In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-1112V
Filed: November 19, 2021
PUBLISHED

EILEEN SCHMIGEL,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Finding of Fact; Onset; Chronic Inflammatory Demyelinating Polyneuropathy (CIDP); Influenza (Flu) Vaccine

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for petitioner.
Wei Kit Tai, U.S. Department of Justice, Washington, DC, for respondent.

Finding of Fact[1]

On August 18, 2017, petitioner, Eileen Schmigel, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that she suffered chronic inflammatory demyelinating polyneuropathy ("CIDP") resulting from the adverse effects of the influenza ("Flu") vaccine that she received on October 21, 2015. (ECF No. 1, p. 1.) Upon review of petitioner's medical records, respondent concluded that onset of petitioner's condition was likely in March of 2016, approximately five months after her vaccination, which he indicates is "well outside the accepted timeframe to demonstrate vaccine causation." (ECF No. 28, p. 11.) Petitioner now moves for a finding of fact that her symptoms began "between one (1) and five (5) weeks of vaccination." (ECF No. 72, p. 1.) For the reasons discussed below, I find that petitioner experienced numbness, tingling, and fatigue, no later than late November of 2015.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

I. Procedural History

This petition was initially assigned to Special Master Sanders. (ECF No. 6.) Petitioner filed a Statement of Completion on February 28, 2018 (ECF No. 22) and respondent filed his Rule 4(c) Report recommending against compensation on June 11, 2018. (ECF No. 28.) Respondent's report primarily raised the issue of the timing of onset of petitioner's alleged CIDP and also noted that none of petitioner's physicians had attributed her CIDP to her flu vaccine. (*Id.*)

Petitioner subsequently filed additional medical records and affidavits by Kristin Johnson, a coworker (Ex. 23), Ginger Williams, a friend (Ex. 24), herself (Ex. 26), Lina Robertson, a former supervisor (Ex. 25), and Kathleen Sorensen, her sister (Ex. 34). (ECF Nos. 30-31, 33-34, 56.) Petitioner filed an expert report by neurologist Nizar Souayah, M.D., on January 9, 2019. (ECF No. 40; Ex. 30.) Dr. Souayah opined that petitioner's CIDP was caused by her October 21, 2015 flu vaccine. (Ex. 30.) His opinion was premised on his assessment that onset of petitioner's CIDP symptoms occurred within five *weeks* of her vaccination. (Ex. 30, p. 16.) Respondent filed a competing expert opinion by neurologist Peter Donofrio, M.D., on May 23, 2019. (ECF No. 42; Ex. A.) Based on the contemporaneous medical records, Dr. Donofrio assessed onset of neurologic symptoms as occurring approximately four and a half *months* following vaccination. (Ex. A, p. 10.)

The case was then reassigned to me on August 29, 2019. (ECF No. 46.) In a status conference held November 26, 2019, I advised the parties that, given the differing assumptions of the parties' experts regarding onset, a fact hearing and fact finding would be necessary to resolve this case. (ECF No. 47.) A fact hearing was held September 25, 2020. (Transcript of Proceedings at ECF No. 67 (hereinafter ("Tr.").) Petitioner testified along with two other witnesses, Ms. Robertson and Ms. Sorensen. On April 19, 2021, petitioner filed the instant motion for a finding of fact as to the timing of onset of her CIDP. (ECF No. 72.) Respondent filed his response on June 21, 2021. (ECF No. 73.) No reply was filed. Petitioner's motion is now ripe for resolution.[2]

II. Factual History[3]

A. As reflected in petitioner's medical records

At the time of vaccination, petitioner was located in Ridgecrest, California. (*See, e.g.,* Ex. 1, p. 1.) Prior to vaccination her medical history included, *inter alia*, attention

[2] That is, the record is sufficiently developed and the parties have had a full and fair opportunity to present their respective cases. Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *see also Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020).

[3] Although I have reviewed the entirety of the record compiled to date, including petitioner's complete medical history, the factual history discussed in this decision is limited to describing the evidence most relevant to identifying the date of onset of petitioner's symptoms.

deficit disorder, diabetes and atrial fibrillation ("afib"). (Ex. 2, pp. 1-2; Ex. 3, p. 1.) She had established care with her primary care physician in March of 2014. (Ex. 16, p. 21.)

Just prior to receiving the flu vaccine at issue, petitioner presented to an orthopedist with a comminuted fracture to her right distal radius. (Ex. 21, p. 1.) She underwent a closed reduction and her arm was splinted. (*Id*.) Petitioner received the flu vaccination at issue in this case on October 21, 2015, during a primary care follow up regarding her broken arm. (Ex. 1, p. 1.)

Petitioner had several follow up encounters with her orthopedist in California on October 27, 2015,[4] November 3, 2015,[5] and November 17, 2015. (Ex. 22, pp. 1-4.) Respondent stresses that petitioner had no pain or complaints at these follow up encounters and that the November 3 and November 17 encounters explicitly record that petitioner had no numbness or tingling. (ECF No. 73, p. 4.) Importantly, these observations were recorded in the context of an examination of petitioner's right wrist status post fracture. (Ex. 22, pp. 1-2.) Numbness and tingling in petitioner's right hand were among her presenting symptoms prior to the resetting of her broken arm. (*Id*. at 6.)

