In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 15, 2021

R.S., Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	PUBLISHED No. 15-1207V Special Master Nora Beth Dorsey Motion for Relief from Judgment; Vaccine Rule 36; RCFC 60(b); Influenza ("Flu") Vaccine; Guillain-Barré Syndrome ("GBS"); Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal Gammopathy, and Skin Changes ("POEMS") Syndrome.

Ronald C. Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for respondent.

ORDER ON REMAND DENYING PETITIONER'S MOTION FOR RELIEF FROM JUDGMENT[1]

I. INTRODUCTION

On October 15, 2015, R.S. ("R.S." or "petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012),[2] alleging that as a result of receiving an influenza ("flu") vaccine on October 1, 2013, she suffered from Guillain-Barré syndrome ("GBS") and polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes ("POEMS") syndrome. Petition at 1-2 (ECF No. 1). On December 19, 2019, the undersigned

[1] When the decision denying entitlement was originally issued, the undersigned advised her intent to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner filed a timely motion to redact certain information. The decision was reissued with initials, R.S. or S., in place of petitioner's name.

[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 Order to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

issued a decision denying entitlement. Decision dated Dec. 19, 2019 (ECF No. 136). Subsequently, petitioner sought review of the decision. Motion for Review, filed Jan. 21, 2020 (ECF No. 144). Judge Ryan T. Holte denied petitioner's motion for review. Opinion and Order dated June 19, 2020 (ECF No. 157). Judgment entered on June 19, 2020, dismissing the petition. Judgment dated June 19, 2020 (ECF No. 158).

Petitioner filed her present motion for relief from judgment on June 21, 2021, requesting that "her case be reopened in order to file additional medical records and medical expert opinion based on [her] recent medical course." Petitioner's Motion for Relief from Judgment ("Pet. Mot."), filed June 21, 2021, at 5 (ECF No. 165). Petitioner received a flu vaccine on November 8, 2020.[3] Id. at 2. She alleges that approximately two weeks later, "she developed the onset of bilateral leg weakness and numbness." Id. at 7. Petitioner asserts that this event represented a "rechallenge episode" that "constitutes persuasive evidence" of the causal role of her 2013 flu vaccination. Id. Further, petitioner contends that these events constitute "newly discovered evidence," providing the basis for her motion pursuant to RCFC 60(b)(2). Id. "To the extent that this Court finds [RCFC] 60(b)(6) to be more suitable grounds for reopening judgment," the petitioner incorporates RCFC 60(b)(6) as a basis for her motion. Pet. Reply to Respondent's Response ("Pet. Reply"), filed July 8, 2021, at 5 (ECF No. 170).

Respondent argues petitioner has not met the requirements of RCFC 60(b)(2) or 60(b)(6). Respondent's Memorandum in Response to Pet. Mot. ("Resp. Response"), filed July 1, 2021, at 8-13, 13 n.7 (ECF No. 167); Resp. Sur-Reply in Support of Resp. Response ("Resp. Sur-Reply"), filed July 28, 2021, at 4 n.1, 4-10 (ECF No. 173).

Under Vaccine Rule 36(a)(1), the present motion was before Judge Holte. However, on November 9, 2021, Judge Holte remanded the motion to the undersigned due to the significant fact-finding that would be required to decide if petitioner is entitled to the relief sought. Order dated Nov. 9, 2021, at 2 (ECF No. 174).

After carefully analyzing and weighing the applicable rules, case law, and evidence presented, in accordance with the applicable legal standards, the undersigned finds that petitioner has failed to establish that she is entitled to relief from judgment. Therefore, petitioner's motion is **DENIED**.

II. PROCEDURAL HISTORY

The petition was filed in this matter on October 15, 2015, and subsequently, petitioner filed medical records and supporting affidavits. Pet. Exhibits ("Exs.") 1-23. On February 22, 2016, respondent filed his Rule 4(c) Report, recommending against compensation. Resp. Report ("Rept.") at 2.

On August 5, 2016, petitioner filed an expert report by Dr. Norman Latov. Pet. Ex. 29. Respondent thereafter filed a responsive expert report by Dr. Dennis Bourdette on January 6,

[3] Petitioner's motion indicated petitioner received the flu vaccine at issue on November 7, 2020; however, records indicate the vaccine was administered on November 8, 2020. See Pet. Mot. at 2; Pet. Ex. 88 at 1.

2017. Resp. Ex. A. On January 26, 2017, the undersigned ordered petitioner to file a supplemental expert report addressing the opinions of Dr. Bourdette. Order dated Jan. 26, 2017 (ECF No. 34). Petitioner submitted a supplemental report from Dr. Latov on March 27, 2017. Pet. Ex. 31.

On May 2, 2017, the undersigned held a Rule 5 status conference with the parties. Order dated May 2, 2017 (ECF No. 39). Given the complexities of the case, the undersigned did not offer her preliminary findings. Id. at 1. Rather, both parties agreed that expert reports addressing the hematologic aspect of petitioner's claim would be helpful. Id.

Respondent filed an expert report by Dr. Brea Lipe on June 16, 2017. Resp. Ex. C. On December 4, 2017, petitioner submitted a responsive report from Dr. Latov. Pet. Ex. 38. Petitioner filed an expert report from Dr. Samir Parekh on October 11, 2018. Pet. Ex. 57.

An entitlement hearing was held on January 29-30, 2019. The parties filed post-hearing briefs on April 26, 2019 and July 24, 2019, respectively. Pet. Post-Hearing Submission, filed Apr. 26, 2019 (ECF No. 121); Resp. Post-Hearing Submission, filed July 24, 2019 (ECF No. 134). The undersigned issued a decision on December 19, 2019 dismissing petitioner's case. Decision dated Dec. 19, 2019. Petitioner filed a motion for review on January 21, 2020, which was denied by Judge Holte on June 19, 2020, and judgment entered that day. Opinion and Order; Judgment.

On June 21, 2021, petitioner filed the present motion for relief from judgment pursuant to Vaccine Rule 36 and RCFC 60(b). Pet. Mot. at 3. The motion has been fully briefed by the parties.

On November 9, 2021, Judge Holte remanded the present motion to the undersigned. Order dated Nov. 9, 2021. Judge Holte explained that "[t]he Court 'issue[s] its own findings of fact' when it is setting aside the Special Master's findings of fact." Id. at 2 (quoting § 12(e)(2)(B)). After a review of petitioner's motion and various filings, he determined that "significant fact-finding would be required to decide if [petitioner] is entitled to relief, and because "the Special Master has not yet made any findings of fact regarding the new evidence presented by petitioner," the case was remanded. Id.

This matter is now ripe for adjudication.

III. FACTUAL SUMMARY[4]

A. Medical History Prior to Vaccination in 2013

R.S. was born on August 23, 1972. Pet. Ex. 3 at 35. Prior to her receipt of the vaccine at issue in this matter, R.S. had no history of neurological abnormalities. Her prior medical history is significant for cherry angiomas, basal cell neoplasms, and depression. Pet. Ex. 2 at 1; Pet. Ex. 3 at 35-36.

[4] Sections A and B of the factual summary are largely taken from the undersigned's dismissal decision. See Decision at 4-9.

B. Receipt of Vaccination in 2013 and Subsequent Clinical Course

1. Medical Treatment in 2013

R.S. received a flu vaccine on October 1, 2013. Pet. Ex. 1 at 1. No adverse reaction was noted at the time of vaccine administration. Id.

