

In the United States Court of Federal Claims

No. 14-706V

(Filed: September 4, 2019)¹

KATHLEEN WYATT,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

National Childhood Vaccine Injury
Act, 42 U.S.C. §§ 300aa-1 et seq.;
Lack of Defined and Recognized
Injury; Expert Credibility
Determination; Injury Lasting
Fewer than Six Months.

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OPINION AND ORDER

WILLIAMS, Senior Judge.

On August 5, 2014, Petitioner filed a claim for compensation under the National Vaccine Injury Compensation Program, alleging she sustained “joint pain in lower and upper extremities, radiating to upper torso” from a flu vaccination that she received on October 1, 2012. Pet. at 1. On December 17, 2018, the Special Master dismissed the petition, finding that Petitioner failed to prove both that she sustained a defined and recognized injury and that her symptoms endured for at least six months as required by the Vaccine Act.

¹ Pursuant to Vaccine Rule 18 of the Rules of the United States Court of Federal Claims, the Court issued its Opinion under seal to provide the parties an opportunity to submit redactions. The parties did not propose any redactions. Accordingly, the Court publishes this Opinion.

Petitioner timely filed a Motion for Review on January 16, 2019. For the reasons stated below, Petitioner's Motion for Review is denied, and the Special Master's decision denying entitlement is sustained.

Background²

On October 1, 2012, Petitioner, a 60-year-old woman, received the flu vaccine, Fluarix. Petitioner's prior medical history included melanoma, a brain tumor, dyspnea, fatigue, and chronic low white blood cell count. Within a week after the vaccination, Petitioner began experiencing sharp shooting pain in her upper and lower extremities. Pet'r's Ex. 1 at 4. On October 16, 2012, Petitioner visited her primary care physician, Dr. Charles MacCallum, and reported soreness in her upper extremities, mobility issues and fatigue in her fingers, and Dr. MacCallum noted that Petitioner received the flu shot two weeks earlier. Pet'r's Ex. 7 at 196. Dr. MacCallum prescribed prednisone and ordered blood work, which returned positive for anti-nuclear antibodies (ANA) and a parvovirus antibody. Dr. MacCallum referred Petitioner to a rheumatologist, Dr. Aminda Lumapas, for myalgias and joint symptoms. Pet'r's Ex. 5 at 9.

At the time she received the vaccine, Petitioner was working as a Senior Physical Therapist at University Hospitals Ahuja Medical Center in Beachwood, Ohio. On October 15, 2012, at the direction of her supervisor, Petitioner visited the registered nurse at the corporate health department, Ms. Donna Gigliotti, who reported Petitioner's case to the Vaccine Adverse Event Reporting System ("VAERS"). In the VAERS report, Ms. Gigliotti stated that Petitioner experienced "joint pain in lower and upper extremities radiating to upper torso affecting [activities of daily living]" beginning on October 10, 2012, some 9 days after Petitioner received the vaccine. Pet. Ex. 4 at 1.

On October 28, 2012, Petitioner fell down the stairs at her home, fracturing her left ankle. Pet'r's Ex. 2 at 3-4. On November 1, 2012, Petitioner saw an orthopedist, Dr. Robert Corn, and reported that she fell because she "misjudged the bottom two steps [at her home]." Pet'r's Ex. 9 at 139. Records of this appointment contain no mention of pain or weakness in Petitioner's extremities and "only minimal distress other than her left ankle." *Id.* Records from two follow-up appointments concerning the ankle injuries in November and early December 2012, similarly contain no mention of pain or weakness in Petitioner's extremities. *Id.* at 133, 136. However, on December 18, 2012, Petitioner contacted Dr. Corn by letter requesting that he fill out a travel insurance form, stating that she continued to experience joint pain in both her upper and lower extremities since receiving her flu vaccine on October 1, 2012. *Id.* at 163.

On January 3, 2013, Petitioner had a consultation with rheumatologist Dr. Lumapas and complained of painful joints and shooting pain throughout her lower extremities. Pet'r's Ex. 10 at 308. According to the medical records, Dr. Lumapas was unsure if these symptoms were related to the vaccination. Dr. Lumapas noted Petitioner's positive anti-nuclear antibodies ("ANA") and

² This background is derived from the Special Master's decision, Wyatt v. Sec'y of Health & Human Servs., No. 14-704V, 2018 WL 7017751 (Fed. Cl. Dec. 17, 2018) ("Dec."), as well as from exhibits filed by Petitioner.

preexisting decreased white blood cell count and ordered additional bloodwork “concerning her [positive ANA].” Id. at 314 (noting that Petitioner may have had a positive ANA in the past).