Petitioner did not seek any medical care again until March of 2016, after she had relocated from California to Missouri. (Ex. 2, p. 1.) She established care with Eric Vonholten, D.O., on March 18, 2016. (*Id*.; *see also* Tr. at 46.) Petitioner provided a broad medical history of attention deficit disorder, atrial fibrillation, and diabetes. (*Id.* at 1-2.) Although petitioner is characterized as seeking care "mainly" for her attention deficit disorder, she also reported that she had "some issues with peripheral numbness and tingling that she's had for quite a long time." (*Id*.) Nothing in this record clarifies how long "quite a long time" would be however. Her Review of Systems also recorded pain in her back, hands, and feet. (*Id*. at 2.) On physical exam, petitioner was noted to have normal gait and station and no focal neurological deficits. (*Id.* at 3.) Petitioner was assessed with, *inter alia,* peripheral neuropathy. (*Id*.) Petitioner did not return to this provider.

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[4] Respondent asserts in his Rule 4 Report and in his motion response that petitioner was also seen by her orthopedist on October 29, 2015. (ECF No. 28, p. 2 (citing Ex. 22, p. 199); *see also* ECF No. 73, p. 4.) Respondent cites to a page 199 of Exhibit 22, but Exhibit 22 only has 33 pages. Upon my review of Exhibit 22, I do not see any evidence that petitioner had an orthopedic office visit on October 29, 2015. Petitioner presented for a follow up appointment on October 27, 2015, at which time x-rays appeared to show "good alignment," but petitioner's orthopedist was concerned that no "true lateral" imaging was performed and he recommended such imaging. (Ex. 22, p. 4.) Notably, requisition forms included in petitioner's medical records indicate that petitioner went to another facility for x-ray imaging. (*Id.* at 8-13.) There is a record with a "visit date" of October 29, 2015; however, that record indicates only that petitioner's x-ray imaging was reviewed and that "a message was left for the patient regarding x-ray findings." (*Id.* at 3.) Thus, this record does not indicate that petitioner actually spoke to her orthopedist. Accordingly, it does not support respondent's assertion that petitioner "had no complaints when briefly seen on October 29, 2015." (ECF No. 28, p. 2; ECF No. 73, p. 4.)

[5] Respondent misidentifies this encounter as occurring on November 5, 2015. (ECF No. 28, p. 2 (citing Ex. 22, p. 2); *see also* ECF No. 73, p. 4.)

Instead, on April 8, 2016, petitioner established care with a different primary care provider, Rajamanickam Purushothaman, M.D. (Ex. 3, pp. 1-2.; *see also* Tr. at 47.) Petitioner's reported history again focused heavily on her history of attention deficit disorder, diabetes, and atrial fibrillation. (*Id.* at 1.) However, she also reported that "she's recently been having [a] problem with left-sided numbness from face to lower extremity." (*Id*.) Nothing in this record further contextualizes the characterization of "recently." On physical exam, petitioner could move all of her extremities without difficulty, but had "slightly impaired sensation for light touch and pinprick lower extremity." (*Id*. at 2.) A CAT scan of petitioner's head was ordered, which was normal. (*Id*. at 3, 12.)

On April 12, 2016, petitioner returned to the same primary care provider. (Ex. 3, pp. 6-8.) This time, petitioner's primary complaint was "multiple joint pains, tingling of the left side of the body, and [n]umbness." (*Id*. at 6.) The joint pain is recorded as having been occurring "intermittently for the past 2-3 months"; however, no duration is noted for the numbness and tingling. (*Id*.) Three months prior to April 12, 2016, would be about mid-January of 2016. Petitioner received a rheumatology referral. (*Id*. at 8.)

The same day, petitioner contacted a third primary care physician seeking to establish care. (Ex. 20, p. 30.) Petitioner spoke to a nurse on the phone. She reported that she was having "numbness all over her body including hands, arms, legs, back, mouth and tongue." (*Id.*) She acknowledged that she had sought care from her current primary care doctor but indicated that she was having difficulty getting in touch with him. (*Id*.) Petitioner was given an appointment for the following September and was encouraged to continue trying to contact her current doctor's office and to go to the emergency department if her condition worsened. (*Id*.)

Petitioner subsequently presented to the emergency department on April 17, 2016, complaining of numbness and tingling in both of her hands, feet, legs, and shoulders, as well as in her tongue for "at least six weeks."[6] (Ex. 5, p. 1.) She felt she had chronic fibromyalgia. (*Id*.) Six weeks prior to April 17, 2016, would be approximately the first week of March. Petitioner also described diffuse neck and back pain and indicated that she was feeling opposite touch sensations (i.e. things felt hot when they were cold and vice versa). On physical exam, she had normal deep tendon reflexes, normal gait, and normal strength; however, she had diminished light touch sensation with secondary tingling diffusely. (*Id.* at 2.) Petitioner had an MRI of the brain performed which was negative for any abnormality. (*Id.* at 8.) No cause was found for petitioner's diffuse numbness. (*Id.*)

On April 22, 2016, petitioner established care with another primary care physician. (Ex. 6, pp. 1-4.) Initially, petitioner is recorded as reporting that "for the last

[6] Other notations in this emergency department record state that petitioner's symptoms began six weeks ago rather than "at least" six weeks ago. (*E.g.* Ex. 5, p. 5 (11:02 Triage Assessment states "pain began six weeks ago."); Ex. 5, p. 6 (13:36 assessment states "pain began 6 weeks ago").) Notably, however, the notations are not consistent. During the 11:02 triage assessment, petitioner's pain is noted to be continuous and in the 13:36 assessment it is noted to be intermittent. (*Compare* Ex. 5, p. 5, *and* Ex. 5, p. 6.)

