In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-650V

Filed: December 14, 2021

JACQUELINE BERG, *Daughter and Executrix of the Estate of MARILYN MOSS,* Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	TO BE PUBLISHED Influenza Vaccine; Chronic Inflammatory Demyelinating Polyneuropathy (CIDP); Dismissal Decision

Howard Scott Gold, Gold Law Firm, LLC, Wellesley Hills, MA, for Petitioner
Darryl R. Wishard, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On June 1, 2016, Jacqueline Berg ("Petitioner"), on behalf of her deceased mother, Marilyn Moss, filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that Ms. Moss suffered a significant aggravation of her chronic inflammatory demyelinating

[1] This Decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Decision will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

polyneuropathy ("CIDP") due to her receipt of the influenza vaccine on September 25, 2013. Petition at 1 ("Pet."), ECF No. 1.

Upon review of the evidence in this case, I find that Petitioner has not preponderantly demonstrated that she suffered from CIDP prior to her vaccination; accordingly, the flu vaccine cannot have significantly aggravated her condition.

I. Procedural History

On June 1, 2016, Jacqueline Berg filed a petition on behalf of her late mother, Marilyn Moss, alleging that an influenza vaccination significantly aggravated Ms. Moss's pre-existing CIDP. ECF No. 1.

On July 18, 2016, Petitioner filed her affidavit and medical records associated with her claim. Exs. 1-17. On September 22, 2016, Petitioner filed additional medical records. Ex. 18.

On October 24, 2016, Respondent filed a Rule 4(c) Report, presenting his analysis of Petitioner's claims and concluding that the case was not appropriate for compensation under the terms of the Vaccine Act. ECF No. 12.

On April 25, 2017, Petitioner filed an expert report from Dr. Marcel Kinsbourne as well as his curriculum vitae. Ex. 19, 19-A. On March 24, 2017, Petitioner filed the medical literature in support of Dr. Kinsbourne's expert report. Exs. 19-B through 19-R.

On July 27, 2017, Respondent filed a responsive expert report from Dr. Peter Donofrio, Dr. Donofrio's CV and the medical literature associated with his report. ECF No. 28; Exs. A-R. On June 16, 2020, Respondent filed an updated curriculum vitae for Dr. Donofrio. ECF. No. 51; Ex. X.

On December 4, 2017, this case was assigned to my docket. ECF No. 33.

On June 6, 2018, Respondent filed an amended Rule 4(c) Report alleging that Petitioner's evidence did not support CIDP as a pre-existing diagnosis for Ms. Moss. ECF No. 35

On July 26, 2018, Petitioner filed a supplemental expert report from Dr. Kinsbourne and the associated medical literature. ECF No. 38; Ex 20. On October 1, 2018, Respondent filed a responsive supplemental expert report from Dr. Donofrio and the associated medical literature. ECF No. 40; Ex. S-V. On July 26, 2018, Petitioner filed a second supplemental expert report from Dr. Kinsbourne and the associated medical literature. ECF No. 44; Ex. 21. On November 26, 2019, Respondent filed a second responsive supplemental expert report from Dr. Donofrio and the associated medical literature. ECF No. 46; Ex. W.

On December 19, 2019, the parties filed a Joint Status Report confirming that all evidence had been filed in this case and they were ready for a briefing schedule for a ruling on the record. ECF No. 47.

On May 13, 2020, Petitioner filed a Motion for Ruling on the Record. ECF No 50. On June 16, 2020, Respondent filed a response to Petitioner's Motion for Ruling on the Record. ECF No. 52. On July 12, 2020, Petitioner filed a reply to Respondent's response to Petitioner's Motion Ruling on the Record. ECF No. 52.

I held a status conference on July 7, 2021 where I informed the parties that I had questions for their respective experts concerning Ms. Moss's diagnosis that I believed would be best handled through a hearing. ECF No. 56. I conducted a hearing concerning the question of diagnosis on September 15, 2021. After the hearing, Petitioner filed additional medical literature (Ex. 22) and Respondent filed an additional expert report (Ex. Z) and one additional piece of medical literature (Ex. Y). The parties indicated the record was complete on December 2, 2021. ECF No. 67. This matter is now ripe for adjudication.

II. Medical Records

Marilyn Moss was born on May 26, 1928. Pet. at 1. She was 85 years-old when she received a flu vaccine on September 25, 2013. Prior to her vaccination, Ms. Moss lived in an independent senior living community, and was independent with the activities of daily living before breaking her ankle. Ex. 13 at 8. Long before Ms. Moss received her flu vaccination in September of 2013, she complained to health care providers of symptoms like those she alleges were aggravated by the vaccination.

A. Pre-Vaccination Records: Treatment with Dr. Brain Rebello (2010-2013)

Ms. Moss saw her primary care physician, Dr. Brian Rebello, an average of once or twice per month. *See generally*, Ex. 15. Her first appointment of record with Dr. Rebello was on August 11, 2010, when Ms. Moss presented for her annual physical and complained of loss of balance. Ex. 15 at 1. At that time, she reported no tingling, numbness, or weakness in her extremities. *Id*. Dr. Rebello noted that she presented with a past medical history of restless leg syndrome, neuropathy, gastroesophageal reflux, polymyalgia rheumatica,[3] hyperlipidemia,[4] fibromyalgia,[5] cervical spinal stenosis, and hypertension. *Id*. She had previously undergone several surgeries, including an appendectomy, hysterectomy, Arthrodesis Posterior Technique Atlas-Axis (C1-C2),

[3] Polymyalgia Rheumatica, or polymyalgia arteritica, is a syndrome in the elderly characterized by proximal joint and muscle pain and a high erythrocyte sedimentation rate. *Dorland's Illustrated Medical Dictionary*. (33 ed. 2019), https://www.dorlandsonline.com/dorland/definition?id=99324&searchterm=polymyalgia%20arteritica (Last visited May 17, 2021) (hereinafter "Dorland's").

