Ex. 6 at 99-100. Later on January 24, 2014, at the hospital, Dr. Brusen and Dr. Revshankoo recorded that petitioner "was riding bike last fall and did a 45 mile bike ride Jan[uary]1st and was in bed for a day afterwards." Otherwise, their history mirrors that of Dr. Bevelacqua. Pet. Ex. 4 at 5. On January 25, 2014, neurologists Dr. Weimer and Dr. Reilly recorded a similar history. Namely, petitioner had no complaints prior to January 2014. She went on a 45 mile bike ride on January 12; she went on a 25 mile bike ride on January 13; and she experienced cramping and fatigue beginning on January 13. Pet. Ex. 4 at 11. These contemporaneous medical records were quite detailed, created by numerous treating neurologists and other physicians at a well-regarded academic hospital, and for the purpose of accurately assessing and treating petitioner. They are also internally consistent and they logically describe the onset of GBS in mid-January. While it is possible that

the contemporaneous medical records are inaccurate or incomplete, that seems unlikely. Moreover, that is petitioner's burden to prove.

I will note that the original petition (filed September 2, 2016) generally mirrors the contemporaneous medical records. It provides that petitioner was in "very good health before and after the flu shot until the symptoms of [GBS] developed." Petition at ¶ 6. It provides that at some unspecified time after the flu vaccination, petitioner noticed a sensation of "numbness in her feet which she attributed to the effects of riding her bike." Id. at ¶ 9. Petitioner began to feel that her heels were "dry," "cracking," and "couldn't warm up" "on or about January 10, 2014." Id. at ¶ 10. By "about January 14-15, 2014," her symptoms progressed to include pain, cramping, tightness, and tingling in her lower extremities. Id. "Around January 16th or 17th," her upper and lower extremities were weak. Id. at ¶ 11. The original petition provides that she initially thought that these symptoms were due to her bike rides, until she went to the hospital and was diagnosed with GBS. Id. The original petition does not contend that the medical records were inaccurate or incomplete.

Once petitioner learned through her counsel that respondent and the undersigned considered it difficult for petitioner to establish that the flu vaccination caused the onset of GBS more than 4 months thereafter, her account seemed to change. On January 31, 2017, Dr. Brawer (retained by petitioner's counsel) recorded that petitioner developed persistent, unabated fatigue within 24 hours of the vaccination. This is not reflected in the contemporaneous medical records. Petitioner's amended petition (dated April 6, 2017) and her affidavit (dated November 13, 2017) provide that she did not seek medical attention for this fatigue because she attributed it to her busy schedule and her new, progressively longer bike rides.

I find it difficult to believe that petitioner began to experience persistent unabated fatigue around the time when she began bike riding and when she received the flu vaccination. Petitioner may have experienced some fatigue associated with her bike rides. However, the medical records do not reflect this persistent, unabated fatigue. Moreover, it seems that she was building stamina and going on increasingly long bike rides during this time. According to the contemporaneous medical records, in January 2014, she went on at least two 45-mile rides and one 25-mile ride. Petitioner does not say that these records are inaccurate. It seems doubtful that she could have built her capability to this point while experiencing persistent unabated fatigue.

Petitioner only provides the specific date of one bike ride when she was unable to keep up with her boyfriend and turned back. This was on Martin Luther King Day, January 20, 2014. See Pet. Affidavit at 4-5. However, that was only four days before her presentation to Dr. Bevelacqua. This specific recollection is consistent with the onset of her GBS.

Petitioner also acknowledges that the medical records also do not reflect sensory symptoms prior to January 2014. The original petition provided that she began to experience numbness in her feet at some unspecified time after the vaccination, followed by other sensory symptoms in her lower extremities "on or about January 10, 2014." See Petition at ¶ 10. But later, petitioner and Dr. Brawer suggested that these sensory symptoms began "before the first week of December 2013." Pet. Ex. 11 at 1; Amended Petition at ¶ 4; Pet. Ex. 29 at 2; Pet.

Affidavit at 5. Petitioner does not explain why her recollection changed. This is significant, but not dispositive, to the factual issue.