7 weeks she's had paresthesias all over." (*Id.* at 1.) This is consistent with what she reported at the emergency department five days earlier. She also reported tingling in her face and tongue, burning sensations in her feet, and back pain, without a specific reference to onset. (*Id.*) However, in the same history, petitioner is also reported as indicating that "[s]he also feels very tired. It started after she lost her balance and fell and broke her right wrist." (*Id.*) Based on the contemporaneous record of petitioner's treatment for her right wrist injury, this places onset in October of 2015. (Ex. 21, p. 1.) On physical exam, petitioner had normal strength but diminished sensation to monofilament in her feet. (Ex. 6, p. 2.) She was referred to a neurologist. (*Id.*)

Petitioner received a cervical spine MRI on May 3, 2016, which showed mild degenerative changes. (Ex. 21, p. 5-6.) At a massage clinic visit on May 6, 2016, petitioner was observed to be experiencing "severe nerve pain" in all of her extremities which she reported began in October of 2015. (Ex. 14, p. 3.) Petitioner reported to Dr. Hankins on May 9, 2016 that her condition had deteriorated to the point that she could no longer perform her job duties and that she had been experiencing severe numbness and tingling for the past ten weeks, placing onset of these symptoms at around mid-February of 2016. (Ex. 21, p. 9.)

Petitioner received an EMG/NCS study on her upper extremities on May 24, 2016. (Ex. 7, p. 1.) Petitioner reported that she was experiencing a sensation of pins and needles in her upper extremities for around twelve weeks, or since February 2016. (*Id.*) The NCS showed bilateral median sensory/motor neuropathy consistent with moderate to severe carpal tunnel syndrome ("CTS"), and bilateral ulnar motor neuropathy, lacking features of cubital tunnel syndrome. (*Id.*) The EMG was unremarkable. (*Id.*) Neither study revealed evidence for cervical radiculopathy, myopathy, or plexopathy. (*Id.*) A note on this record however indicates that the providers suspected a possible underlying peripheral neuropathy and referred petitioner to a neurologist and orthopedist. (*Id.* at 2.)

Petitioner began physical therapy for her left shoulder on May 25, 2016. (Ex. 8, p. 6.) She reported that the "pins and needles" sensation in her hands and feet began twelve weeks prior, or late February of 2016. (*Id.*)

On June 30, 2016 petitioner was seen by Dr. Martin Schudy for a consultation. (Ex. 9, p. 1.) Petitioner reported that she had recently moved from California to Missouri and that she had fractured her right wrist in October of 2015. (*Id.*) However, Dr. Schudy's note continued that "[o]n further questioning it is now clear that she was already having balance and tingling issues." (*Id.*) He further indicated that "[a]bout 4 months ago, she was trying to move a boat with her son's assistance and felt a sudden increase in sensation of generalized tingling followed by weakness." (*Id.*) This event would have taken place in late February of 2016. Notably, this record suggests that petitioner was already experiencing sensations of tingling and weakness prior to February of 2016, but that those sensations "increased" after she exerted herself while moving this boat with her son.

Petitioner next saw neurologist Dr. Tania Beltran Papsdorf on July 20, 2016 where she reported that onset of her neurological symptoms began four and a half months prior, or early February 2016. (Ex. 10, p. 1.) She reported that onset of these symptoms was "very quick . . . ." (*Id.* at 3.) Petitioner denied fatigue, weakness, and ataxia, but reported issues with balance and strength in addition to constipation, incontinence, sweating, dizziness, and lightheadedness. (*Id.*) Petitioner showed normal reflexes, sensation, coordination, gait, and strength aside from a 4+ toe extension and 5- toe flexion. (*Id.* at 3-4.) Dr. Papsdorf diagnosed petitioner with diabetic peripheral neuropathy and ordered an additional EMG and NCS. (Ex. 10, p. 4.) Dr. Papsdorf also observed "[e]vidence of both small and large fiber peripheral neuropathy." (*Id.*) Dr. Papsdorf did not suspect CIDP, changed petitioner's medication to Lyrica, and opined that petitioner would not benefit from IVIG due to the lack of demyelination on her NCV testing which showed a greater likelihood of axonal loss. (*Id.* at 5.)