On January 8, 2013, Petitioner saw Dr. Corn, who released Petitioner to return to work on a limited basis after confirming that Petitioner’s ankle had almost fully healed. Petitioner claimed that, upon returning to work on January 11, 2013, she continued to experience pain, though more in her hands and forearms than in her legs, and struggled to perform work tasks. Pet’r’s Ex. 17 at 4-5.

Petitioner saw Dr. MacCallum again on January 14, 2013, and continued to complain of shooting pain in her hands and feet. Pet’r’s Ex. 7 at 195. In a letter to Petitioner’s employer seeking an exemption for Petitioner from future flu shots, Dr. MacCallum stated that Petitioner had “developed polyarthritis in her hands and feet after receiving a flu shot on [October 1, 2012].” Pet’r’s Ex. 8 at 289. X-rays taken that day indicated mild marginal osteophytosis, and there was no radiographic evidence of inflammatory arthritis. Pet’r’s Ex. 21 at 19; Pet’r’s Ex. 6 at 24.

Petitioner had a follow-up appointment with Dr. Lumapas on January 17, 2013, and Petitioner reported that she was feeling better and having less difficulty manipulating her hands. Pet’r’s Ex. 10 at 299. After reviewing the results of Petitioner’s bloodwork, Dr. Lumapas wrote:

Patient with joint and muscle symptoms after getting flu vaccine in October found +ANA and decrease in WBC, though has had a decrease in WBC [in] 2008. Unsure flu injection caused symptoms or ANA as ANA has not been checked previously. Possible after flu vaccine had a reactive arthritis process that has now resolved. Patient does not want to get flu vaccine again b/c she does not want to have the same problems. Positive ANA but at this time I am unsure of the significance of this. Does not have results consistent with SLE, just mild inflammation. Patient’s symptoms have resolved.

Id. at 307.

On February 1, 2013, Dr. Corn issued a Return to Work Authorization allowing Petitioner to return to work full time with no restrictions. Pet’r’s Ex. 9 at 168. Petitioner saw Dr. MacCallum on September 14, 2013, complaining of strep throat and facial pain, and again on September 30, 2013, concerning anxiety, anger, stress, and a cold sore. Pet. Ex. 7 at 194, 192. Petitioner returned to Dr. MacCallum’s office three times in December 2013, complaining of fatigue and gastrointestinal issues. Petitioner did not mention myalgias, joint pain, joint swelling, or other rheumatological issues at these visits. Pet’r’s Ex. 26 at 5-9; Pet’r’s Ex. 21 at 20-25.

Petitioner submitted one record of a medical assessment for 2014, from her annual employer-mandated tuberculosis screening on February 12, 2014, when she indicated that she did not suffer from “illness,” “extreme fatigue,” or “weakness.” Pet’r’s Ex. 21 at 9.

In 2015, Petitioner sought treatment for sinusitis and pain in her left hip that began when Petitioner fell in a parking lot on August 1, 2015, but she denied numbness, tingling, fever, chills,

or any other neurological issues, and did not mention extremity pain or weakness, other than that relating to her hip. Pet'r's Ex. 26 at 4; Pet'r's Ex. 34 at 4, 7.

On December 8, 2015, Petitioner saw Dr. Lawrence Saltis, a neurologist at Western Reserve Health System, and reported "pain in feet and hands that started in 2012 after a flu vaccine." Pet'r's Ex. 32 at 1-2. This doctor's visit is the first time since Petitioner's January 14, 2013 visit with Dr. MacCallum that Petitioner mentioned that she felt joint or extremity pain related to the vaccination. According to records from this appointment, Petitioner notified Dr. Saltis that she had previously seen a rheumatologist, but that they didn't "hit it off." Id. at 1. Dr. Saltis noted that Petitioner was "very emotional" at this visit, but upon examination, exhibited no swelling or inhibited range of motion, except for "decreased sensation of the lower left leg with poorly downgoing plantars on her left side" - - the site of the injured hip. Id. at 2. Dr. Saltis also noted Petitioner's positive ANA and elevated C-reactive proteins ("CRP"). Id. at 1.