On November 6, 2013, roughly four weeks following her vaccination, R.S. presented to Dr. Gopalan Umashankar, a neurologist employed with Cottage Hospital in Woodsville, New Hampshire. Pet. Ex. 6 at 1-2. R.S. complained of weakness and numbness in her legs. Id. at 1. She reported to Dr. Umashankar that three days following her receipt of the flu vaccine, she experienced severe diarrhea and stomach pain that lasted a couple of days. Id. Around October 10, 2013, R.S. reported that she developed numbness in the tips of her toes, which eventually ascended to the pads of her feet and toes. Id.

At the time of her visit with Dr. Umashankar, petitioner's symptoms had progressed over the past week to include pain in the calves and hips, fatigue, palpitations, numbness in the fingers, unsteady gait, and drooling. Pet. Ex. 6 at 1. Upon examination, petitioner's dorsiflexors were noted to be weak, and reflexes in her ankles, biceps, and knees were diminished. Id. at 2. A mid-shin sensory deficit was also noted. Id. Dr. Umashankar assessed R.S. with "probabl[e]" GBS[5] due to the markedly diminished reflexes, sensory deficits, and facial involvement, though it was noted that additional testing would be needed to confirm the diagnosis. Id. R.S. was admitted to Dartmouth Hitchcock Medical Center ("Dartmouth") that same day for further testing. Id.

Upon admission to Dartmouth, R.S. was seen by a second neurologist, Dr. Elijah Stommel. Pet. Ex. 7 at 1-6. Consistent with the history provided to Dr. Umashankar, R.S. reported that she developed a "GI bug" three days following her receipt of the flu vaccine on October 1, 2013. Id. at 1. By mid-October of that year, she developed toe and finger numbness, calf pain, weakness in the lower extremities, low back pain, palpitations, drooling, and eye strain. Id. at 1-2. Dr. Stommel reviewed R.S.'s history and opined that her course was "concerning for acute inflammatory demyelinating polyneuropathy" or AIDP. Id. at 6. Dr. Stommel further noted the viral illness reported prior to the onset of symptoms which would be consistent with such a diagnosis. Id. A lumbar puncture conducted during R.S.'s hospital stay showed a slightly elevated protein of 57 (range: 15-45) with normal glucose. Id. at 44. An electromyography ("EMG") was consistent with a generalized peripheral neuropathy with demyelinating features. Id. at 56. R.S.'s lab tests also indicated that she had thrombocytosis, with an elevated platelet count of 473 x10(3)/mcL. Id. at 4. Her immunoglobulin A ("IgA") level was within normal limits at 174 (range: 70-400mg/dL). Id. at 5. R.S. was discharged on November 11, 2013, with diagnoses of GBS and AIDP. Id. at 54. Discharge notes indicated that she received a dose of Solu-medrol (200mg) and a five-day course of IVIG treatment with noted improvement in extremity strength. Id. at 54-58.

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[5] GBS is a peripheral neuropathy involving rapidly-progressive and ascending motor paralysis caused by demyelination of the peripheral nerves. See Pet. Ex. 29, Tab C at S21-S22.

R.S. was hospitalized a second time at Littleton Regional Healthcare ("Littleton Regional") in Littleton, New Hampshire from November 26-29, 2013 due to difficulties with her speech and gait. Pet. Ex. 5 at 658-59. Upon admission, R.S. reported that she did well over a two-week period, but started to experience increased tingling in the legs and fingers, difficulty walking, chest pain, and voice issues, roughly 36 hours prior to presentation. Id. at 658. It was noted that she received a flu vaccine in early October. Id. at 658-59. Emergency room treaters assessed her with a GBS flare and recommended further treatment with IVIG. Id. at 659. Her thrombocytosis persisted, with labs indicating her platelets remained elevated at 707 K/uL. Id. at 628. On November 27, 2013, Dr. Stephen Goldberg conducted a serum protein electrophoresis ("SPEP") test without immunofixation ("IFE") to test for monoclonal gammopathy. Pet. Ex. 7 at 600. R.S. tested negative for the monoclonal protein, but two beta region peaks were recorded. Id. The assessment remained GBS with treatment related fluctuation. Pet. Ex. 5 at 681. Discharge records indicated that R.S.'s paresthesia and gait improved following IVIG treatment. Id. Her deep tendon reflexes remained absent, and she continued to experience residual tingling in the toes. Id.

R.S.'s health continued to worsen. Less than two weeks later, she was readmitted to Littleton Regional on December 10, 2013 for persistent lower extremity weakness, sensory loss, and paralysis in the lower extremities. Pet. Ex. 5 at 544; Pet. Ex. 7 at 324-26. Upon admission, petitioner complained of worsening paresthesia, continued gait abnormalities, and leg pain. Pet. Ex. 5 at 485-87. R.S. received two additional infusions of IVIG at Littleton Regional, with no improvement in strength. Pet. Ex. 7 at 314-16. She was transferred back to Dartmouth on December 12, 2013 for further evaluation and treatment. Id. She finished her five-day course of IVIG at Dartmouth with a steady improvement in strength noted following her last treatment. Id. at 342. R.S. was discharged on December 15, 2013, with instructions to follow up with her primary neurologist as needed. Id. at 325.

On December 20, 2013, petitioner presented for a follow-up appointment with Dr. Stommel. Pet. Ex. 7 at 471-72. Petitioner reported that she continued to experience weakness, but could ambulate well with a walker. Id. On examination, Dr. Stommel noted residual complaints, including sensory loss in the lower extremities, weakness in both legs, and subtle weakness in the biceps. Id. at 471. A repeat nerve conduction study ("NCS") revealed a slight worsening in active denervation in the left tibialis. Id. Given the progression of her symptoms, Dr. Stommel recommended that she continue IVIG treatments. Id. Dr. Stommel also prescribed Cellcept. Id. Lab testing conducted on December 26, 2013, and January 15, 2014, indicated that R.S.'s thrombocytosis remained persistent with elevated platelet levels of 554 k/uL and 583 k/uL, respectively. Id. at 477, 484. R.S. remained relatively stable throughout the remainder of 2013, though she continued to complain of tremors, foot pain, blurred vision, fatigue, weakness, and diminished sensation in the lower extremities. Pet. Ex. 7 at 478-79.

2. Medical Treatment in 2014

R.S. presented to Littleton Regional for a fourth hospitalization on January 27, 2014. Pet. Ex. 5 at 63-65, 379. The history recorded at discharge indicated that she was diagnosed with GBS initially on November 6, 2013, and suffered three relapses all of which required IVIG treatment. Id. at 63. Upon admission, R.S. complained of cognitive issues, fever, and chills. Id.

at 63-64. She also had "trouble remembering things." Id. at 64. The attending physician diagnosed R.S. with aseptic meningitis secondary to an IVIG infusion she received on January 23, 2014. Id. at 69. An MRI of the thoracic spine showed a spinal cord neoplasm at the T12-L1 level. Id. at 379. The attending neurologist opined that the neoplasm was likely incidental and not related to petitioner's paresthesia, which he deemed to be related to a chronic inflammatory demyelinating polyneuropathy ("CIDP")[6] diagnosis. Id. at 64.