Petitioner's PCP, Dr. Schudy, wrote on July 26, 2016 that "Dr. Papsdorf is concerned that [petitioner] developed an axonal sensorimotor demyelinating peripheral neuropathy secondary to insulin neuritis, [due] to rapid decline in chronic hyperglycemia." (Ex. 9, p. 6.) Dr. Schudy scheduled an additional NCV test to reassess for CIDP. (*Id.*) Petitioner reported that shortly after moving to Missouri, "a local doctor discontinued many of her medications including Cardizem." (*Id.*) Dr. Schudy believed petitioner experienced infrequent paroxysmal atrial fibrillation and scheduled a four-month follow up. (*Id.* at 8.)

The following day, petitioner underwent an EMG and NCS, the results of which were:

> [S]uggestive of a possible demyelinating diffuse peripheral neuropathy such as CIDP, however, this study is not complete due to the patient's intolerance of the study. Proximal muscles should be tested to look for more denervation and reinnervation patterns (in CIDP would expect worsening proximally). The left hand should be tested as well to look for possible conduction block. This study showed worsening from the study done in June 2016 . . . . A diabetic amyotrophy [] cannot be ruled out complete[ly] [and] needle study with proximal muscle testing should be recommended, however, the upper extremity findings would not be expected in a diabetic amyotrophy.

(Ex. 19, p. 65.)

An August 24, 2016 record from Dr. Schudy describes a visit by petitioner to the ER on August 22, 2016, for "possible [CIDP] . . . onset 4.5 months ago," with "fast" progression and treatment with IVIG. (Ex. 20, p. 4.) This would place onset of petitioner's CIDP symptoms at mid-April 2016.

Petitioner was next seen by neurologist Dr. Brennen Bittel on September 20, 2016 "for evaluation of CIDP." (Ex. 4, p. 1.) Petitioner reported that, "[a]fter the flu shot, she began to feel just extreme fatigue. She attributed it to moving [and] the stress of that, but then by February, she had noticed some tingling in her feet." (*Id.*) Petitioner also reported that her PCP suspected CIDP, as did a neurology consult following an EMG. (*Id.*) Dr. Bittel observed mild weakness in petitioner's hip flexors and finger abductors, absent reflexes of her brachioradialis and legs, reduced sensation in her distal legs, and an antalgic gait. (*Id.* at 5.) Dr. Bittel's impression was "CIDP with symptom onset in Feb 2016." (*Id.* at 5-6.) Dr. Bittel prescribed nortriptyline for petitioner's pain and recommended a seven-month follow up if needed. (*Id.* at 6.)

Dr. Bittel noted on April 10, 2017, that petitioner had received IVIG every three weeks until January when she began receiving it every six weeks. (Ex. 17, pp. 20-21.) Petitioner reported that her strength had completely returned and wondered why she still needed IVIG considering she did not receive any further benefit from it. (*Id.)* Petitioner reported that she had been to a pain specialist and was taking oxycodone twice daily as well as Cellcept since that February. (*Id.*) Dr. Bittel believed that petitioner may have monophasic CIDP and that she could stop taking Cellcept. (*Id.*) He also recommended that petitioner taper off IVIG and scheduled a three-month follow up. (*Id.*)

By May 12, 2017, petitioner's IVIG had been tapered down to ten-week intervals and she reported that her symptoms had returned after the fifth week off IVIG. (Ex. 17, pp. 32-38.)

Petitioner next saw neurologist Dr. Dipika Aggarwal on August 9, 2017 to establish care for her now diagnosed CIDP. (Ex. 17, pp. 32-38.) She reported an onset date of February 2016, a diagnosis date of July 2016, and that she began IVIG in September of 2016. (*Id.*)

On November 10, 2017, petitioner reported to neurologist Dr. Ruthanna Hunger that her "[s]ymptoms started in Oct 2015 after flu shot – she had pain, fatigue. Pain in back and shoulder. Then in Feb 2016 – developed drop foot – left. Had tingling in extremities and muscle atrophy." (Ex. 19, p. 2.) Dr. Hunger concurred with Drs. Bittel and Aggarwal's diagnoses and recommended that petitioner continue IVIG. (*Id.*)

B. As described in testimony and affidavits

1. Petitioner's affidavit and testimony

Petitioner filed an affidavit signed July 27, 2018, detailing the progression of her CIDP. (Ex. 26.) Petitioner averred that she began experiencing "muscle aches, fatigue, and weakness," in late November of 2015. (*Id.*) She also stated that she reported feeling pain and fatigue, but not numbness or tingling at a November 17, 2015 appointment with Dr. Shah. (*Id.*) She explained that she also experienced "prickly feeling[s] in her fingers and toes," at this appointment, but that she did not report it to Dr. Shah because she was concerned that she would not be released if she reported her

sensory symptoms. (*Id.*) She also noted that she was under the impression that these symptoms which she withheld from Dr. Shah were due to her wrist fracture. (*Id.*) Petitioner offered substantially the same testimony during the fact hearing. (Tr. at 14-15, 19.)

Petitioner additionally testified that prior to her vaccination she had no serious health conditions, only a broken wrist in October of 2015 and evidence of atrial fibrillation in March of the same year. (Tr. at 7.) She never experienced any numbness, tingling, or weakness prior to her vaccination and had no issues with walking or balance. (Tr. at 8.) Petitioner had a physically demanding job as a real estate agent prior to onset of her condition which required her to be on her feet for a majority of the day walking, painting, staging furniture, and doing other tasks to prepare her properties for showings. (Tr. at 7-8.)