Additionally, the original petition was consistent with the contemporaneous medical records. It did not challenge the medical records, which provide that petitioner began experiencing sensations of numbness, cold, and cracked skin in her feet in January 2014. Dr. Brawer's first report dated January 31, 2017, did not state that the medical records were wrong. Pet. Ex. 11. Neither did the amended petition dated April 6, 2017. Respondent's expert Dr. Matloubian raised the issue of when the sensory symptoms began. Resp. Ex. A. Only then, in Dr. Brawer's second report dated August 16, 2017, did Dr. Brawer contend that the treating physicians "inadvertently and erroneously comingled the paresthesias and other symptoms that clearly began prior to the first week in December of 2013" with the weakness and difficulty walking which began in January 2014. Pet. Ex. 29 at 2. This further suggests that the later accounts are inconsistent and not sufficiently compelling to outweigh the contemporaneous medical records.

I also note that the Court may not accept petitioner's claims alone, unsubstantiated by medical records or other corroborating evidence. § 13(a)(1). Petitioner has not submitted affidavits from other individuals with firsthand knowledge of these events.

While Dr. Brawer recorded petitioner's recollection of these symptoms, he does not serve to corroborate them. Namely, these symptoms allegedly occurred in late 2013 and Dr. Brawer was meeting with petitioner for the first time (at her counsel's request) in 2017. He did not have any firsthand knowledge of what occurred several years prior, before he ever met petitioner. Moreover, he is not a disinterested party. Dr. Brawer did conduct a full medical evaluation and recommended that petitioner obtain additional testing and treatment with other doctors. However, he was not acting solely as a treating physician. He was contacted by counsel after the Vaccine Program claim was initiated. He is also serving as an expert in support of petitioner's claim. These circumstances go to my evaluation of Dr. Brawer's credibility as a factual witness. Moberly, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); see also Porter, 663 F.3d at 1250 ("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"); Reusser, 28 Fed. Cl. at 523 (providing that a "disinterested person . . . . is generally more reliable than the recollection of a party to a lawsuit").

Accordingly, although I have fully considered the later accounts from petitioner and Dr. Brawer, I believe that they are unlikely to reliably reflect events that occurred at least three years prior. I cannot confidently conclude that petitioner began experiencing persistent, unabated fatigue "within 24 hours" after the vaccination. There is some possibility that after the vaccination, she experienced some temporary fatigue along with her temporary arm pain (similar to being "punched in the arm," according to her affidavit). This mild fatigue and arm pain commonly follows the flu vaccination and others. But as discussed above, I have significant doubt that any fatigue was persistent and unabated over the next several months. I also doubt that she experienced other sensory symptoms prior to early January 2014. Thus, petitioner has not carried her burden of presenting "consistent, clear, cogent, and compelling" evidence that

should outweigh the detailed contemporaneous medical records. Camery, 42 Fed. Cl. at 391 (internal citations omitted); see also Burns, 3 F.3d at 417 (holding that the special master can make a rational determination to afford greater weight to contemporaneous medical records than to other evidence, such as testimony given later in time).

C. Assessment of SLE

After personally evaluating petitioner on January 31, 2017, Dr. Brawer offered an assessment of SLE. This was based on her diagnosis of GBS, as well as the persistent fatigue and weakness before and after the onset of GBS; sensory symptoms before the onset of GBS; one episode of headache with fortification spectra; hemolytic anemia, thrombocytopenia, a positive ANA test, myositis/ joint inflammation, transverse myelitis and/ or systemic vasculitis, malar erythema, and one miscarriage. Respondent's expert Dr. Matloubian thoroughly discussed each of these issues.

The experts agreed that SLE is one of the most complex autoimmune diseases to diagnose and that occasionally, GBS presents as one part of SLE. However, it seems unlikely that occurred in the present case. As discussed above, I do not accept that petitioner developed persistent fatigue and sensory symptoms before the recognized onset of GBS in January 2014. Petitioner contends that she continues to have fatigue and weakness. However, Dr. Matloubian persuasively explained that these are non-specific symptoms that would be consistent with residual symptoms of GBS, which petitioner undisputedly had. He stated that some individuals, despite receiving prompt and appropriate treatment for GBS, experience residual fatigue and weakness.

I also have doubts that petitioner's sensory symptoms began before January 2014. Based on the contemporaneous medical records, it is more likely that these symptoms all began in January 2014 and were consistent with the onset of GBS.