On January 13, 2016, an MRI on Petitioner's spine revealed small, broad-based disc protrusions without significant spinal stenosis, and bilateral foraminal narrowing. Id. at 4. Electromyograms (EMGs) on Petitioner's upper extremities were performed on January 18, 2016, and revealed mild axonal peripheral neuropathy with mild right carpal tunnel syndrome, but no other neurological deficits. Id. at 5. Petitioner returned to Dr. Saltis on February 4, 2016, to review the results of her MRI and EMGs, and Dr. Saltis diagnosed Petitioner with "polyneuropathy associated with underlying disease," "monoclonal gammopathy," and "sensory disturbance," and noted Petitioner's elevated CRP and positive ANA. Id. at 10-12. Dr. Saltis did not prescribe any medication, but ordered additional bloodwork, which revealed no abnormalities other than the positive ANA. Dr. MacCallum testified at a November 16, 2017 hearing that, after examining Dr. Saltis' notes from the February 4, 2016 visit, he believed Dr. Saltis' diagnosis to be "just basically a sensory disturbance" without suggesting a cause for Petitioner's symptoms. Tr. 41. Petitioner received extensive orthopedic care in the first half of 2016, to treat the hip injury she suffered from the August 2015 fall. See generally Pet'r's Ex. 32.

Petitioner's Medical Opinions

Petitioner submitted two "opinion letters" from Dr. MacCallum dated February 3, 2016, and June 24, 2016. Dr. MacCallum testified that he wrote the February 3, 2016 letter because Petitioner's counsel contacted him asking for his medical opinion on "some matters." Tr. 43. The letter states:

[Petitioner] started to develop extreme weakness, arthralgias, and difficulty walking up and down stairs. . . . Although there is no way to prove the cause and effect, these kinds of symptoms are extremely unlikely due to just a transient viral infection. In my opinion, the most plausible explanation of the bizarre symptoms and persistent weakness would be an autoimmune reaction to the vaccine. Guillain Barré syndrome only occurs in one out of every million vaccines but she certainly could be one that development a variant. . . . Evaluation by rheumatology failed to unearth any significant autoimmune disease.

Pet'r's Ex. 31 at 1. At the time Dr. MacCallum wrote this opinion letter, he had not personally examined Petitioner for three years. Tr. 63. Dr. MacCallum testified:

A. I don't recall what she was doing with herself during those couple years. But I -- so that letter that I wrote in February was based on just what we had known had gone on a few years before. I just assumed that she had not improved.

Q. But you have nothing in your record to suggest whether she did or she didn't, correct?

A. Correct.

Tr. 70-71. Dr. MacCallum was unaware that Petitioner had undergone nerve conduction studies in January 2016, that showed mild carpal tunnel syndrome but no other neurological deficits. Tr. 56.

Dr. MacCallum's second opinion letter records Petitioner's visit on June 24, 2016, to "discuss vaccines and paperwork." Pet'r's Ex. 35 at 2. In the "History of Present Illness" section, Dr. MacCallum provided a short explanation of Petitioner's symptoms and treatment in the three months following her October 1, 2012 vaccination, stating that:

- a week after the vaccination, Petitioner developed pain in her left hand that progressed to her right hand and then her lower extremities;
- Petitioner was still experiencing this pain in her extremities and had since developed atrophy in her hands;
- Petitioner experienced some mild degree of relief but after discontinuing the prednisone the symptoms greatly worsened resulting in a fall that fractured her fibula in three places;
- Dr. Lumapas' rheumatology assessment "was completely negative."

Id.

Dr. MacCallum opined:

To have such adverse events within a week of a vaccine seems to implicate the vaccine. We can see rare cases of Guillian-Barré (sic) Syndrome and other neurologic problems as a result of vaccination. The fact that there were no other precipitating facts [prior to the flu vaccine] seems to logically incriminate the vaccine as being the cause" of petitioner's symptoms. Unfortunately, there can be no tests that can prove this, only the temporal relationship.