[4] Hyperlipidemia is a general term for elevated concentrations of any or all of the lipids in the plasma, such as hypertriglyceridemia or hypercholesterolemia. Dorland's, https://www.dorlandsonline.com/dorland/definition ?id =23870&searchterm=hyperlipidemia (Last visited May 17, 2021).

[5] Fibromyalgia is pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points. https://www.dorlandsonline.com/dorland/definition?id=18554&searchterm=fibromyalgia (Last visited May 17, 2012).

and Laminectomy[6] with Exploration and/or Decompression Of Spinal Cord and/or Cauda Equina[7] without Facetectomy Foraminotomy[8] or Discectomy[9] of 1 or 2 Vertebral Segments (Thoracic). *Id.* Other medical records indicate that Ms. Moss had a bladder lift (no date given) and thumb surgery (no date given). *Id.* at 123; Ex. 4 at 54. At her August 11, 2010 appointment, Dr. Rebello assessed Ms. Moss with hyperlipidemia, restless leg syndrome, myopathy,[10] hypertension ("HTN"), gastroesophageal reflux disease ("GERD"), spinal stenosis,[11] and osteopenia.[12] Ex. 15 at 2.

On November 5, 2010, Ms. Moss complained to Dr. Rebello of gastric reflux symptoms and dysphasia.[13] Ex. 15 at 3. On December 21, 2010, Ms. Moss again complained to Dr. Rebello of severe balance issues, loss of equilibrium, and dizziness as well as an echoing and some pressure in her ear but no pain. *Id.* at 9-10. Dr. Rebello assessed her with vertigo. *Id.* at 10.

1. History of Lumbar Back and Joint Pain

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[6] A laminectomy is the excision of the posterior arch of a vertebra. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=27531&searchterm=laminectomy (last visited May 17, 2021).

[7] The cauda equina is defined as the collection of spinal roots that descend from the lower part of the spinal cord and are located within the lumbar cistern of the caudal dural sac. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=63754&searchterm=cauda+equina (last visited May 17, 2021).

[8] Foraminotomy is defined as the operation of removing the roof of intervertebral foramina, done for the relief of nerve root compression. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=19029&searchterm=foraminotomy (last visited May 17, 2021).

[9] A discectomy is the excision of an intervertebral disk. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=14476 (last visited May 17, 2021).

[10] Myopathy is defined as any disease of a muscle. https://www.dorlandsonline.com/dorland/definition?id=32891&searchterm=myopathy (last visited May 17, 2021).

[11] Spinal stenosis is defined as a narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may be either congenital or due to spinal degeneration. Called also *lumbar spinal s.* Dorland's, https://www.dorlandsonline.com/dorland/definition?id=108389&searchterm=spinal+stenosis (last visited May 17, 2021).

[12] Osteopenia is any decrease in one's bone mass below the normal. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=35878&searchterm=osteopenia (Last visited May 17, 2021).

[13] Dysphagia is an impairment of speech, consisting in lack of coordination and failure to arrange words in their proper order, due to a central lesion. Dorland's, https://www.dorlandsonline.com/dorland/ definition?id=15267&searchterm=dysphasia (last visited May 17, 2021).

Dr. Rebello's records demonstrate that as early as 2011, Ms. Moss's lumbar and pelvic spine and joints were already in a steady state of decline. On April 8, 2011, she received a right L4 and a right L3 transforaminal epidural steroid injection from Dr. Stein at the Spine Institute of South Florida; however, she continued to have pain down the front of her right leg into her thigh, knee and shin, and reported numbness and tingling in her right leg for more than a year. Ex. 15 at 129. Dr. Stein noted that she had an antalgic gait[14] and decreased sensation in her right leg. *Id*. Based on the results of a CAT scan, he diagnosed Ms. Moss with severe lumbar stenosis at L2-L3 and L3-L4 with right lumbar radiculopathy.[15] *Id*. Dr. Stein administered another steroid injection, but her pain persisted. *Id.* at 129, 141, 146. On August 31, 2011, Ms. Moss complained to her urologist of having "to bend over and walk like a question mark" over the past few months. *Id.* at 130. A chest x-ray performed on September 15, 2011 noted degenerative spondylosis[16] and scoliosis.[17] *Id.* at 239.

Ms. Moss underwent a lumbar laminectomy in October of 2011, without improvement. *See* Ex. 15 at 31.[18] She had a lot of back pain, and she felt no improvement in her right leg on October 28, 2011. *Id.* at 31, 33. She reported "tremendous pain" in her posterior to Dr. Rebello on November 15, 2011 and complained that her pain was still ongoing on November 16, 2011. *Id.* at 37, 39.

A post-operative MRI of Ms. Moss's lumbar spine on November 17, 2011 revealed no evidence of central canal stenosis; but did evidence broad-based left lateral disc protrusion at L3-L4; small focal extruded disc with cephalad migration at L3-L4 without significant effacement of the subarachnoid space; and foraminal encroachment at multiple levels as a result of bulging discs and facet hypertrophic changes. Ex. 15 at 244.

When Ms. Moss returned to her surgeon, Dr. Eskenazi, on November 29, 2011, she was using a cane and complained of right-sided anterior medial thigh pain. Ex. 15 at 141. Dr.

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[14] An antalgic gait is a limp adopted so as to avoid pain on weight-bearing structures (as in hip injuries), characterized by a very short stance phase. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=77912&searchterm=antalgic+gait (last visited May 17, 2021).