On February 4, 2014, petitioner presented to the Massachusetts General Hospital ("MGH") neuromuscular clinic for an evaluation of her persistent symptoms. Pet. Ex. 8 at 26-30. The health history recorded during this visit indicated that R.S.'s symptoms began with progressive lower limb weakness in October 2013 and thereafter progressed to include severe fatigue, calf pain, gait abnormalities, and sensory deficits. Id. at 26-29. The attending physician, Dr. Michael Bowley conducted a repeat EMG/NCS, both of which continued to show evidence of sensory and motor polyneuropathy. Id. at 8-10. Dr. Bowley concluded that R.S. likely had CIDP, with multiple subsequent relapses, given her clinical history of rapidly evolving motor deficits, distal areflexia, and elevated cerebrospinal fluid. Id. at 28. R.S.'s "initial improvement" with IVIG was also considered to be supportive of such a diagnosis; however, Dr. Bowley indicated that her repeated relapses did not respond as well to further IVIG treatment. Id. Dr. Bowley recommended that she increase her mycophenolate dose and use corticosteroids as needed. Id. at 29. Her platelet count remained elevated at 627 k/uL. Pet. Ex. 9 at 131. A SPEP test conducted on February 4, 2014, showed an abnormal pattern of two IgA lambda components at 0.22 and 0.06 g/dL in the beta region, but was negative for monoclonal protein. Pet. Ex. 8 at 3-4.

Petitioner was hospitalized for a thoracic laminectomy and mass resection on February 12, 2014, both of which were unrelated to her underlying disease course. Pet. Ex. 9 at 25, 127-28. Prior to the surgery, her treaters discovered a spinal mass and recommended removal out of concern for lymphoma. Id. at 116-19. Pathologic testing indicated that the mass was a T12 hemangioma. Id. On February 18, 2014, R.S. was transferred to a rehabilitation facility for occupational and physical therapy. Pet. Ex. 10 at 36-39. Upon discharge on March 14, 2014, petitioner could ambulate and transfer with a walker. Id. at 38. Her discharge diagnoses included extradural spinal mass and post-T12 laminectomy, with a secondary diagnosis of GBS/CIDP. Id. at 32.

On May 27, 2014, R.S. presented for a follow-up appointment at MGH with Dr. Jennifer Dineen. Pet. Ex. 8 at 14-18. She reported that she continued to experience fatigue, weakness in her legs, tremors, nerve pain, gait abnormalities, and blurry vision. Id. at 15-16. Her exam revealed a sensory and motor neuropathy with features indicative of a demyelinating polyneuropathy. Id. at 15. Dr. Dineen recommended that R.S. continue Cellcept and maintain Gabapentin as needed. Id. at 18. She also decreased petitioner's Prednisone dosage to 30mg daily. Id. Dr. Dineen did not think that further IVIG treatment would be helpful at this time. Id.

[6] CIDP is a chronic form of GBS, which progresses slowly over time, but manifests similar symptoms. Resp. Ex. E, Tab 1 at 477.

3. POEMS Diagnosis and Treatment in July and August 2014

R.S. presented to Littleton Regional on July 14, 2014, with complaints of postural headaches, diplopia, incontinence, and cognitive issues. Pet. Ex. 22 at 194. Upon admission, petitioner was evaluated by Dr. Umashankar in the emergency room. Id. A lumbar puncture revealed an elevated opening pressure with no white blood cells detected, and a normal total protein at 38 mg/dl. Id. at 195. A brain MRI conducted during the visit was also normal. Id. Given the above, R.S.'s treaters felt her symptoms were consistent with benign intracranial hypertension. Id. Prior to her discharge, R.S. was also evaluated by an ophthalmologist, Dr. Krista Haight, for complaints associated with eye pressure, pain, and hazy vision. Pet. Ex. 53 at 1. Dr. Haight assessed petitioner with papilledema. Id. at 3.

From July 31 to August 5, 2014, R.S. presented to MGH for complaints related to persistent headaches and vision changes. Pet. Ex. 18 at 1232. Upon admission, R.S. was evaluated by a neurologist, Dr. Mingming Ning. Id. Cerebrospinal fluid testing was unrevealing. Id. Intake notes indicated that R.S. had symptoms of CIDP-like neuropathy, thrombocytosis, and papilledema. Id. Dr. Ning suspected that R.S. might have POEMS[7] syndrome and recommended a hematology consult. Id. A SPEP draw with immunofixation, conducted on August 1, 2014, revealed a persistent IgA lambda monoclonal protein with components at 0.15 and 0.06 g/dl. Id. at 1163, 1165. The free light chain evaluation showed normal kappa levels, and elevated lambda at 31, which was considered to be within a normal ratio limit. Id. at 1163. It was also noted that R.S. had possible sclerotic lesions in the mandible and right pelvis following a skeletal survey, though a bone scan showed no definitive sclerotic lesions. Id.

R.S. returned to MGH on August 12, 2014. Pet. Ex. 18 at 441, 1152. Upon admission, she complained of lethargy, reduced appetite, and blurry vision. Id. She also reported that her symptoms of weakness remained stable, though she had lost movement in her right toe. Id. at 441, 1167. Treaters questioned the need to continue Cellcept and Prednisone in light of the alternative treatment plan for suspected POEMS syndrome. Id. at 1086. Petitioner was evaluated by the attending hematologist, Dr. Annemarie Fogerty, on August 13, 2014. Id. at 1163. Dr. Fogerty assessed petitioner with a progressive neuropathy, dual M-spike, and thrombocytosis, concerning for POEMS syndrome. Id. It was noted that petitioner satisfied the two major criteria for the condition (i.e., neuropathy and monoclonal gammopathy), as well as two minor criteria: papilledema and thrombocytosis. Id. Petitioner's vascular endothelial growth factor ("VEGF")[8] levels, taken on August 14, 2014, were noted to be elevated at 1799 (reference range: 31-86), and the diagnosis of POEMS syndrome was confirmed. Id. at 444, 446.

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[7] POEMS syndrome is a paraneoplastic syndrome due to an underlying plasma cell disorder. Pet. Ex. 29, Tab F at 214.

[8] VEGF levels are elevated in patients diagnosed with POEMS syndrome. Pet. Ex. 29, Tab F at 215. VEGF is known to target endothelial cells and induce a rapid and reversible increase in vascular permeability. Id. It is expressed by osteoblasts in bone tissue, macrophages, tumor cells, including plasma cells, and megakaryocyte/platelets. Id.

Prior to her discharge on August 18, 2014, petitioner was evaluated by another hematologist, Dr. Andrew Yee. Pet. Ex. 18 at 1082. Dr. Yee discussed POEMS syndrome with R.S. and explained her course in light of the accepted diagnostic criteria. Id. In his opinion, multiple clinical factors identified in R.S.'s prior history, including polyneuropathy, IgA lambda gammopathy, markedly elevated VEGF levels, thrombocytosis, and papilledema, supported a POEMS diagnosis. Id. Dr. Yee also discussed treatment options with R.S., including a stem cell transplant. Id. Petitioner's records reveal that Dr. Yee recommended Revlimid and dexamethasone for her POEMS-related symptoms. Id.

4. Medical Care in 2015

R.S. underwent an autologous stem cell transplant on January 29, 2015. Pet. Ex. 18 at 385-93. Of note, her VEGF levels improved with treatment. Id. at 386. R.S.'s platelets also returned to normal. Pet. Ex. 19 at 1, 28.