Id. In the "Diagnoses/Problems" section, Dr. MacCallum listed Petitioner's depression, inflammatory polyarthropathy, muscle spasticity, myalgia, polyneuropathy, and tingling in the

extremities, but not Guillain Barré syndrome (“GBS”). Id. at 4. When Dr. MacCallum made this June 24, 2016 assessment, he did not have the results of the EMGs performed on Petitioner’s upper extremities, which came back negative except for mild carpal tunnel syndrome. Tr. 56.

At the hearing, Dr. MacCallum opined that the most plausible explanation for Petitioner’s symptoms was an autoimmune reaction to the vaccine, but that, whatever that autoimmune reaction was, it was not GBS. Tr. 45. When asked why he believed that the vaccine caused Petitioner pain and weakness in her extremities, Dr. MacCallum stated that it was solely due to the temporal relationship between the vaccine and the symptoms. Tr. 73-74. After reviewing Petitioner’s medical records, Dr. MacCallum testified that he believed that no other doctor had provided a definitive diagnosis of Petitioner’s injury or indicated that Petitioner’s symptoms were caused by the vaccination. Tr. 32-33, 42, 47-48.

Petitioner provided an expert report from Dr. Philip DeMio on February 10, 2016. Pet’r’s Ex. 29.³ Dr. DeMio noted that prior to the vaccination Petitioner was in excellent health and led an active life and that, the day after she received the vaccination, she began experiencing “pain which was uncharacteristic in her left upper extremity including the hand” that developed in “weakness, numbness, tingling, and later ‘shooting pain’ (the latter three are dysesthesias).” Id. at 1. Dr. DeMio opined that these symptoms were caused by the vaccine and that Petitioner had “autoimmunity with a minimally improved Guillain-Barré Syndrome, with severe persisting sequelae.” Id. at 2. Dr. DeMio described GBS as “an inflammatory peripheral neuropathic autoimmune disease whose pathology is thought to arise from mechanisms including molecular mimicry by microbial antigens including those that are present in the influenza vaccine that [Petitioner] received.” Id. Dr. DeMio stated that “[Petitioner’s] symptoms and their course of onset, plateauing, and some improvement, along with the results of her medical tests and treatment clearly make the diagnosis of autoimmunity and Guillain-Barre’ Syndrome, and they exclude other diagnoses.” Id.

Dr. DeMio based his diagnosis on “the time course in association with her . . . vaccination, and the “the lack of another temporally associated reasonable trigger.” Id. at 3. Dr. DeMio did not cite any medical record or medical literature to support this diagnosis. Dr. DeMio’s report does not mention Dr. Lumapas’ January 17, 2013 assessment that both the pain in Petitioner’s extremities and any possible reactive arthritis had been resolved, or the EMG results indicating no neurological deficits other than mild carpal tunnel syndrome. Id.

On June 30, 2016, the Special Master ordered Petitioner to submit a supplemental expert report to address “the seeming inaccuracies and inconsistencies” in Dr. DeMio’s first report, citing, among other things, Dr. DeMio’s unsupported conclusion that treating physicians had performed “full medical work-ups, leading to findings of pathology on tests and exams” and had diagnosed

³ Dr. DeMio obtained his medical degree from Case Western Reserve University in 1984, and completed residencies in pathology and emergency medicine. Pet’r’s Ex. 42 at 1. Dr. DeMio treats patients with chronic tick-borne and other infections and Autism Spectrum Disorder as well as “chronic pain and disease.” Dec. *18. As part of his current practice, Dr. DeMio sees “many patients with chronic illnesses including neurodegenerative disease, neuropathy, illness associated with vaccination, and autoimmunity.” Pet’r’s Ex. 29 at 1.

Petitioner with autoimmunity and inflammatory arthritis. June 30, 2016 Order, ECF No. 55 at 1-2. The Special Master ordered Dr. DeMio to “include specific references to the exact medical records, test results, and literature upon which Dr. DeMio has relied in concluding that petitioner suffers from a vaccine-related injury.” Id. at 2. The Special Master further ordered that Dr. DeMio’s supplemental report address each of the three Althen⁴ prongs “or it will be insufficient.” Id.