[15] Lumbar radiculopathy is any disease of lumbar nerve roots, such as from disk herniation or compression by a tumor or bony spur, with lower back pain and often paresthesias. One type is sciatica. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=101394&searchterm=lumbar+ radiculopathy (last visited May 17, 2021).

[16] Spondylosis can be defined as either 1. ankylosis of a vertebral joint. 2. degenerative spinal changes due to osteoarthritis. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=46749&searchterm=spondylosis (last visited May 17, 2021).

[17] Scoliosis is an appreciable lateral deviation in the normally straight vertical line of the spine. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=45060&searchterm=scoliosis (last visited May 17, 2021).

[18] The medical records on filed do not appear to include specific records related to Ms. Moss's lumbar laminectomy.

Eskenazi's physical exam indicated full strength in her lower extremities, and dysesthesias in the L3 distribution in the right side, which was very sensitive to touch but no pain with hip movement bilaterally. *Id*. He concluded that Ms. Moss's pain was likely secondary to some degree of nerve root inflammation, and he advised her to wear a lumbar support. *Id*. When she returned to Dr. Eskenazi on January 3, 2012, she had numerous complaints of pain; however, Dr. Eskenazi could not explain her complaints based on his physical exam and her post-op MRI. *Id.* at 146. He recommended an MRI of the thoracic spine and an evaluation by a rheumatologist. *Id*. The MRI imaging was unremarkable overall but did reveal multiple fairly mild multilevel thoracic vertebral body degenerative/spondylitic changes, "not surprising for [Ms. Moss]'s age." *Id.* at 146, 251.

Ms. Moss saw Dr. Eskenazi again on February 14, 2012 complaining of overall fatigue and an inability to walk secondary to feeling tired. Ex. 15 at 147. Dr. Eskenazi again noted that Ms. Moss had various pain complaints which he could not explain. *Id*. Upon physical examination, he found her to be neurologically intact, and her lumbar MRI revealed no residual stenosis. *Id*. Dr. Eskenazi suggested that Ms. Moss see a rheumatologist or internist to explain her fatigue and noted that there was not much else he could offer her at that point. *Id*.

Ms. Moss reported to several doctors that she had trouble walking after her surgery. Ex. 15 at 141, 143, 159, 185, 251. In January of 2012, she still had an antalgic gait and was using a cane. *Id.* at 146. Subsequently, she required a rolling walker. *See* Ex. 4 at 20.

On February 21, 2012, Ms. Moss complained to Dr. Rebello that her lower back pain was getting worse. Ex. 15 at 47. On February 27, 2012, a whole-body nuclear medicine bone scan revealed degenerative disease in the cervical and lumbar spine. *Id.* at 250. On April 4, 2012, Ms. Moss received therapeutic epidural injections due to stenosis of the spine, bilateral, L3-L4, L4-L5. *Id.* at 151. That same day, Ms. Moss reported that her pain had improved by 75 percent. *Id.* at 153. An MRI of the lumbar spine performed on July 26, 2012 revealed left inferior foraminal lateral protrusion of the disc; no evidence of central canal stenosis; and facet degenerative changes at several levels with evidence of mild to moderate foraminal encroachment at L2-L3 and L3-L4. *Id.* at 272.

An MRI of the lumbar spine on August 17, 2012 revealed diffuse degenerative disc disease with significant loss of the normal disc space between L3 and S1; anterolisthesis L2-L3 with straightening of the normal lumbar lordosis; no radiographic evidence of instability; and degenerative disc disease with previous laminectomy. Ex. 15 at 275. On September 5, 2012, Ms. Moss received a facet joint injection, bilateral, L2-L3, L3-L4, L4-L5 for lumbar spondylosis (exacerbated from lumbar extension and lateral bending bilaterally). *Id.* at 185. The contemporaneous notes from September 5, 2012 state that Ms. Moss had left and right sacroiliac joint ("SIJ") arthropathy, i.e. joint disease, which seemed to be causing most of her pain at that time, and that her hips may also require future treatment. *Id.* at 185-86. On October 17, 2012, Ms. Moss received a facet joint injection, bilateral, L2-L3, L3-L4, L4-L5, and she was diagnosed was degenerative joint disease shoulder region, pelvic region, and thigh region (hip)(buttock)(femur). *Id.* at 176-77. On November 5, 2012, Ms. Moss received a hip intraarticular injection, and hip arthrogram, bilateral. *Id.* at 79.

2. History of Shoulder Pain

Ms. Moss also experienced problems with her right shoulder. On June 21, 2011, Ms. Moss received an injection in her right shoulder for bursitis/rotator cuff rupture. Ex. 15 at 21-22. On February 29, 2012, she reported pain in her right shoulder and was assessed with another rotator cuff rupture. *Id.* at 49. On March 6, 2012, she again complained to Dr. Rebello of pain in right shoulder, and Dr. Rebello recommended physical therapy. *Id.* at 51.

3. History of Edema/Lymphedema

In April of 2012, Ms. Moss began to complain of swelling in her legs and feet. Ex. 15 at 53. From April through October of 2012, Dr. Rebello treated her with diuretics for lymphedema[19] and instructed her to wear compression stockings, perform calf exercises, keep her limbs elevated, and maintain a low salt diet. *Id.* at 53, 58, 60, 64, 66, 68, 69, 71, 72, 74, 77, 78, 82. Despite trying different doses and combinations of diuretics, Ms. Moss's symptoms failed to show any signs of improvement. Dr. Rebello ordered a venous duplex study, but the results were negative for deep venous thrombosis. *Id.* at 53, 265.