On June 17, 2015, R.S. presented to Dr. Angela Dispenzieri, a hematologist at the Mayo Clinic, for a second opinion regarding her POEMS diagnosis. Pet. Ex. 19 at 27. Dr. Dispenzieri noted that petitioner had been diagnosed with POEMS in August 2014 based on a set of factors, including: demyelinating peripheral neuropathy, IgA lambda monoclonal protein, hypertrichosis, white nails, papilledema, peripheral edema, and thrombocytosis. Id. Dr. Dispenzieri placed the onset of petitioner's illness in October 2013, when she experienced new onset fatigue and numbness/tingling in the feet, along with eruptions of cherry angiomas on the skin. Id. By October/November 2013, her symptoms progressed to include muscle pain, difficulty walking, ascending hip pain, numbness in the fingers, and slight drooling. Id. Her initial hospitalization in November 2013 for presumed GBS/CIDP was noted, along with her initial marked improvement with IVIG treatment. Id.

Following her initial hospitalization, Dr. Dispenzieri noted that R.S.'s course worsened. Pet. Ex. 19 at 27. Additional treatment with IVIG, Cellcept, and Prednisone through 2014 did not result in similar levels of improvement. Id. Following her POEMS diagnosis, R.S. started treatment with Revlimid and dexamethasone between September 2014 and December 2014, which resulted in a significant decrease in the serum VEGF, but only marginal improvement in her lower extremity neuropathy symptoms. Id. at 28. Further treatment with cyclophosphamide mobilization, high-dose melphalan, and stem cell infusion resulted in good improvement. Id. All in all, Dr. Dispenzieri opined R.S.'s course was consistent with POEMS syndrome. Id. at 30.

As of May 2015, R.S. continued to be treated for POEMS. Pet. Ex. 18 at 562. She routinely experienced fatigue, intermittent headaches, hot flashes, foot swelling and discomfort, and diminished strength in both feet. Id. at 563-64. A neurological exam conducted on May 29, 2015 showed normal function apart from marked weakness and sensory loss in the lower limbs. Id. at 565. Her gait was also improved. Id.

C. Summary of Medical Records Filed in Support of Petitioner's Motion

In support of her current Motion, petitioner filed medical records documenting her flu vaccination on November 8, 2020, which is at issue here, as well as records from Littleton

Regional, Littleton Regional Primary Care Physicians, and the Mayo Clinic. See Pet. Exs. 88-91.[9] These records document petitioner's past history as well as her clinical course from 2018 until January 2021.[10]

On October 1, 2015, petitioner received a flu vaccine. Pet. Ex. 91 at 5, 682. No adverse reaction was noted.

From May to July 2018, petitioner had a "[p]ossible relapse [of her POEMS] with papilledema, edema, hemangiomata, and [] nausea." Pet. Ex. 91 at 110. She was treated with Revlimid and dexamethasone. Id.

On November 29, 2018, petitioner presented to the Emergency Department ("ED") of Littleton Regional with complaints of chest pain. Pet. Ex. 89 at 68. The immunization record from this visit documents that petitioner received a flu vaccine in 2017. Id. at 71. There is no documentation suggesting that petitioner experienced any adverse reaction to the vaccination.

Petitioner presented to the Littleton Regional ED on December 19, 2018 for a headache that was not responsive to medications. Pet. Ex. 89 at 64. Petitioner reported that her headaches were usually caused by increased intracranial pressure. Id. She reported a "history of cancer with [POEMS] syndrome and . . . an episodic rise in intracranial pressure." Id. Petitioner underwent a therapeutic lumbar puncture, which relieved her symptoms. Id. The records document that petitioner received flu vaccines in 2017 and 2018. Id. at 66. No adverse reaction to these vaccinations was noted.

On December 28, 2018, petitioner spoke with her hematologist, Dr. Dispenzieri, by telephone, about needing a lumbar puncture to treat her increased intracranial pressure. Pet. Ex. 91 at 643. Dr. Dispenzieri was not sure whether petitioner's increased intracranial pressure was due to POEMS. Id.

Petitioner underwent a brain MRI on January 9, 2019, which showed several new enhancing lesions. Pet. Ex. 91 at 427-28. Dr. Dispenzieri referred petitioner to Dr. Scott Eggers for an evaluation of her abnormal MRI. Id. at 427. Dr. Eggers reviewed petitioner's "complex history of POEMS syndrome and raised intracranial pressure with papilledema that ha[d] required ventriculoperitoneal shunting." Id. Physical examination revealed petitioner had a "bilateral steppage gait, [and was] unable to rise on heels and barely on toes." Id. at 429. She had "[m]oderate to severe symmetric weakness below the knees with very mild bilateral quadriceps and hamstring weakness." Id. Dr. Eggers concluded that clinically, petitioner appeared stable. Id.

On February 4, 2019, petitioner returned to see Dr. Dispenzieri, complaining of a "complete lack of energy" and pain. Pet. Ex. 91 at 541. Dr. Dispenzieri noted that petitioner's

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[9] The undersigned has reviewed all of the records and documents filed, but only references those that are relevant to her present Order.

[10] The records that have been filed in support of petitioner's motion do not appear to be complete. However, they are sufficient for purposes of evaluating petitioner's present Motion.

pain in feet and headache associated with increased intracranial pressure were previously signs of relapse (in July 2018). Id. Dr. Dispenzieri diagnosed petitioner with "POEMS syndrome, relapsed disease." Id. at 547.

Moving forward, petitioner saw Dr. Dispenzieri on September 3, 2020, complaining of a "[c]omplete lack of physical energy," depression, anxiety, and nausea. Pet. Ex. 91 at 111. She reported falling "several times per week." Id. Her neuropathy was unchanged. Id. Dr. Dispenzieri did not think that petitioner was having a relapse, and was unsure whether petitioner's symptoms were related to POEMS. Id. at 118.

The following day, September 4, 2020, petitioner had an appointment with neurologist Dr. Jennifer Martinez-Thompson for peripheral neuropathy.[11] Pet. Ex. 91 at 58. EMG/NCS done September 3, 2020 showed "severe length-dependent mixed axonal demyelinating sensorimotor peripheral neuropathy." Id. at 59. Compared to a prior EMG performed in July 2016, there was some improvement. Id. Petitioner reported that her weakness had improved, she still had mild foot drop, but was able to walk independently. Id. She sometimes used a cane for walking long distances. Id. Her numbness had also improved, although she continued to have numbness to above the knees. Id. Also, petitioner complained of "burning, tingling, pricking sensation[s] in her shins." Id. at 61. This neuropathic pain was "very disturbing . . . and limiting most of her daily activities." Id.

Review of symptoms was "[p]ositive for numbness or shooting pain in hands, arms, legs, or feet, loss of balance or tendency to fall easily, headaches and weakness in arms or legs." Pet. Ex. 91 at 61. Physical examination revealed "significant weakness in distal lower extremities (slight improvement in plantarflexion and eversion compared to last visit)." Id. at 61-62. Decreased sensation was noted above the knee level. Id. at 62. Petitioner had hyperalgesia and allodynia in both feet. Id. Reflexes were -2 at the knees but absent at the ankles. Id. Petitioner was unable to walk or stand on her heels. Id. The neurology fellow, Dr. Pitcha Chompoopong, concluded that petitioner's "POEMS seem[ed] to be in remission" and that her distal lower limb pain was likely neuropathic. Id.