On September 22, 2016, Dr. DeMio submitted a two-page supplemental report in which he diagnosed Petitioner with “autoimmunity, inflammation, polyneuropathy, and arthritis.” Pet’r’s Ex. 36 at 1. In the letter, Dr. DeMio recounted parts of Petitioner’s history, including symptoms observed by Drs. MacCallum, Corn and Lumapas in the months after her vaccination, but inexplicably included multiple references to Petitioner as “employee.” Id. Dr. DeMio included a list of five articles but failed to explain how any of these articles supported his diagnosis. Id. at 2; see also Pet’r’s Exs. 37-41. While Dr. DeMio’s supplemental report referred generally to Petitioner’s medical records, it did not include any specific reference to a medical record or test result that supported his opinion that the flu vaccine caused Petitioner’s GBS, autoimmunity, inflammation, polyneuropathy, and arthritis. Id. at 1-2. Dr. DeMio did not specifically address any of the Althen prongs. Id. The Special Master determined that “Dr. DeMio also provided no references to any objective testing, contemporaneous medical records, medical opinion of treating physicians, or medical literature to support this conclusion, even after being ordered to do so.” Dec. *22 (citing Order at 2, ECF No. 55).

Discussion

In Vaccine Act cases, the Court of Federal Claims may: (1) uphold the findings of fact and conclusions of law and sustain the special master’s decision; (2) set aside findings of fact or conclusions of law “found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law;” or (3) “remand the petition to the special master for further action in accordance with the court’s direction.” 42 U.S.C. § 300aa-12(e)(2)(A)-(C) (2012); see Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005). In reviewing a special master’s factual findings and legal conclusions, the court’s role is not to “reweigh the factual evidence,” “assess whether the Special Master correctly evaluated the evidence,” or “examine the probative value of the evidence or the credibility of the witnesses.” Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal citation and quotation marks omitted). Reversible error is “extremely difficult to demonstrate” if the special master has “considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision” Hines ex rel. Sevier v. Sec’y of Dep’t of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

⁴ In Althen v. Secretary of Health & Human Services, the Federal Circuit set forth a three-pronged test for proving causation in vaccine cases: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Here, the Special Master determined that Petitioner did not establish a defined and recognized vaccine-related injury, and that, to the extent Petitioner's symptoms could constitute an injury, those symptoms did not persist for six months after the vaccination, as required for compensation under the Vaccine Act. Finally, the Special Master found that Petitioner failed to prove causation-in-fact under Althen. Petitioner challenges these findings in her Motion for Review.

The Special Master Reasonably Concluded that Petitioner Did Not Prove That She Suffered from a Defined and Recognized Injury

The Special Master concluded that, while Petitioner proved that she suffered from several different symptoms following her vaccination, Petitioner did not prove by a preponderance of the evidence that she suffered from a "defined and recognized" injury. As an "initial step" before a special master determines whether a vaccine was the cause-in-fact of a petitioner's injury, the petitioner must first prove by a preponderance of the evidence that she suffers from a "defined" and "medically recognized" injury, not "merely . . . a symptom or manifestation of an unknown injury". Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011); Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010) ("[I]dentifying the injury is a prerequisite to the [Althen] analysis."). "In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." Lombardi, 656 F.3d at 1353; Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) ("If a special master can determine that a petitioner did not suffer [a vaccine-related injury], there is no reason why the special master should be required to undertake the separate (and frequently more difficult) [Althen analysis]").

The record supports the Special Master's finding that, following her vaccination on October 1, 2012, Petitioner suffered from a series of symptoms - - hand discomfort, weakness and pain in her lower and upper extremities, fatigue, and an ankle fracture from a fall, but that "no treating physician diagnosed [Petitioner] with GBS or any other definable injury or illness causally related to the flu vaccine." Dec. *20-21 (citing Pet'r's Ex. 1 at 3-4; Pet'r's Ex. 5 at 4; Pet'r's Ex. 7 at 195; Pet'r's Ex. 10 at 308). The Special Master found that, following her vaccination, Petitioner only received one credible possible diagnosis - - polyarthritis as reflected in Dr. MacCallum's January 14, 2013 note. Pet'r's Ex. 8 at 289. However, as Petitioner's rheumatologist, Dr. Lumapas, determined, any reactive arthritis process that may have followed the vaccination had been resolved in less than four months' time - - by January 17, 2013. Pet'r's Ex. 10 at 307. See Lasnetski v. Sec'y of Health & Human Servs., 128 Fed. Cl. 242, 250 (2016) (upholding the Special Master's finding that the petitioner did not prove a clear and definitive injury where Petitioner began suffering from a host of symptoms following her vaccination but never received a defined and recognized injury diagnosis, despite receiving numerous evaluations by specialists, including a rheumatologist).