On May 24, 2012, Ms. Moss was admitted to Delray Medical Center for gastrointestinal issues. Ex. 15 at 123. While there, a physical exam revealed minimal edema in the lower extremities. *Id.* at 124. The results of a venous duplex were negative other than for generalized muscle pain "which had been chronic in this patient with fibromyalgia." *Id.* at 124, 126. Upon discharge, she was told to follow up with Dr. Rebello for peripheral edema, to hold off on taking diuretics due to her gastrointestinal issues and to wear compression stockings. *Id.* at 126. Despite the negative venous duplex results, her discharge diagnoses included venous insufficiency.[20] *Id.* at 126.

On June 27, 2012, Ms. Moss's complaints became more severe. Ex. 15 at 78. She routinely complained to Dr. Rebello of "feeling very tired, joint pains all over, hard of hearing wearing hearing aids, deceased vision, trouble sleeping, [and] numbness in feet." *Id.* at 68. Dr. Rebello

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[19] Edema is defined as the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues. It may be localized (as from venous obstruction, lymphatic obstruction, or increased vascular permeability) or systemic (as from heart failure or renal disease). Dorland's, https://www.dorlandsonline.com/dorland/definition?id=15589&searchterm=edema (Last visited May 17, 2021). Lymphedema is the chronic unilateral or bilateral edema of the limbs due to accumulation of interstitial fluid as a result of stasis of lymph, secondary to obstruction of lymph vessels or disorders of lymph nodes. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=29013&searchterm=lymphedema (last visited May 17, 2021).

[20] A venous insufficiency is an impairment of venous return from the lower limbs (venous stasis), usually characterized by edema, warmth, and erythema, particularly of the lower third of the extremity; chronic insufficiency leads to stasis ulcers of the ankle or over the medial malleolus. The most common cause is valvular insufficiency, often in combination with obstruction. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=82942&searchterm=venous+insufficiency (last visited May 17, 2021).

suggested that she try a compression pump for persistent swelling in her feet and assessed her with venous insufficiency, neuropathy,[21] and myopathy. *Id.* at 69.

From July 2012 through May 2013, Ms. Moss complained of fatigue, foot and joint pain, loss of balance, tingling/numbness/weakness in her feet, decreased sense of taste, decreased range of motion in her lower body, headaches, and not sleeping well. Ex. 15 at 71, 72, 74, 77, 80, 83, 85, 86, 90-105. Specifically, in March 2013, Petitioner reported tingling and numbness in her toes and loss of balance. *Id.* at 90. She continued to experience tingling and numbness in her lower legs and feet, as well as loss of balance in April and May 2013. *Id.* at 101-03, 105-07. Dr. Rebello placed her back on diuretics in July and assessed her with vertiginous syndrome[22] in August. *Id.* at 72. Throughout that period, Dr. Rebello continued the same course of treatment for edema -- advising Ms. Moss to do calf exercises, maintain a low salt diet, elevate her limbs, and wear compression stockings. *Id*.

On October 5, 2012, Ms. Moss informed Dr. Rebello that she had fallen the week before and hit her head. Ex. 15 at 80. She reported being depressed about her health situation and was having panic attacks. *Id*. Dr. Rebello prescribed an SSRI for depression and recommended against any travel due to her unstable medical status. *Id.* at 82. On November 5, 2012, Ms. Moss reported another fall. *Id.* at 83. Dr. Rebello assessed her with neuropathy and advised Ms. Moss to use an assist device while ambulating. *Id.* at 85. He also assessed her with peripheral vascular disease,[23] claudication[24] and recommended an arterial doppler of her lower limbs to study vascularity. *Id.* at 84. The results of the carotid and vertebral artery duplex ultrasounds were negative for significant plaque or stenosis in either carotid bifurcation. *Id.* at 282. Both vertebral arteries showed antegrade flow. *Id.* at 282. On April 18, 2013, Dr. Rebello prescribed a blood thinner for vascular disease and claudication. *Id.* at 103.

At each appointment with Dr. Rebello, he recorded the results of Ms. Moss's neurological examination as "cranial nerves normal, normal power tone reflexes b/1 upper lower limbs, sensory system normal." *See generally* Ex. 15.

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[21] Neuropathy is defined as a functional disturbance or pathologic change in the peripheral nervous system, sometimes limited to noninflammatory lesions as opposed to those of neuritis; the etiology may be known or unknown. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=33813&searchterm=neuropathy (last visited May 17, 2021).

[22] Vertiginous syndrome, aka vertigo, is an illusory sense that either the environment or one's own body is revolving; it may result from diseases of the internal ear or may be due to disturbances of the vestibular centers or pathways in the central nervous system. The term is sometimes erroneously used to mean any form of dizziness. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=52968&searchterm=vertigo (last visited May 17, 2021).

[23] Peripheral vascular disease is a type of arteriosclerosis, a group of diseases characterized by thickening and loss of elasticity of the arterial or vascular walls. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=4216 (last visited May 17, 2021).

[24] Claudication is defined as limping or lameness. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=10009&searchterm=claudication (last visited on May 17, 2021).

B. Huntington Hills Center for Health & Rehabilitation

On June 3, 2013, Ms. Moss fell while changing her pants and sustained a bi-malleolar compound fracture of her left ankle. Ex. 12 at 92. She underwent surgery three days later, and her ankle was stabilized with a titanium plate and screw. Ex. 4 at 2. Upon discharge from the hospital on June 13, 2013, Ms. Moss was admitted to Huntington Hills Center for Health & Rehabilitation where she underwent in-patient rehabilitation through September of 2013. Ex. 12 at 24. At the time she was admitted, she had a short hard cast on her left ankle and was using a self-propelled wheelchair. *Id.* at 37.