In her affidavit, petitioner averred that "[b]y Christmas 2015, I was experiencing muscle aches, fatigue, foggy brain, muscle weakness, pain in my back, shoulder, and hips, and soreness in my wrists, which increased in intensity [as] time went on." (Ex. 26, p. 2.) She explained that her hand symptoms gradually progressed to numbness and tingling which eventually spread to her feet as well. (*Id.*) She stated that she was unable to walk, but believed her symptoms were caused by a pinched nerve that occurred during the fall that fractured her wrist. (*Id.*) Petitioner noted that by January of 2016, she was experiencing "unbearable" pain. She also noted that she began to feel unstable on her feet and odd sensations such as dry clothes feeling damp or having "hot and cold sensations" all over her body. (*Id.*)

In testimony, petitioner indicated that in January of 2016, her symptoms drastically changed, progressing from a feeling of "pins and needles" to pain, as if she were "holding a cactus." (Tr. at 26.) Petitioner also experienced inconsistent sensations associated with temperatures, and sensations in her feet. (*Id.*) Petitioner indicated that she was not having difficulty walking in January 2016, but that it was nonetheless painful to do so. (Tr. at 28.) Petitioner testified that in February of 2016 she developed drop foot and her symptoms became significantly worse, spreading to both sides of her body. (Tr. at 32-33.)

Although she reported February 2016 as the date of onset to most of her care providers, petitioner testified that she did so because she thought she was only suffering from a pinched nerve before February 2016. (Tr. at 53-54.) She explained that because her condition changed so drastically in February of 2016, she thought this drastic change signaled the onset of her condition. (*Id.*) However, she now believes that her onset occurred much earlier in the form of numbness and tingling in her extremities around the time she moved to Missouri in November of 2015. (Tr. at 18-19.)

Petitioner testified that some of her medical records contained inaccuracies regarding her weight, certain dates, family medical history, neurological exam results, and history of neck pain, however, she did not know why or how these inaccuracies occurred. (Tr. at 11-12.)

2. Kathleen Sorensen's affidavit and testimony

Petitioner's sister, Kathleen Sorensen, submitted an affidavit dated April 7, 2020, and also testified in support of petitioner. (Ex. 34.) Ms. Sorensen testified that petitioner told her in November of 2015 that she was experiencing some "funky numbness or tingling or something going on, but it was in her feet." (Tr. at 70-71.) She also testified that petitioner mentioned numbness in her feet, tingling in her hands, soreness in her shoulders and back, and significant fatigue during her move in November 2015. (Tr. at 74-75.) Ms. Sorenson also testified that she noticed petitioner had trouble walking during the move. (Tr. at 76-77.) In her affidavit, Ms. Sorensen recounted that she went to petitioner's home in Missouri on November 20, 2015, and observed in person for the first time that petitioner was experiencing fatigue and reduced strength while unpacking. (Ex. 34, pp. 1-2.)

3. Lina Robertson's affidavit and testimony

Petitioner also filed an affidavit from her supervisor at Re/Max, Lina Robertson. (Ex. 25.) Ms. Robertson avers that she first met petitioner as her real estate agent while petitioner was searching for a house in Missouri. (*Id.* at 1.) According to Ms. Robertson's affidavit, petitioner "didn't mention any health issues, appeared well, and spoke of activities with her kids and grandkids." (*Id.*) Ms. Robertson writes that shortly after Thanksgiving, petitioner reported that she was feeling extremely tired, had back and shoulder pain, and experiencing "prickly feelings," which she believed was caused by a pinched nerve. (*Id.* at 1.) In mid-December of 2015 however, Ms. Robertson observed petitioner at the office noting that she "looked tired and . . . walked unbalanced." (*Id.*) Ms. Robertson also testified at the fact hearing. She provided testimony substantially similar to her affidavit. (Tr. at 93-94, 97.) Ms. Robertson testified that in mid-December of 2015, she observed petitioner walking into her office and distinctly observed an abnormal gait that she described as "twitchy," "guarded", and "slow." (Tr. at 98-100.) Ms. Robertson also confirmed that her relationship with petitioner was professional rather than personal and that they no longer work together. (Tr. at 93, 105.)

4. Kristin Johnson's affidavit

Petitioner filed an affidavit from her coworker, Kristin Johnson on July 13, 2018. (Ex. 23.) Ms. Johnson avers that in January of 2016, petitioner confessed to her that she had not been coming into the office because was not feeling well and unable to work. (*Id.* at 1.) Petitioner asked Ms. Johnson not to tell anybody at their workplace about petitioner's inability to work because she was "new to RE/Max." (*Id.*)