The Special Master properly rejected Petitioner's argument that Dr. MacCallum, Petitioner's treating physician, and Dr. DeMio, Petitioner's expert, had diagnosed her with a defined and recognized injury. To the extent that Dr. MacCallum's February 2, 2016 opinion letter could be characterized as diagnosing Petitioner with Guillain-Barré Syndrome, the Special Master reasonably relied on Dr. MacCallum's testimony clarifying that he had made no such diagnosis.

Tr. 35-36 (“I don’t believe she had Guillain-Barré syndrome.”); Tr. 39 (“I do not believe this was Guillain-Barré. Guillain-Barré is just a good example of a neurological disorder as an adverse reaction to a vaccination.”).

So too, the Special Master reasonably rejected the diagnoses that Dr. MacCallum made in his June 24, 2016 letter - - that Petitioner had polyarthropathy, muscular spasticity, and polyneuropathy related to her flu vaccine. The sole basis for these diagnoses was the temporal relationship between the vaccination and Petitioner’s symptoms. See Tr. 73 (“So is it your opinion that simply because her symptoms started 7 days or 24 hours or whatever it is that she may say following the flu vaccine that it had to be the flu vaccine.” “Yes.”); Tr. 74 (“So it’s based on temporal relationship?” “Correct.”); Tr. 68, 70-71. Dr. MacCallum was unaware that EMGs performed on Petitioner in 2016 showed no neurological deficits except mild carpal tunnel syndrome. Tr. 56. Dr. MacCallum himself acknowledged that “there’s been no definitive diagnosis.” Tr. 48. No other physician diagnosed Petitioner with an injury or disease associated with the flu vaccine, other than the possible reactive arthritis process that Dr. Lumapas found to have been resolved January 17, 2013 - - fewer than four months after Petitioner received the vaccine. See Pet. Ex. 10 at 307, 314; Pet. Ex. 32 at 1-2; Tr. 35-36, 47-48.

In a similar vein, the Special Master appropriately gave no weight to Dr. DeMio’s three-page report diagnosing Petitioner with vaccine-related “autoimmunity with a minimally improved Guillain-Barré (sic) Syndrome, with severe persisting sequelae,” and his two-page addendum, diagnosing Petitioner with “autoimmunity, inflammation, polyneuropathy, and arthritis.” Pet’r’s Ex. 29 at 2; Pet’r’s Ex. 36 at 1. The Special Master properly determined that Dr. DeMio lacked the requisite medical expertise to render an opinion on Petitioner’s injury, due to his lack of specialized training in the fields of autoimmune or neurological disorders. Dec. *25 (citing Dia v. Sec’y of Health & Human Servs., No. 14-954, 2016 WL 6835549, at *1 (Fed. Cl. Spec. Mstr. Oct. 24, 2016) (“[A]lthough Dr. DeMio’s background is in autism, he did not explain his qualifications to opine about peripheral neuropathy.”); Holt v. Sec’y of Dep’t of Health & Human Servs., No. 05-0136V, 2015 WL 4381588, at *16 (Fed. Cl. Spec. Mstr. June 24, 2015) (“[Dr. DeMio] is board certified in emergency medicine. He has no formal specialized training in . . . any of the several areas [pediatrics, immunology, neurology, or gastroenterology], in which he proffered opinions. His only publications involved chapters on arthritis, gout, inflammation, and nutrition in an integrative medicine textbook.”)). In her Motion for Review, Petitioner did not counter the Special Master’s evaluation of Dr. DeMio’s qualifications and expertise, and there is no basis for this Court to disturb the Special Master’s findings on Dr. DeMio’s qualifications. See Moberly ex rel. Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010) (stating that a “special master is entitled to require some indicia of reliability to support the assertion of the expert witness”).