On June 14, 2013, the day following her admission to Huntington Hills, Ms. Moss was transferred to the Emergency Room at St. Joseph's Plainview Hospital in respiratory distress. Ex. 17 at 146. The admitting record noted that her past medical history included hypertension, pneumonia, coronary artery disease, congestive heart failure ("CHF"), COPD, constipation, depression, ORIF of left ankle, myalgia, osteoarthritis, and high cholesterol. *Id.* at 146. While there, she was diagnosed with combined systolic and diastolic acute or chronic heart failure, acute chronic bronchitis, and acute non-ST elevation myocardial infarction.[25] *Id.* at 147. She was also found to have pneumonia, likely secondary to aspiration. *Id.*

While admitted to Plainview Hospital Ms. Moss had a chest x-ray which showed pulmonary vascular congestion and questionable left lower lobe infiltrate; an echocardiogram which demonstrated ejection fraction of 35%, severe depression, mild left ventricular hypotrophy[26] ("LVH"), aortic insufficiency,[27] and mitral regurgitation;[28] an EKG which revealed normal sinus rhythm and a left bundle branch block; and a swallow evaluation which revealed that Ms. Moss's abilities were within normal limits. Ex. 17 at 147-70. Ms. Moss reported having chronic joint pain and a history of fibromyalgia, rated her current pain level 5-6/10 (not related to her current illness), and stated that she had been taking Percocet every five to six hours for the past two years. *Id.* at 174. Ms. Moss received a coronary artery stent and was discharged the same day. Ex. 4 at 2. She

[25] Myocardial infarction is a gross necrosis of the myocardium as a result of interruption of the blood supply to the area; it is almost always caused by atherosclerosis of the coronary arteries, upon which coronary thrombosis is usually superimposed. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=82528&searchterm=myocardial+infarction (last visited May 18, 2021).

[26] Hypotrophy the enlargement or overgrowth of an organ or part due to an increase in size of its constituent cells. *See also hyperplasia* and *proliferation.* Dorland's, https://www.dorlandsonline.com/dorland/definition?id=24054 (last visited May 18, 2021).

[27] An aortic insufficiency is a defective functioning of the aortic valve, with incomplete closure resulting in aortic regurgitation. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=82910&searchterm=aortic+insufficiency (last visited May 18, 2021).

[28] Mitral regurgitation is the backflow of blood from the left ventricle into the left atrium, owing to mitral valve insufficiency; it may be acute or chronic, and is usually due to mitral valve prolapse, rheumatic heart disease, or a complication of cardiac dilatation. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=103414&searchterm=mitral+regurgitation (last visited May 18, 2021).

was re-admitted to Huntington Hills on June 18, 2013, and her re-admitting diagnoses were CHF (Systolic), NSTEMI, s/p STENT, s/p FALL, s/p ORIF Left Ankle Fracture 6/9/13. Ex. 12 at 34. Her medical history included fall, fractured left ankle, HLD, COPD, fibromyalgia, neuropathy, GERD, CAD, OA, and HTN. *Id.* at 41.

Upon being readmitted to Huntington Hills the second time, Ms. Moss was placed on aspiration precautions. Ex. 12 at 35. Ms. Moss did not feel like such precautions were necessary, and on June 19, 2013, she was recommended for a swallow evaluation. On June 25, 2013 the precautions were decreased after it was determined that Ms. Moss could cut small bites of food, feed herself independently and that she showed no signs or symptoms of aspiration across trials, although she did display mild prolonged mastication. Ex. 12 at 61, 63, 92.

On June 27, 2013, Ms. Moss's cast and sutures were removed, and she denied any parathesis or complaints of pain at the incision site. Ex. 12 at 99. The cast was reapplied, and her doctor recommended that she remain non-weight bearing on her left leg while using a walker. *Id*. On July 17, 2013, Ms. Moss received a platform boot but was again ordered to remain non-weight bearing on her left leg. *Id.* at 142. On August 1, 2013, her cast was removed, and Ms. Moss received a CAM walker boot. *Id*. On August 29, 2013, she was advanced to 100% weight bearing as tolerated with her CAM walker boot and could remove the boot at night. *Id.* at 163, 207. After her cast was removed, Ms. Moss regularly reported pain in her lower left extremity, but by September 4, 2013, she was able to ambulate with a walker. *Id.* at 170, 178, 180, 181, 194, 195, 206, 207, 216, 226, 229, 240, 242. Her physical therapy discharge notes indicate that she made significant progress throughout her stay, but that she was still only partial weight bearing on her left leg which limited her progress in occupational therapy sessions. *Id.* at 576.

On September 6, 2013, a chest x-ray revealed no evidence of acute pulmonary disease; however severe osteoporosis was evident as well as a moderate degree of osteoarthritis. Ex. 12 at 221. On September 18, 2013, Ms. Moss was discharged from Huntington Hills and transferred to Brandywine Independent Living Center with 24 hour split shift care. *Id.* at 245. She was discharged with a transport chair, rolling walker, and required a 3-in-1 commode and shower set. *Id.*

C. Post-Vaccination Medical Records: Brandywine Independent Living Center

After transferring to Brandywine Independent Living Center, Ms. Moss had her first visit with her new primary care provider, Dr. Marc Allen on September 25, 2013. Ex. 4 at 1. She presented in a wheelchair and requested a prescription for a powered wheelchair with a cushion. *Id.* Ms. Moss's current problems included, among others, idiopathic peripheral neuropathy, spinal stenosis (lumbar region), vitamin D deficiency, and dizziness. *Id.* at 3-4. A neurological examination revealed that cranial nerves II-XII were grossly intact; grossly normal tone and muscle strength and reflexes: 2 bilaterally. *Id.* at 4. Sensation was normal to touch and pinprick, and vibration and proprioception senses were intact. *Id*. Dr. Allen assessed Ms. Moss with dizziness, prescribed Antivert,[29] advised her to drink more fluids and to follow up with a

[29] Antivert (meclizine hydrochloride) is an antihistamine used in the management of nausea, vomiting, and dizziness associated with motion sickness and of vertigo associated with disease affecting the vestibular

neurologist. *Id*. At that appointment, Dr. Allen administered the influenza vaccination (Fluvirin) to Ms. Moss. *Id.* at 32.