A health questionnaire completed on November 4, 2020, documented that petitioner was having "numbness or shooting pain in hands, arms, legs[,] or feet;" "[w]eakness in arms and/or legs;" and "[l]oss of balance or tendency to fall easily." Pet. Ex. 91 at 93.

Petitioner received the flu vaccine at issue on November 8, 2020. Pet. Ex. 88 at 1.

On December 12, 2020, petitioner presented to the ED at Littleton Regional. Pet. Ex. 89 at 53. Dr. Richard M. Levitan stated that petitioner was "referred by neurology for admission for IVIG; complaining of weakness and pain in lower legs." Id. Petitioner reported that she had "chronic weakness in her lower legs, but feels more weak than usual." Id. She also reported having more pain than usual, and that her neurologist was concerned that she was "having a recurrence of [GBS]." Id. Dr. Levitan's physical examination revealed "[d]iscomfort with

[11] Petitioner left for another appointment before she was seen by Dr. Martinez-Thompson, and therefore, Dr. Martinez-Thompson relied on the clinical notes and physical findings of Dr. Pitcha Chompoopong, a neurology fellow, who saw petitioner that day. Pet. Ex. 91 at 58, 60, 676.

palpation diffusely below the knees bilaterally" and good range of motion. Id. at 55. Petitioner was "able to lift [her] legs off the bed, [but could not] toe walk." Id. She had "[g]ood strength in her upper extremities." Id. Labs indicated that petitioner's "inflammatory makers [were] normal." Id. at 57. Dr. Levitan's clinical impression was polyneuropathy, POEMS. Id.

On admission to the hospital, history and physical examination were performed by Dr. Stephen Goldberg. Pet. Ex. 89 at 41. Chief complaint was weakness. Id. In history of present illness, Dr. Goldberg documented that petitioner had a flu shot five weeks before admission. Id. Petitioner reported that two-and-one-half weeks prior, she had become weaker, and over the last few days, she had difficulty walking. Id. A lumbar puncture performed the day before showed mildly elevated protein. Id. Petitioner reported paresthesias in her arms. Id. at 45. Leg strength was assessed as 1-2 out of 5. Id. Petitioner was admitted for IVIG treatment. Id. at 49. She received six treatments of IVIG, and was discharged on December 17, 2020. Id. at 18.

On January 4, 2021, petitioner was seen for follow up after her hospital discharge by her neurologist, Dr. Umashankar. Pet. Ex. 90 at 1. She complained of fatigue and pain and "felt that she needed another round of IVIG infusion." Id. Petitioner's husband, a physician, "[felt] that this [was] myalgia encephalitis syndrome or chronic fatigue syndrome." Id. Muscle strength was 5/5 in the lower limbs, except for bilateral tibialis anterior, which was 2-3/5, and extensor hallucis longus, which was 1-2/5. Id. at 4. Petitioner was able to walk without assistance. Id. Dr. Umashankar' s diagnoses were POEMS syndrome and polyneuropathy. Id. He noted that "[i]nterestingly[,] she had a flu shot about 2 weeks before the onset of symptoms in December 2020." Id. He wrote, "I am honestly stumped if this was worsening of her neuropathy of POEMS syndrome or if this was [GBS]." Id. Dr. Umashankar referred petitioner to the MGH neuromuscular team for a second opinion. Id.

Several weeks later, on January 26, 2021, petitioner returned to Littleton Regional with "progressive distal extremity numbness and weakness over the past week or so. She [was] confined to a walker as her lower extremities [were] unable to feel and move." Pet. Ex. 89 at 33. Petitioner also reported a day of right ear pain. Id. Admitting diagnoses were "[f]lare of POEMS disease, chronic pain, chronic anxiety." Id. at 1. Petitioner was discharged on January 30, 2021, after receiving IVIG with good results. Id. "Her neurological status improved back to near baseline" and she was able to walk without assistance. Id. at 1-2. She was discharged home and instructed to follow up with neurology and MGH neuromuscular neurology. Id. at 2, 6.

IV. APPLICABLE LEGAL STANDARDS

Vaccine Rule 36(a) allows a party to seek relief from judgment pursuant to RCFC 60. In determining whether a judgment should be set aside or altered, "the need for finality of judgments" must be balanced against "the importance of ensuring that litigants have a full and fair opportunity to litigate." Kennedy v. Sec'y of Health & Hum. Servs., 99 Fed. Cl. 535, 539 (2011) (citing United Student Aid Funds, Inc. v. Espinosa, 559 U.S. 260, 276 (2010)); see also Bridgham ex rel. Libby v. Sec'y of Health & Hum. Servs., 33 Fed. Cl. 101, 104 (1995) (discussing the "tension between the goals of ensuring that the court's judgment appropriately reflects the adjudication of the parties' rights and of providing the parties with certainty as to those rights").

"The court has discretion regarding whether to grant relief under [RCFC] 60(b), 'and the court may weigh equitable considerations in the exercise of its discretion.'" Curtis v. United States, 61 Fed. Cl. 511, 512 (2004) (quoting Dynacs Eng'g Co. v. United States, 48 Fed. Cl. 240, 241-42 (2000)). RCFC 60(b) as a remedial provision is to be "liberally construed for the purpose of doing substantial justice." Patton v. Sec'y of Health & Hum. Servs., 25 F.3d 1021, 1030 (Fed. Cir. 1994).

Under RCFC 60(b), the court may grant relief from a final judgment on the following grounds:

> (1) mistake, inadvertence, surprise, or excusable neglect;
> (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under RCFC 59(b);
> (3) fraud . . . , misrepresentation, or misconduct by an opposing party;
> (4) the judgment is void;
> (5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
> (6) any other reason that justifies relief.

RCFC 60(b).

Motions for relief under RCFC 60(b) "seek . . . to set aside a final decision and it is incumbent upon the motion-filer to demonstrate that [s]he . . . is entitled to relief." Kennedy, 99 Fed. Cl. at 550. The motion's statements are "not like a pleading . . . in which the factual allegation[s] are presumed true." Id.

As a threshold matter, RCFC 60(c)(1) requires that "[a] motion under RCFC 60(b) must be made within a reasonable time—and for reasons (1), (2), and (3), no more than a year after the entry of the judgment or order or the date of the proceeding." RCFC 60(c)(1). Any motion seeking relief under RCFC 60(b)(1) that is filed after the one-year mark is completely barred. See United States v. Berenguer, 821 F.2d 19 (1st Cir. 1987); Freeman v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 280, 283 (1996); Kenzora v. Sec'y of Health & Hum. Servs., No. 10-669V, 2015 WL 6121582, at *2 (Fed. Cl. Spec. Mstr. Sept. 25, 2015).

RCFC 60(b)(2) provides that "the court may relieve a party . . . from a final judgment, order, or proceeding" if there is "newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under [RCFC] 59(b)." Under this rule, the moving party must show the proffered evidence is (1) newly discovered and (2) material. Mark Dunning Indus., Inc. v. United States, 143 Fed. Cl. 735, 738 (2019).