5. Ginger Williams's affidavit

Petitioner filed an affidavit from her close friend Ginger Williams on July 17, 2018. (Ex. 24.) Ms. Williams avers that at the end of October of 2015, she called

petitioner who reported that she was experiencing muscle aches and pains. (*Id.* at 1.) Ms. Williams also avers that in early November of 2015, petitioner reported that she was experiencing constant fatigue, brain fog, increased muscle aches, and new pain in her shoulders, back, and arms. (*Id.*) Finally, Ms. Williams avers that she visited petitioner in January of 2017 and at that point petitioner explained her complete history, including that she was experiencing a "pins and needles" sensation in her arms, hands, and feet, extreme back and shoulder pain, and extreme sensation to different temperatures. (*Id.* at 1-2.) Ms. Williams avers that at that time she observed that petitioner could not walk, drive or stand. (*Id.*)

C. Petitioner's journal

Around March of 2016, petitioner began documenting her visits to various doctors including the various treatments and therapies she received and the test results that were relayed to her by her specialists. (Ex. 33.) The first entry occurs in March of 2016. (Ex. 33, p. 1.) Petitioner writes that she was not having success getting an appointment by describing the symptoms she was experiencing, so she instead asked for an appointment to address her ADD which was scheduled for March 18, 2016 with Dr. Vonholten. (*Id.*) Petitioner writes on March 18, 2016 that she told Dr. Vonholten she had experienced numbness in both of her feet and hands for several months.[7] She writes that "hand and feet problems started months ago," and that she "[t]old him [m]uscle and nerves for many months." (*Id.*)

On April 17, 2016, petitioner wrote that she began carrying a card of her symptoms to present to doctors and nurses. (*Id.* at 4.) She notes that her medical records "show different eruptation [sic] and errors of my communication with the [d]octors and nurses . . . ." (*Id.*) Petitioner wrote on April 22, 2016 that she "[told] most doctors onset was January – February 2016 because that's when it was at its [sic] worse [sic] muscle and nerves both sides and got dropped [sic] foot."[8] (*Id.* at 6.)

The remainder of petitioner's journal documents her struggles securing prompt treatment and diagnosis but does not bear directly on the issue of onset.

D. Expert opinion relevant to onset

a. Petitioner's expert, Dr. Nizar Souayah

Petitioner's expert, Dr. Nizar Souyah writes that CIDP is "characterized clinically by a presence of symmetric weakness that involves proximal and distal muscles progressing over a period of two months," but notes that "its clinical presentation and course are variable." (Ex. 30, p. 6.) Dr. Souyah also writes that "[t]he disease usually

[7] In this entry, petitioner later crossed out "several months," wrote "a long time," and added "He wouldn't listen" in her own writing.

[8] Petitioner later added to this entry in her own handwriting, "[p]rior to Feb tired, pinch nerve pain back shoulders."

starts with distal arm weakness," and that he believed that "[petitioner's] [CIDP] symptoms started approximately 5 weeks after influenza vaccination and progressed over the next several months." (*Id.* at 7.) This would place her onset at around late November or early-December of 2015.

b. Respondent's expert, Dr. Peter Donofrio

Respondent's expert, Dr. Peter Donofrio cites several diagnostic criteria for CIDP in his expert report. (Ex. A, p. 9.) The criteria note that typical onset is recognized by progressive, stepwise, or recurrent symmetric proximal and distal weakness, sensory dysfunction in all extremities developing over two months, potential cranial nerve effects, and absent reduced tendon reflexes in all extremities. (*Id.*; *see also* Ex. D, p. 3.) Atypical CIDP is recognized by the same criteria, except that tendon reflexes may be normal in unaffected limbs, and additional symptoms may include pure motor or sensory presentations, and asymmetric or focal presentations. (Ex. D, p. 3.) Dr. Donofrio writes that "[i]f one chooses to use the onset of numbness and tingling as the first feature of [CIDP], it began in late February or early March 2016." (Ex. A. p. 8.) The remainder of his report however focuses on the medical theory linking the flu vaccine to CIDP and not onset of petitioner's condition.

III. Legal Standard

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove their claim by a preponderance of the evidence. A special master must consider the record as a whole, but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1).

Medical records generally constitute trustworthy evidence. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). "The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." *Id*. However, it must also be noted that there is no presumption that medical records are accurate or complete as to all of a patient's conditions. *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). Afterall, "[m]edical records are only as accurate as the person providing the information."

Parcells v. Sec'y of Health & Human Servs., No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). Nonetheless, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991) (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992). Where medical records are clear, consistent, and complete, they ordinarily receive substantial weight.[9] *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy*, 23 Cl. Ct. at 733). When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the Special Master must consider the credibility of the individual offering the testimony. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

IV. Party Contentions

a. Petitioner

In support of her position, petitioner argues that the lay testimony offered in this case supports a finding that onset of her symptoms occurred between October 28, 2015 and November 22, 2015. First, she argues that each fact witness testified that they noticed a change in petitioner's strength and energy in either late November of 2015 or early December of 2015. (ECF No. 72, p. 7.) Petitioner points to the testimony of Lina Robertson, who testified that she witnessed petitioner arrive at the office in December of

[9] For example, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

2015 with a noticeable gait abnormality. (*Id.*) Next, petitioner cites her sister's testimony that petitioner was unable to help in her move to Missouri at the end of November 2015 and instead sat in a chair giving directions. (*Id.*) Petitioner notes that her sister testified that petitioner's gait was unsure, as if her "foot was asleep." (*Id.*)