Ms. Moss returned to Dr. Allen on October 23, 2013 for an annual exam. Ex. 4 at 16. Her neurological examination revealed normal cranial nerves, "gait: turning normal, tandem steady, and toe walk normal; sensation: normal to touch and pinprick; vibration and proprioception senses intact; full, painless range of motion of all major muscle groups and joints." *Id.* at 26. Dr. Allen again assessed Ms. Moss with other specified idiopathic peripheral neuropathy and coronary artery disease (CAD) and ordered a carotid ultrasound. *Id.* at 18-19.

On October 23, 2013, pursuant to Dr. Allen's referral, Ms. Moss also saw Dr. McMonigle. Ex. 4 at 16. In reporting the history of her present illness to Dr. McMonigle, Ms. Moss reported that she was in her usual state of health until she began falling two years prior. *Id.* at 20. Ms. Moss told Dr. McMonigle that she did not experience any dizziness, lightheadedness, or diplopia[30] before falling, but that she did feel unbalanced and her legs felt heavy and numb. *Id.* She reported that she had a lumbar laminectomy due to lower back pain which resulted in her needing a to use a walker instead of a cane. *Id*. More recently, Ms. Moss reported having a low voice for "several months", as well as wrist pain, and weakness and numbness in her hands. *Id*. She denied any fasciculations other than her legs occasionally feeling restless and needing to get out of bed at night. *Id.* Ms. Moss reported that the course of her symptoms had been progressively worsening, of moderate intensity, and occurring several times a day. *Id*.

Dr. McMonigle assessed Ms. Moss with paresthesia, abnormal gait, mild depression, and a vitamin D deficiency. Ex. 4 at 22, 26. Dr. McMonigle ordered extensive testing and lab work in an effort to rule out neuropathy, normal pressure hydrocephalus (NPH), and/or cerebrovascular accident (CVA). *Id.* at 22. Dr. McMonigle recommended that Ms. Moss continue physical therapy. *Id.*

On October 25, 2013, Ms. Moss appeared at Planview Hospital for a follow up regarding her coronary artery disease and hypertension. Ex. 4 at 33. She reported that she was doing "okay" but complained of having slurred speech at times and occasionally feeling like her throat was closing. *Id.* at 33. She was assessed with coronary artery disease and hypertension; however, an EKG/ECG demonstrated that her condition was stable. *Id.* at 36. Her doctor recommended that she stop taking Diovan to improve her throat symptoms and stop taking oxycodone and Ambien to improve her slurred speech. *Id.*

On November 5, 2013, Ms. Moss presented at Head Over Heals Physical Therapy for an initial evaluation of her muscle weakness/gait abnormality pursuant to Dr. Allen's referral. Ex. 13 at 8. She was in a wheelchair, and her chief complaints were that she had developed dropfoot while undergoing rehab for her left ankle fracture; that she was experiencing increased imbalance over

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system; administered orally. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=29992 (last visited May 28, 2021).

[30] Diplopia is the perception of two images of a single object; called also *ambiopia*, *double vision*, and *binocular polyopia*. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=14354&searchterm=diplopia (last visited May 18, 2021).

the past few months; and that her current condition was limiting her overall functional abilities. *Id.* Ms. Moss stated that prior to her fall in June of 2013, she was independent with all the activities of daily living. *Id.* The therapist evaluated her strength for both right and left upper and lower extremities and found that Ms. Moss could ambulate 50 feet with a rolling walker. *Id.* at 9. Ms. Moss was assessed with difficulty walking community distances, negotiating stairs/curbs, moving around and/or changing and maintaining body position during bed mobility, and transferring from sit to stand from low surfaces or car transfers. *Id.* at 9. She was deemed to be 84% impaired. *Id.* at 5. Subsequently, Ms. Moss attended ten physical therapy sessions from November 17, 2013 through December 16, 2013. *Id.* at 16.

On November 12, 2013, Ms. Moss had an MRI of the brain. Ex 4 at 92. The imaging revealed normal pressure hydrocephalus, no acute hydrocephalus, and no hemorrhage of hydrocephalus. *Id.* The radiologist's impressions were:

> ventriculomegaly[31] with slight disproportionate size the ventricles as compared to cortical sulci with periventricular foci of T2 prolongation suggestive of transparent spread of CSF which can be consistent with chronic normal pressure hydrocephalus in the appropriate clinical setting; patchy and confluent white matter abnormality in the subcortical, periventricular and deep white matter distribution consistent with moderate small vessel ischemic changes; moderate chronic mucosal disease of the paranasal sinuses most pronounced at the level of ethmoid sinuses bilaterally; and small right mastoid effusion.

Ex. 13 at 92-93.