Under RCFC 60(b)(2), "newly discovered evidence" is limited in scope to "evidence of facts which existed at the time of decision and of which the aggrieved party was excusably ignorant." TDM Am., LLC v. United States, 100 Fed. Cl. 485, 490 (2011). That is, it "only encompasses facts which existed at the time the court made its decision and entered judgment."

Q Integrated Cos., LLC v. United States, 131 Fed. Cl. 125, 132 (2017); see also Sigmatech, Inc. v. United States, 144 Fed. Cl. 159, 181 (2019).

In addition to the requirement that the proffered evidence be newly discovered, RCFC 60(b)(2) also requires that it be material. Mark Dunning Indus., Inc., 143 Fed. Cl. at 738. "Newly discovered evidence is material if the court's decision would have been different had the court been aware of it prior to judgment." Id. at 740. The moving party must show that the "evidence is material and controlling and clearly would have produced a different result if presented before the original judgment." Venture Indus. Corp. v. Autoliv ASP, Inc., 457 F.3d 1322, 1328 (Fed. Cir. 2006); see also Sigmatech, Inc., 144 Fed. Cl. at 175. Thus, in order to vacate judgment and reopen a case under RCFC 60(b)(2), evidence must be both newly discovered and material.

The catch-all provision of RCFC 60(b)(6) provides for relief from judgment upon "any other reason that justifies relief." RCFC 60(b)(6). "The court is limited in granting relief under RCFC 60(b)(6) in two respects: (1) the grounds asserted for relief must not be the same as those listed in [RCFC] 60(b)(1)–(5), and (2) there must be a valid reason that justifies affording the relief, usually broadly described as extraordinary circumstances." Q Integrated, 131 Fed. Cl. at 132; see also Kenzora, 2015 WL 6121582, at *2 (citing Freeman, 35 Fed. Cl. at 283; Kennedy, 99 Fed. Cl. at 547; Liljeberg v. Health Servs. Acquisition Corp., 486 U.S. 847, 863 (1988)). Clauses (1)-(4) are mutually exclusive with clauses (5) and (6), and thus, relief under clause (6) cannot be asserted on one of those grounds. Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P'ship, 507 U.S. 380, 393 (1993); Kenzora, 2015 WL 6121582, at *2.

In addition, in order to justify relief, a showing of "extraordinary circumstances" is required. Kennedy, 99 Fed. Cl. at 548 (citing Ackermann v. United States, 340 U.S. 193, 202 (1950)). RCFC 60(b)(6) permits the decision maker to grant relief from judgment to a party only in circumstances in which a "grave miscarriage of justice" would otherwise result. Id. at 540 (quoting United States v. Beggerly, 524 U.S. 38, 47 (1998)). This narrow use of RCFC 60(b)(6) is essential in order to preserve the finality of judgments. Id. at 548 (citing Gonzalez v. Crosby, 545 U.S. 524, 535 (2005)). The party seeking relief from judgment "must show that the extraordinary circumstances prevented [the] party from taking timely action to prevent or correct an erroneous judgment." Q Integrated, 131 Fed. Cl. at 132 (internal citations omitted).

V. PARTIES' POSITIONS

A. Petitioner's Contentions

Petitioner seeks relief from judgment pursuant to RCFC 60(b)(2), on the basis of "newly discovered evidence." Pet. Mot. at 5. She seeks to have her case reopened so that she may "file additional medical records and medical expert opinion based on petitioner's recent medical course." Id. In the alternative, "to the extent that [the] Court finds [RCFC] 60(b)(6) to be more suitable grounds for reopening judgment . . . for the purpose of doing substantial justice, the petitioner [] incorporates her [RCFC] 60(b) motion to include both 60(b)(2) and 60(b)(6)." Pet. Reply at 5.

Petitioner summarized the facts underlying her original claim, stating that "approximately two (2) weeks following the administration of her October 1, 2013 flu vaccination, [she] developed symmetric ascending weakness, sensory loss, and hyporeflexia concerning for [AIDP]." Pet. Mot. at 6. She further states that she was "diagnosed with GBS, and subsequently, POEMS." Id. Petitioner states that the undersigned determined that "the onset of [petitioner's] peripheral neuropathy was more likely than not POEMS syndrome at the outset of her neurological symptoms." Id.

In the present motion, petitioner states that at the time of her flu vaccination on November 8, 2020, her "POEMS syndrome was stable,"[12] but that "approximately two (2) weeks following [her] November 2020 administration of the [flu] vaccination, she developed the onset of bilateral leg weakness and numbness which progressed distally, and required the administration of IVIG." Pet. Mot. at 2, 7. Petitioner asserts that this is evidence of "rechallenge following the 2020 flu vaccination [which] constitutes persuasive evidence regarding the role of petitioner's 2013 flu vaccination." Id. at 7. "In light of this newly discovered evidence, the petitioner respectfully requests that the Court grant relief from final judgment, so that her case may be reopened to file additional medical records and medical expert opinion for the Special Master's consideration." Id.

In support of her motion, petitioner relies on Cabrera ex rel. L.C. v. Secretary of Health & Human Services, No. 13-598V, 2019 WL 4898479 (Fed. Cl. Spec. Mstr. Sept. 10, 2019). Petitioner notes that in Cabrera, "the injured minor had a relapse of his condition" after judgment entered. Pet. Reply at 5. The evidence at issue in Cabrera "did not exist at the time of the Special Master's Decision, and the Court granted petitioners' motion for relief from judgment based on a showing of newly discovered evidence under 60(b)(2)." Id. at 6. Petitioner characterizes her medical condition following her November 8, 2020 flu vaccination as a relapse, similar to that suffered by the minor in Cabrera. Id. Petitioner also asserts that her medical course after she received the flu vaccination on November 8, 2020 constitutes evidence of challenge-rechallenge. Id. In summary, petitioner states "[t]he course of petitioner's 2020 symptomatology was so strikingly similar to her initial presentation in 2013, both within two weeks of receiving the flu vaccination, that it justifies consideration by this Court." Id. at 14.

B. Respondent's Contentions

Respondent argues that petitioner has not met the requirements of RCFC 60(b)(2) because she has failed to show that the proffered evidence is either "newly discovered" or "material." Resp. Response at 8. As to the issue of whether the evidence is newly discovered, respondent asserts that the medical records of petitioner's November 2020 vaccination and her alleged episode of rechallenge "did not exist at the time of the Special Master's decision in December 2019 or, crucially, at the time of [the] Court's decision in June 2020." Id. Instead, respondent contends that the records were "created later as a result of new factual developments." Id. According to respondent, the vaccination in November 2020 and subsequent

[12] In her motion, petitioner asserts that she was medically stable until her 2020 flu vaccination. Pet. Mot. at 2; Pet. Reply at 13 n.7. This does not appear to be accurate. From May to July 2018, petitioner had a possible relapse. Pet. Ex. 91 at 110. Also, on February 4, 2019, petitioner was diagnosed with a relapse by Dr. Dispenzieri. Id. at 541, 547.

medical care had not occurred when the court entered judgment, and thus, the records do not constitute newly discovered evidence. Id. at 8-9. Instead, respondent argues that the records constitute "newly created evidence, which cannot now be retrospectively grafted onto petitioner's original claim in order to change the result." Id. at 9 (emphasis omitted).