Petitioner also argues that the medical records corroborate her own testimony. However, she does not cite any actual records that corroborate her own testimony, and instead, recites the testimony itself, noting that "[t]he only records within petitioner's alleged onset window pertained to petitioner's wrist treatment in October and November of 2015. However, as petitioner explained, she was not yet concerned about her symptoms at that time," and that "[s]ome subsequent medical records, which are even further removed from the onset, point to February 2016 at the start date. However, petitioner explained that it was around February when she noted a worsening of her condition. In fact, she noticed her symptoms worsening in January." (*Id.* at 7-8.) Finally, petitioner explains that she reported that the weakness in her arms and legs "suddenly increased approximately four months prior, which would have been February of 2016," to Dr. Schudy. (*Id.* at 8.) Petitioner argues that this specific report that her symptoms increased in February of 2016 necessarily means they occurred prior to that time. (*Id*.)

b. Respondent

Respondent urges the Court to disregard petitioner's post vaccination fatigue as the point of onset for her CIDP symptoms, explaining that petitioner's medical records do not document any reports of fatigue that began following her broken wrist. (ECF No. 73, p. 15.) Respondent notes that although petitioner's sister testified that petitioner appeared weak and unable to assist during her move to Missouri, she also testified that she did not really "remember [tiredness] being a huge issue. [She] just figured it was from the wrist or whatever," and that "[people say] 'I'm tired' all the time," figuring that petitioner was simply tired on account of the move and her recently broken wrist. (*Id.*) Respondent also argues that petitioner's fatigue following her vaccination is nonspecific and not neurologic in nature, and that petitioner's first report of neurological symptomology began roughly four months after vaccination in February of 2016. (*Id.* at 16.) The remainder of respondent's argument focuses on the issue of entitlement as opposed to onset. (S*ee id.* at 16-18.)

V. Discussion

The inconsistencies between the contemporaneous medical records, affidavits, testimony, and other documentation present a significant challenge when evaluating the record as a whole. However, in spite of these inconsistencies, several pieces of evidence, including several medical records and the testimony of petitioner's former employer, Ms. Lina Robertson, carry significant weight in favor of finding that at least some of petitioner's neurological symptoms began in late November of 2015. Specifically, the evidence preponderates in favor of a finding that petitioner experienced onset of numbness and tingling beginning in late November 2015. There is also

preponderant evidence she also experienced fatigue at that time; however, onset of weakness is not demonstrated until July of 2016.

Petitioner's medical records suggest at least five different periods of onset for her peripheral numbness and tingling: October of 2015 shortly after her flu shot (Ex. 14, p. 3), February of 2016 (Ex. 8, p. 6; Ex. 9, p. 1; Ex. 10, p. 1; Ex. 17, pp. 32-39; Ex. 19, p. 2), during the first week of March 2016 (Ex. 5, p. 1; Ex. 6, p. 1), "quite a long time" before March 18 (Ex. 2, p. 2), and "recently" relative to April 8 (Ex. 3, p. 1). Accordingly, taken as a whole, the medical records are not clear and consistent, reducing their weight.[10] *Lowrie*, 2005 WL 6117475, at *19. Notably, petitioner's initial treatment record of March 18, 2016 confirms as of that date that petitioner was experiencing peripheral numbness and tingling "for quite a long time," strongly suggesting that those later records placing onset in early March or later are unlikely to be accurate.[11] (Ex. 5, p. 1; Ex. 6, p. 1; Ex. 3, p. 1.)

Additionally, although February of 2016 is the most frequently referenced period of onset in the medical records, there are several reasons why this fact alone should not control. First, initial onset occurring in February of 2016 is also not necessarily consistent with petitioner's initial treatment record indicating that petitioner was experiencing peripheral numbness and tingling "for quite a long time." (Ex. 2, p. 2.) Furthermore, one among these records placing onset in February of 2016 actually explains that what petitioner experienced at that time was an "increase" in symptoms she associated with a specific incident she experienced while trying to move a boat with her son. (Ex. 9, p. 1.) Dr. Schudy's June 30, 2016 record explains that he questioned petitioner with respect to the details of her history and that "[o]n further questioning it is now clear that she was already having balance and tingling issues" before her move to Missouri and that she experienced an "increase" in symptoms in February of 2016.[12]

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[10] Petitioner also submitted an electronic journal documenting the progress of her disease and treatment. (*See* Ex. 33.) However, I do not find petitioner's journal particularly useful in determining the date of onset because it was started in March of 2016 and largely restates the medical records with regard to onset. Petitioner's testimony and journal both indicate that she had difficulty communicating with her physicians, felt frustrated with her access to care and the quality of care she received, and may not have been entirely forthcoming with her physicians in all instances. This presents a further challenge in weighing both petitioner's medical records and her testimony.

[11] However, there is no evidence of record to suggest that "quite a long time" refers to any time prior to the period of onset alleged by petitioner. As respondent stressed, petitioner's prior encounters in California in late October and the first half of November 2015 showed no evidence of numbness or tingling. (ECF No. 73, p. 4; Ex. 22, pp. 1-4.)