On November 18, 2013, Ms. Moss saw Dr. McMonigle for a follow-up visit. Ex. 4 at 11. Her neurological examination revealed that all cranial nerves were intact except for XII related to Ms. Moss's soft speech. *Id.* at 13. She exhibited a "slowed and steppage gait; tone and strength: normal overall tone, no atrophy, no fasciculations; bilateral dorsiflex, intrinsic hand muscles 4/5, otherwise 5/5*;* reflexes: toes down going; 1 bilateral; Sensation: DSS: no extinction; decreased light pin, temperature and vibration proception in stocking glove distribution." *Id*. Dr. McMonigle ordered additional testing including needle electromyography (four extremities with or without related paraspinal areas); nerve conduction of each motor nerve (amplitude and latency/velocity study with F-wave study); nerve conduction of each sensory nerve (amplitude and latency/velocity study with F-wave study); H-reflex (amplitude and latency study; record gastrocnemius/soleus muscle); sudomotor and autonomic testing; and VNG test. *Id.* at 13-14.

On November 18, 2013, the summary of Ms. Moss's lower extremity EMG test revealed that the potentials for the peroneal and tibial nerves were not recordable. Sural and plantar responses were normal. F and H waves were absent, and the needle study was normal. Ex. 4 at 68. Dr. McMonigle's impression was "abnormal study indicating lumbar radiculopathy." *Id.* at 62.

[31] Ventriculomegaly is a gross enlargement of a ventricle of the brain, as by hydrocephalus. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=52829&searchterm=ventriculomegaly (last visited May 18, 2021).

On November 25, 2013, the results of Ms. Moss's upper extremity motor and sensory nerve studies revealed that the motor potentials for bilateral median nerves were of prolonged distal latency with decreased amplitude and velocity. Ex. 4 at 64. The ulnar motor potentials were of decreased amplitude and velocity. *Id*. The sensory potentials for the lunar nerves were normal. *Id*. The sensory potential for the bilateral median nerves were of decreased velocity with normal amplitude and latency, and F waves were prolonged. *Id.* The needle study was normal. *Id.* at 63. Dr. McMonigle's impression was an abnormal study indicating bilateral moderate to severe median neuropathy at the wrist and cervical radiculopathy. *Id.* at 64.

On November 25, 2013, Ms. Moss saw Dr. McMonigle for a follow up visit. Ex 4 at 6. Dr. McMonigle's assessment was cerebrovascular disease, chronic sinusitis, abnormal laboratory test findings without diagnosis, normal pressure hydrocephalus, Vitamin D deficiency, mild depression, abnormal gait, paresthesia, spinal stenosis (lumbar region) without neurological claudication, CTS, and cervical radiculopathy. *Id.* at 8. The results of Dr. McMonigle's physical neurologic examination were identical to those recorded on November 18, 2013. Dr. McMonigle again ordered nerve conduction studies of the motor and sensory nerves and an MRI of the cervical spine *Id.* She recommended that Ms. Moss continue physical therapy for her abnormal gait, that she practice proper body mechanics and no lifting in connection with her lumbar stenosis, and that she continue her cardiovascular treatment for her cerebrovascular disease. *Id.* at 9. She referred Ms. Moss to a neurosurgeon for normal pressure hydrocephalus and an internist for her abnormal laboratory test findings without diagnosis. *Id.*

On November 26, 2013, Ms. Moss saw Dr. Stieg at NY Presbyterian Hospital, Weill Cornell Medical Center, pursuant to Dr. McMonigle's referral. Ex. 4 at 37. Ms. Moss reported that she first fell two years ago, and that she was recently diagnosed with footdrop, possibly related to her lumbar disease. *Id.* Ms. Moss's major concern at that time was her slurred speech and the possibility that she may have suffered a stroke. *Id.* A physical examination revealed that she had 4/5 weakness bilaterally in her hip flexors, a right footdrop for which she was wearing an orthotic, diminished sensation in her lower extremities, but the ability to distinguish between sharp and dull stimulus. *Id.* at 38.

Dr. Stieg's notes indicate that although Ms. Moss had recovered from her left ankle fracture and was weight bearing in August of 2013, she was now experiencing numbness and paresthesia in her feet bilaterally, noting that her feet "feel dead." Ex. 4 at 37. Upon physical examination, Dr. Stieg observed that Ms. Moss was in a wheelchair and was unable to walk without two people holding her because of her ankle and foot problems. *Id.* at 38. He reviewed the EMG of Ms. Moss's upper extremities showing bilateral to moderate median nerve neuropathy. He agreed that the EMG of her lower extremities showed a lumber radiculopathy. *Id.* He noted that the MRI of her brain demonstrated slight ventriculomegaly with temporal horn enlargement but normal third ventricle and some slight transependymal flow which was non-predicative for hydrocephalus. *Id.*

Overall, Dr. Stieg was not convinced that Ms. Moss had hydrocephalus as her gait was the major issue; her slurred speech was a separate although great concern. Ex 4 at 38. He stated that Ms. Moss's gait could certainly be attributed to her lumbar spine disease, right dropfoot and difficulty with her left foot. *Id.* Dr. Stieg did not recommend placement of a ventriculoperitoneal shunt at that time, and noted that even if Dr. McMonigle recommended it, Dr. Stein doubted that

it would improve Ms. Moss's gait significantly. *Id.* Dr. Stieg referred Ms. Moss to another neurologist, Dr. Stuebgen, for another opinion. *Id.* An addendum to Dr. Stieg's notes states that Ms. Moss cancelled her appointment with Dr. Stuebgen.

On December 15, 2013, Ms. Moss was evaluated by Dr. Ellstein at Hand Surgery Associates of Long Island at the request of Dr. Allen. Ex. 4 at 53. Her chief complaint was an altered sensation in both hands and fingertips "which she states has been present for months and worsening over time." *Id.* She had previously been advised to wear wrist braces at night, but she complained that they were too uncomfortable. *Id.* Dr. Ellstein noted a history of osteoarthritis and rheumatoid arthritis, and a prior CMC arthroplasty performed on her left hand for which no further details were given. *Id.* at 54. He assessed Ms. Moss with bilateral carpal tunnel syndrome and disturbance of skin sensation. *Id.* at 55. He administered a cortisone injection in both wrists. *Id*.