With regard to the question of materiality, respondent, quoting Venture Industries Corporation, states that petitioner must show that "that the evidence is material and controlling and clearly would have produced a different result if presented before the original judgment." Resp. Sur-Reply at 6-7 (quoting Venture Indus. Corp., 457 F.3d at 1328). Respondent argues that the medical records filed by petitioner "do[] not preponderantly prove the three Althen prongs in such a clear and controlling way that, if the evidence had been before the original Court, it would have produced a different result." Id. at 7. Thus, respondent concludes that petitioner's motion amounts to "an invitation for the Court to investigate further whether to grant relief by reopening the case and reweighing facts—an invitation that runs afoul of [RCFC] 60(b)." Id. Moreover, respondent disagrees with petitioner's characterization of the effect of "challenge/rechallenge evidence." Id. at 7-9. Respondent does not agree that such evidence can satisfy Althen prongs one or three. Id. at 8-9.

Lastly, with regard to RCFC 60(b)(6), respondent contends petitioner has "not presented the extraordinary circumstances required to disturb the finality of the judgment. Petitioner may bring a new and distinct vaccine claim if she chooses. But she may not seek relief from judgment simply to relitigate [her] case." Resp. Sur-Reply at 9-10 (internal quotation marks omitted).

VI. ANALYSIS

A. Relief from Judgment Is Not Available Under RCFC 60(b)(2)

The undersigned finds that the petitioner's motion under RCFC 60(b)(2) is unavailing. Pursuant to this rule, "newly discovered evidence" is limited to facts which "existed at the time the court made its decision and entered judgment." Q Integrated, 131 Fed. Cl. at 132; see also TDM Am., 100 Fed. Cl. at 490-91; Yachts Am., Inc. v. United States, 8 Cl. Ct. 278, 281 (1985), aff'd, 779 F.2d 656 (Fed. Cir. 1985). The evidence that petitioner relies upon here are records of her November 8, 2020 vaccination and her subsequent hospitalization in December 2020. The undersigned's decision was filed in December 2019, and the Court's decision issued on June 19, 2020, when judgment entered. Petitioner did not receive vaccine at issue until November 8, 2020, almost six months later. Therefore, the evidence does not qualify as "newly discovered."

Here, petitioner's evidence is like that proffered in Q Integrated, in that it did not exist at the time the court issued its decision and judgment entered. See Q Integrated, 131 Fed. Cl. at 132. Therefore, the evidence "cannot form the basis to grant the [] relief from judgment under RCFC 60(b)(2)." Id.

Cabrera is not inconsistent with this result. In Cabrera, the special master issued a ruling on entitlement, determining that the petitioners' minor child was entitled to compensation. Cabrera, 2019 WL 4898479, at *1. Subsequently, the parties agreed on an award (proffer) of

compensation. Id. On May 28, 2019, the decision awarding damages issued, and judgment entered on May 31, 2019. Id. On May 30, 2019, the day before judgment entered, the minor child saw his treating rheumatologist who expressed "concern that [the child] was perhaps experiencing a flare" of his vaccine-related injury, juvenile idiopathic arthritis. Id. at *2. Diagnostic testing confirmed that the child was having a relapse of his vaccine-related illness. Id. The evidence of relapse changed the factual presumption underlying the damages proffer, namely that the child was in remission. Id. at *3. Since the child had an unexpected relapse, present and future medical care were no longer accurately reflected in the proffer. See id. The respondent had no objection to the motion. Id. In summary, the medical record documenting the treating physician's concerns about relapse existed prior to the entry of judgment, albeit by one day. As such, the evidence "existed at the time the court made its decision and entered judgment." Q Integrated, 131 Fed. Cl. at 132.

Moreover, petitioner's evidence here does not meet the requirement of materiality under RCFC 60(b)(2) because petitioner has not shown that it is "controlling and clearly would have produced a different result if presented before the original judgment." Venture Indus. Corp., 457 F.3d at 1328. The question of materiality is two-fold: would the evidence have changed the undersigned's analysis and findings as to diagnosis and causation.

In the underlying case, the parties agreed that petitioner was appropriately diagnosed with POEMS syndrome, but they disputed the onset of the condition, as well as the appropriate diagnosis for her neuropathy-related symptoms in October and November 2013. Both parties devoted time at the hearing addressing whether vaccine-induced GBS could be shown to cause POEMS syndrome. The medical records, however, suggested a more pertinent question: whether petitioner ever had GBS at all. The medical theory of causation proffered by petitioner hinged on the undersigned's finding that her neuropathy-related symptoms in October and November 2013 were attributable to a GBS diagnosis, not POEMS. Therefore, if petitioner did not suffer from GBS at the outset, then her claim could not succeed.

A brief summary of the evidence outlined in the decision establishes that petitioner was seen by Dr. Dispenzieri,[13] a hematologist at the Mayo Clinic, in June 2015. Dr. Dispenzieri placed the onset of petitioner's POEMS disease in October 2013, when petitioner had fatigue, numbness/tingling, and eruptions of cherry angiomas of the skin. Pet. Ex. 19 at 27. Both of respondent's experts agreed that Dr. Dispenzieri's opinion was persuasive, and that petitioner had POEMS at the outset of her illness.[14] Dr. Dispenzieri did not opine that GBS or CIDP was an alternative or concurrent diagnosis.

After reviewing and considering the medical records, expert opinions, medical literature, and the testimony at the hearing, the undersigned analyzed the issue of petitioner's diagnosis and found that respondent's expert, Dr. Lipe, was more persuasive, for all of the reasons discussed.

[13] Dr. Dispenzieri has been petitioner's treating physician since 2015.

[14] Dr. Lipe referred to petitioner's visit to the Mayo Clinic, where she was seen by Dr. Dispenzieri, as supportive evidence of the POEMS diagnosis. Decision at 25. Dr. Bourdette agreed. Id. at 29-30.

See Decision at 36-39. Thus, the undersigned found it was improbable that petitioner suffered from GBS as a precursor illness to her later-diagnosed POEMS syndrome.

The newly filed medical records do not provide evidence to the contrary. Instead, the records confirm that since May 2015,[15] the petitioner has continuously had the diagnosis of POEMS syndrome, not GBS. Petitioner received a flu vaccine on November 8, 2020. On December 12, 2020, she presented to the ED at Littleton Regional where she was seen by Dr. Levitan. Dr. Levitan's physical examination revealed "[d]iscomfort with palpation diffusely below the knees bilaterally" and good range of motion. Pet. Ex. 89 at 55. Petitioner was "able to lift [her] legs off the bed, [but could not] toe walk." Id. She had "[g]ood strength in her upper extremities." Id. Labs were drawn, and petitioner's "inflammatory makers were normal." Id. at 57. Dr. Levitan's diagnoses were polyneuropathy and POEMS. Id. Dr. Levitan did not diagnosis petitioner with GBS.

After she was discharged from the hospital, petitioner was seen for follow up by her neurologist, Dr. Umashankar. She complained of fatigue and pain and requested another IVIG infusion. Dr. Umashankar's diagnoses were POEMS syndrome and polyneuropathy. He noted that "[i]nterestingly[,] she had a flu shot about 2 weeks before the onset of symptoms in December 2020." Pet. Ex. 90 at 4. He stated, "I am honestly stumped if this was worsening of her neuropathy of POEMS syndrome or if this was [GBS]." Id. While Dr. Umashankar questioned whether petitioner had GBS, he did not diagnosis her with GBS.