[12] Petitioner similarly testified that in February of 2016, she developed drop foot and at that time became certain she was experiencing a serious neurological issue and not a pinched nerve as she previously thought. (Tr. at 54.) Because drop foot was the condition that made petitioner realize she was suffering from a serious condition, she anchored the date of onset to that event in subsequent visits to her physicians. (*Id.*) Notably, several of the visits placing onset in February occurred consecutively and within a few months of each other. It is not necessarily surprising that petitioner would consistently report the same onset at encounters happening around the same time, reducing the significance of the multiple instances of such reports. Upon learning that CIDP may begin with numbness and tingling in the

(*Id.*) This harmonizes with the "quite a long time" description of peripheral numbness and tingling provided in petitioner's initial March 18 treatment record. (Ex. 2, p. 2.)

There is also significant fact witness testimony supporting onset of numbness, tingling, and fatigue occurring in late November of 2015.[13] First, petitioner's sister testified that when she spoke to petitioner shortly before her move to Missouri, petitioner reported that "[s]he had some funky numbness or tingling or something going on, but it was in her feet . . . ." (Tr. at 71.) She also testified that when she arrived to help petitioner move around November 24, 2016, petitioner reported having numbness in her feet and tingling in her hands as well as other nonspecific symptoms such as myalgias and arthralgias. (Tr. at 74.)

The testimony of Ms. Lina Robertson is perhaps the most helpful in that Ms. Robertson is neither related to petitioner, nor a close friend, and is therefore the most arms-length witness who testified in this case. (*See* Tr 93.) Ms. Robertson testified that she received a report from petitioner in late November of experiencing fatigue as well as "prickly" sensations she at that time attributed to a pinched nerve. (Tr. at 97; Ex. 25, p. 1.) Ms. Robertson was also able to recall a distinct and readily observable difference in petitioner's health prior to and after her vaccination due to their limited contact during that period. (*See* Tr. at 94, 98-100.) Prior to petitioner's vaccination, Ms. Robertson worked as petitioner's real estate agent, showing petitioner houses in Missouri before her move. (Tr. at 93.) She testified that while viewing houses, petitioner had no trouble walking or using her hands and seemed to be a very energetic person. (*Id.* at 94-95.) However, Ms. Robertson testified, when she next saw petitioner in person in mid-December, she noticed a marked difference in her condition. (Tr. at 98-100.) Ms. Robertson testified that petitioner no longer seemed to have the energy she did when they first met, and most importantly, that petitioner seemed to have significant difficulty ambulating, walking in a way that she described as twitchy, guarded, and slow. (*Id.* at 99.) Combined with the other evidence in the record, Ms. Robertson's testimony is consistent with a finding that petitioner began experiencing numbness and tingling in her extremities around late November of 2015.[14]

In her affidavit, petitioner also averred that she experienced weakness as early as November of 2015. (Ex. 26.) However, despite many physical examinations during the course of petitioner's care, weakness was not documented in petitioner's medical

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extremities, petitioner now believes that her onset began long before February 2016, closer to Thanksgiving of 2015. (*Id.* at 53-54.)

[13] The two affidavits provided by non-testifying witnesses are less helpful in resolving this motion. Ms. Williams' affidavit only describes nonspecific symptoms during the alleged period of onset and states that she was not made aware of petitioner's neurologic symptoms until January of 2017. Thus, it is largely unhelpful in determining the date of onset. (Ex. 24.) Ms. Johnson's affidavit is likewise nonspecific as to symptoms occurring in December and January. Ms. Johnson's affidavit would tend to support the conclusion that petitioner's condition further deteriorated in February but is less helpful with respect to the initial onset of symptoms. (Ex. 25.)

[14] Petitioner testified that through January of 2016 she had no difficulty walking, though walking was painful. (Tr. 28.)

records until June 30, 2016, when petitioner first saw Dr. Schudy. (Ex. 9, pp. 1-3.) At that time, however, Dr. Schudy's physical examination found "adequate" strength and muscle tone. (*Id*. at 2.) At least two prior physical examinations during petitioner's April 17, 2016, and April 22, 2016, encounters had confirmed that she had normal strength at that time. (Ex. 5, p. 2; Ex. 6, p. 2.) Petitioner's July 27, 2016 encounter with Dr. Papsdorf is the first time that weakness of any degree was found on physical examination. (Ex. 10, p. 4.) Especially in light of these findings on physical examination, the observations included in the lay witness testimony are inadequate to distinguish weakness as a neurologic sign from the effects of deteriorated health attributable to generalized pain and fatigue. Accordingly, there is not preponderant evidence that petitioner experienced weakness at or prior to Dr. Schudy's June 30, 2016 encounter.

VI. Conclusion

Considering petitioner's medical records, her testimony, the expert reports, and the testimony and affidavits of petitioner's fact witnesses, the record as a whole preponderates in favor of finding that petitioner experienced numbness and tingling in her extremities along with fatigue beginning in late November 2015; however, there is not preponderant evidence on the current record that she suffered weakness until July of 2016. At this time I do not reach the question of whether or how these symptoms, coupled with the overall medical course reflected in the treatment records, support petitioner's allegation of vaccine-caused CIDP. The experts shall have an opportunity to submit additional reports in light of this fact finding.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master