In addition, the Special Master properly rejected Dr. DeMio’s diagnosis and opinion based on the lack of evidentiary support in the record. While Dr. DeMio opined in his February 10, 2016 expert report that his diagnosis of vaccine-related GBS and autoimmunity was supported by “[Petitioner’s] symptoms and their course of onset, plateauing, and some improvement, along with the results of her medical tests and treatment,” his report, as the Special Master found, contained “no references to any objective testing, contemporaneous medical records, medical opinion of treating physicians, or medical literature to support this conclusion.” Dec *22. Moreover, Dr.

DeMio's supplemental report ignored both Dr. Lumapas' rheumatological assessment that Petitioner's symptoms had been resolved and Petitioner's January 2016 EMGs that revealed only a mild carpal tunnel syndrome. Because Dr. DeMio failed to offer an evidence-based assessment underlying his opinion, the Special Master did not abuse her discretion in affording his opinion no weight. See id.; Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 743 (2009) (stating that the Special Master is not required to accept an expert's conclusion "connected to existing data only by the ipse dixit of the expert . . .") (citation and internal quotation marks omitted).

The Special Master Reasonably Concluded that Petitioner Only Suffered from Her Post-Vaccination Symptoms for Fewer than Six Months

The Vaccine Act requires a petitioner to show by preponderant evidence that she "suffered from the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). In Cloer v. Secretary of Health and Human Services, the Federal Circuit stated that the six-month requirement is "a condition precedent for filing a petition for compensation" in the Vaccine Program. 654 F.3d 1322, 1335 (Fed. Cir. 2011).

The Special Master properly found that that Petitioner no longer "suffered any ongoing sequela after February 2013 when [Petitioner] was released back to work full time." Dec. *23. Following her vaccination, Petitioner complained of pain in her joints and extremities during several doctors' visits, with the last complaint on January 14, 2013. However, on January 17, 2013, Petitioner reported to rheumatologist Dr. Lumapas that she was feeling much better and had no joint pain, and Dr. Lumapas determined that Petitioner's joint and muscle "symptoms . . . have now resolved." Pet'r's Ex. 10 at 299. Two weeks later, on February 4, 2013, Dr. Corn cleared Petitioner to return to work full time.

The Special Master reasonably found that February 2013, marked the last time Petitioner suffered from the residual effects of her alleged vaccine-related joint and extremity pain. From February 2013 until December 8, 2015, Petitioner had several visits with physicians complaining of a variety of other ailments, but she never complained of any joint or extremity pain, and in some cases affirmatively denied the existence of such pain. See, e.g., Pet'r's Ex. 7 at 192 (September 2013, complaining of anxiety, anger, stress, and a cold sore); id. at 194 (December 2013, complaining of strep throat, anxiety, and anger); Pet'r's Ex. 26 at 5-9 (December 2013, complaining of fatigue and gastrointestinal issues); Pet'r's Ex. 21 at 9 (noting in a February 12, 2014 tuberculosis screening questionnaire that she did not suffer from "illness," "extreme fatigue," or "weakness"); Pet'r's Ex. 34 at 3-4 (October 2015, regarding unrelated hip injury when Petitioner denied numbness, tingling, fever, chills, and any other neurological issues); id. at 4, 11 (December 7, 2015, regarding unrelated hip injury when Petitioner again denied numbness, tingling, fever, chills, and any other neurological issues).

After February 2013, Petitioner did not mention joint or extremity pain related to her vaccine until December 8, 2015, during a visit with Dr. Saltis. However, the record supports the Special Master's finding that the pain Petitioner reported to Dr. Saltis was not a residual effect of Petitioner's alleged vaccine-related injury. The Special Master reasonably relied on Petitioner's silence over the preceding three years, and in particular, Petitioner's failure to mention these

symptoms the day before, in a December 7, 2015 visit with an orthopedist related to the hip injury that Petitioner sustained in the August 2015 fall. Dec. *23 (citing Pet'r's Ex. 34 at 4, 11). Finally, the record supports the Special Master's finding that Dr. Saltis himself made no association between Petitioner's complaints of pain and her flu vaccination. Id.

Conclusion

The Court **DENIES** Petitioner's Motion for Review and **SUSTAINS** the decision of the Special Master.⁵

⁵ As Petitioner failed to establish two prerequisites necessary to prove a compensable vaccine-related injury, Petitioner failed to prove causation-in-fact under Althen.