Petitioner has not filed any medical records that show that she was diagnosed with GBS following the flu vaccine administered to her in November 2020. Thus, the undersigned finds that the newly filed evidence would not have changed the result of her previous finding that preponderant evidence supported petitioner's diagnosis of POEMS.

The undersigned's conclusion that petitioner did not suffer from GBS at the outset of her illness largely moots petitioner's arguments that the flu vaccine played any role in her development of POEMS syndrome thereafter, given that petitioner's theory required a finding that she experienced vaccine-induced GBS. See Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (finding it was not error for the special master to focus first on whether petitioner suffered an autonomic neuropathy when petitioner asserted the flu vaccine caused autonomic neuropathy, which manifested as dysautonomia and postural orthostatic tachycardia syndrome). However, the undersigned now considers the new evidence offered in support of causation.

Specifically, petitioner contends that the newly filed records provide evidence of rechallenge. Challenge/rechallenge evidence has been recognized as an appropriate form of evidence to satisfy the second prong of Althen. Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1322-26 (Fed. Cir. 2006). "A 'challenge/rechallenge' circumstance exists when a person has a reaction to one administration of a vaccine or drug and then suffers worsening symptoms after an additional administration of the same vaccine or drug." Hirmiz v. Sec'y of Health & Hum. Servs., 119 Fed. Cl. 209, 219 n.11 (2015); see also DePena v. Sec'y of Health &

[15] In the underlying case, the petitioner filed her medical records through May 2015, and these were summarized in the decision denying entitlement. See Decision at 4-9.

Hum. Servs., 133 Fed. Cl. 535, (2017) (describing challenge/rechallenge as "when an individual . . . exhibits a more severe reaction to a second administration of that vaccine"). And as noted by petitioner, Congress stated that "[a]n adverse event can be causally linked to a vaccine more readily if: . . . the event recurs on re-administration of the vaccine (positive rechallenge)." Pet. Mot. at 6 (quoting H.R. Rep. No. 106-977, at 5 (2000)).

While the undersigned recognizes the concept of challenge/rechallenge, it does not appear to be supported by the facts set forth in petitioner's newly filed medical records. These records show that petitioner received flu vaccines in 2015, 2017, and again in 2018. See Pet. Ex. 89 at 66, 71; Pet. Ex. 91 at 5, 682. No adverse reaction to any of these flu vaccines was documented.

In her underlying petition, petitioner alleged that the flu vaccine she received in October 2013 caused her to develop GBS. Based on the concept of challenge/rechallenge, petitioner should have experienced a worsening of her symptoms after receiving the flu vaccine in 2015, 2017, and 2018. However, the records do not document that petitioner had any adverse reaction to the flu vaccines she received in 2015, 2017, and 2018. Thus, the facts do not support a finding of positive rechallenge.

Moreover, petitioner's case (based on her 2013 flu vaccine) was pending in 2015, 2017, and 2018 when petitioner received flu vaccines for those years. If she had experienced a worsening of her symptoms associated with any of those vaccinations, she would have had the opportunity to submit evidence and argue challenge/rechallenge at the time. She did not do so.

In summary, petitioner's argument based on challenge/rechallenge is not supported by the newly filed evidence. The evidence is not controlling or clear, and it does not establish that the undersigned would have issued a different ruling as to causation. Therefore, it does not meet the required criteria of materiality.

B. Relief from Judgment Is Not Available Under RCFC 60(b)(6)

RCFC 60(b)(6) is often referred to as the "catch all" provision. It allows a court to reopen a case and vacate a judgment for "any other reason that justifies relief." RCFC 60(b)(6). The rule must be narrowly construed in order to preserve the finality of judgments. Kennedy, 99 Fed. Cl. at 548 (citing Gonzalez, 545 U.S. at 535). Relief from judgment under RCFC 60(b)(6) must be justified by a showing of "exceptional circumstances," where a "grave miscarriage of justice would result if relief is denied." Id. at 540, 548. However, "[RCFC] 60 relief is not available as a means to relitigate claims that have already been decided; if it were, then no decision would ever be final." Rogero v. Sec'y of Health & Hum. Servs., 143 Fed. Cl. 21, 27. (2019).

Pursuant to the Vaccine Rules promulgated by the Court of Federal Claims, the parties must be afforded "a full and fair opportunity to present [their] case." Vaccine Rule 3(b)(2). The substantial rights of a petitioner may be harmed if they are deprived of "a full and fair opportunity to be heard on the merits." Kollasch ex rel. Q.K. v. Sec'y of Health & Hum. Servs., No. 10-717V, 2021 WL 1728714, at *4 (Fed. Cl. Spec. Mstr. Apr. 6, 2021). "A full and fair

opportunity to be heard [] contemplates a procedural mechanism of adequate notice and a measure of time for the presentation of the party's position." Guillot v. Sec'y of Health & Hum. Servs., No. 03-0775V, 2012 WL 3867160, at *8 (Fed. Cl. Spec. Mstr. Aug. 15, 2012), mot. for relief & mot. for reconsideration denied, 2012 WL 4788569 (Fed. Cl. Spec. Mstr. Sept. 13, 2012); see also Hovey v. Sec'y of Health & Hum. Servs., 38 Fed. Cl. 397, 401 (1997) (holding that petitioners were given a full and fair opportunity to present their case through the use of permitted extensions and late filings). Further, an adequate record must be created to allow motions for review and appeals to be filed. See Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 778 (2006).

Here, petitioner has not demonstrated "exceptional circumstances" or that a "grave miscarriage of justice" would result if her motion is not granted. Petitioner filed her petition on October 15, 2015. She was represented by very competent counsel, experienced in Vaccine Program litigation. Over time, petitioner's clinical course evolved, and it took considerable time for the petitioner to obtain and file all of her medical records. Her clinical course was complex. Numerous expert reports were filed along with numerous medical literature articles. A two-day hearing was held on January 29 and 30, 2019. Petitioner and her husband, a medical doctor, testified. Petitioner's experts, Dr. Latov, a neurologist and Professor of Neurology at Cornell University, and Dr. Parekh, a hematologist and Associate Professor of Hematology and Oncology at the Icahn School of Medicine at Mount Sinai Medical Center, also testified. Pre- and post-hearing submissions were filed by petitioner. After the hearing, petitioner's expert, Dr. Latov, filed additional medical literature. See Pet. Exs. 76-86. Motions for extensions of time were liberally granted to allow petitioner requested time for filing records, briefs, expert reports, or other documents. Petitioner was afforded a full and fair opportunity to present her case and there is no showing that she has been deprived of her substantial rights as related to the adjudication of her claim.

Further, petitioner has not shown any basis to reopen her case based on exceptional circumstances. Petitioner may file a new petition for her alleged injury related to the flu vaccine that she received in November 2020. However, to reopen a case where judgment has entered, on the basis of evidence that occurred seven years after the original vaccination in question, and based on evidence that does not support a different outcome, is contrary to the purpose underlying RCFC 60(b) that there be some finality and end to litigation.

VII. CONCLUSION

The undersigned has great sympathy for the suffering that petitioner has experienced. However, for the reasons discussed above, the undersigned finds that petitioner's newly filed evidence does not warrant reopening and relitigating the claim set forth in her petition filed in 2015, alleging an injury related to the flu vaccine administered to her in October 2013. Therefore, the undersigned **DENIES** petitioner's motion for relief for judgment.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master