I am also inclined to agree with Dr. Matloubian that petitioner's one episode of migraine with aura can be consistent with SLE, but is not a strong diagnostic indicator of SLE. Instead, headaches – particularly migraines – are quite common and have various possible explanations.

Dr. Brawer contended that his assessment of SLE is also supported by findings of hemolytic anemia and thrombocytopenia. During the January – February 2014 hospitalization, petitioner did have some bloodwork results outside of the normal ranges. However, Dr. Matloubian effectively explained that these are mild, possibly consistent with GBS, and not specific for SLE. Dr. Brawer also points to a positive ANA test on March 20, 2017. But as noted by Dr. Matloubian, follow-up testing was negative for antibodies that were more specific for lupus. Dr. Matloubian also effectively rebutted Dr. Brawer's brief conclusions that petitioner had myositis, transverse myelitis and/ or systemic vasculitis in addition to her confirmed GBS. There was no convincing evidence for any of these conditions.

Dr. Brawer also opined that petitioner developed a persistent mild malar rash which he personally observed on January 31, 2017. I do not challenge Dr. Brawer's observation. However, it seems unlikely that none of the multiple physicians who evaluated petitioner made

any notation of a malar rash during her hospitalization or otherwise. Additionally, Dr. Matloubian discussed the difficulty of confirming an SLE malar rash. He also stated that an SLE rash is characterized by itching and burning of skin lesions. Resp. Ex A at 13. He suggested that a dermatologist would be better qualified to view the rash and rule out alternative etiologies. Dr. Brawer has not responded to this point.

Dr. Brawer also opined that petitioner's experience of a first-trimester miscarriage in January 2017, despite taking progesterone supplements, is the "most recent manifestation" of SLE. As noted in my earlier Rule 5 status conference order, I am truly sympathetic to petitioner's experience. However, as Dr. Matloubian explained, miscarriage at that early stage in a pregnancy is not uncommon and can occur for many reasons. SLE is not implicated unless the individual is positive for anti-SSA antibodies or is diagnosed with antiphospholipid syndrome (which requires a finding of three or more consecutive miscarriages before 10 weeks gestation). This is also a non-specific finding that does not provide strong support for an assessment of SLE. Moreover, petitioner was tested for anti-SSA antibodies and antiphospholipid antibodies after her miscarriage in 2017. According to Dr. Matloubian, this ruled out an SLE-related process. Resp. Ex. A at 13.

Dr. Brawer contended that Dr. Matloubian does not have sufficient clinical experience with SLE. Dr. Brawer also stated that Dr. Matloubian's reliance on the ACR diagnostic criteria is inappropriate. He stated that this criteria is too rigid and SLE is instead a diagnosis made at the bedside, based on a totality of the circumstances. However, the ACR lists 11 possible clinical and immunological criteria. The ACR does not seem to require any particular finding or a minimum number for a diagnosis of SLE. It also states that symptoms or organs affected can be separated by time and do not need to occur simultaneously. See Resp. Ex. A at 8-9. Thus, the ACR criteria does not appear to be particularly rigid. And in fact, they are cited in at least two of the several medical journal articles filed by Dr. Brawer. See Pet. Ex. 16, Srivastava et al.; Pet. Ex. 22, Brown and Bertouch. This criteria is somewhat helpful in assessing SLE and it is relevant that petitioner does not seem to fit many of the criteria.

Dr. Brawer also stated that the ACR criteria do not apply to the atypical form of SLE caused by a vaccination. However, Dr. Brawer does not discuss the presentation of this atypical SLE, other than concluding that it is present in the petitioner, Ms. Braun.

Petitioner appears to have had a generally good recovery with no more than IVIG treatment. Dr. Matloubian indicated that SLE would have required more aggressive and significant therapy.

Overall, I find that petitioner has not established by a preponderance of the evidence that she has SLE. It is more likely that she simply developed GBS, as she originally alleged which occurred too remote in time to have any likely connection to the vaccination.

IV. CONCLUSION

For the foregoing reasons, petitioner has not established entitlement to compensation in the Vaccine Program. Therefore, her claim must be **DISMISSED.** In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment forthwith.[30]

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master

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