On December 17, 2013, Head Over Heals Physical Therapy provided Dr. Allen with the results of Ms. Moss's current progress. Ex. 13 at 4. She exhibited a slight increase in strength in her left and right upper and lower extremities and was able to ambulate 65 feet with a rolling walker. *Id.* at 5. Her impairment decreased from 84% in November of 2013 to 81.85%. *Id.* Ms. Moss attended seven physical therapy sessions from December 19, 2013 through January 28, 2014. *Id.*

At her physical therapy session on December 19, 2013, the therapist noted that Ms. Moss was experiencing buckling in both knees and required her wheelchair to follow the therapist. Ex. 13 at 20. Ms. Moss was instructed to contact her doctor to find out why she had continuing weakness with walking. *Id.*

On January 13, 2014, Ms. Moss underwent a CT angiogram of her chest revealing no CT evidence for pulmonary embolism, however multiple degenerative changes of the spine were noted. Ex. 4 at 79, 81-82. A bilateral lower doppler venous sonogram revealed no sonographic evidence for acute deep venous thrombosis. *Id.* at 84-85. A portable chest x-ray revealed no active disease. *Id.* at 88.

On January 15, 2014, Ms. Moss had a consultation with Dr. Gudesblatt at South Shore Neurological Associates, PC. Ex. 4 at 44. Her history of present illness was recorded as follows:

> 1. balance problems – slurred speech
> The symptoms are reported as being incapacitating. The symptoms occur daily. She states the symptoms are unstable. 85-year-old right-handed woman presents for evaluation of difficulty with walking and imbalance. She has had increasing difficulty with walking over the past 3 years. She had complaints of leg weakness and numbness. At that time, she had no complaints of arm weakness or numbness or difficulty with vision. She had a long history of back pain which worsened at that time. She was seen in rheumatologic consultation and felt to have problems with difficulty walking related to her back. A diagnosis of lumbar spinal stenosis was made. She underwent lumbar spinal surgery for decompression and despite having surgery she has had increased difficulty with walking to the point where she required a walker. She underwent further evaluation and no clear cause for her

> difficulty with walking was identified. Over time her walking ability worsened to the point where she is now in a wheelchair. At this time, she also had ongoing difficulty with walking and episodic leg weakness to the point where she would have profound leg weakness and fall without associated chest pain, palpitations, or blackout. She does not report difficulty with memory or thinking. She reports ongoing neck pain and episodic pain extending to the head. She reports difficulty swallowing and occasional choking. She reports change in voice pattern. She is not reporting arm weakness and is able to self-propel the wheelchair. She describes increased leg weakness and numbness. She reports episodic locking up of the fingers. No bowel or bladder problems reported. No family history of similar problems reported.

Id. Dr. Gudesblatt's neurological exam revealed "Rapid hand movements mildly slowed. Motor strength 5/5 upper extremities. Hip flexion 4-/5 bilateral. Knee extension 5-/5 bilateral, dorsiflexion 2/5 bilateral. Knee and ankle jerks absent. Plantar responses flexor bilateral. Motor tone normal sitting. She is not ambulatory. Pinprick and vibration diminished distal lower extremities." *Id.* at 49. He assessed Ms. Moss with polyneuropathy, weakness, and gait disturbance. *Id.* at 50. His contemporaneous notes state that Ms. Moss's history and exam suggest that she has progressive peripheral polyneuropathy with some neural myopathy features causing progressive weakness and difficulty with ambulation. *Id.* "Her complaints of altered speech and swallowing suggest this is a progressive neuropathy affecting other body parts." *Id.* Although there was no clear evidence to support a diagnosis of motor neuron disease, Dr. Gudesblatt noted that it remained a consideration and concern. *Id*. "Whether this represents autoimmune disorder or other disorder is unclear in view of fact that she is a nondiabetic and has not been treated with chemotherapy. It is not likely that her condition is related to normal pressure hydrocephalus or spinal stenosis." *Id.*

On January 27, 2014, the impression of Ms. Moss's MRI of the cervical spine was recorded as broad central disc and osteophyte complex at the C4-5 disc level resulting in cord flattening and deformity but not compression, and prominent bilateral foramina stenosis at C5-6. Ex. 8 at 12. Within the limitations of the examination there was no intrinsic cord signal abnormality. *Id.*

On February 5, 2014, Ms. Moss returned to see Dr. Ellstein at Hand Surgery Associates of Long Island. Ex. 4 at 51. He assessed her with mononeuritis[32] of upper limb and mononeuritis multiplex: carpal tunnel syndrome, and disturbance of skin sensation. *Id.* at 52. Dr. Ellstein administered a cortisone injection into the right and left wrist carpal tunnel, and he advised Ms. Moss to wear wrist braces at night. *Id.* His overall impression was bilateral carpal tunnel syndrome. *Id.*

On February 10, 2014, Ms. Moss returned to Dr. Ellstein for a follow up. Ex. 6 at 4. She complained of persistent/constant numbness and reported that the cortisone injections did not give her any relief. *Id*. She also reported diminished strength and that she had been dropping objects.

[32] Mononeuritis is the disease of a single nerve. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=32025&searchterm=mononeuritis (last visited May 18, 2021).

Id. Because Ms. Moss was being seen by another neurologist and repeat EMG testing would be performed, Dr. Stein deferred any further treatment until receipt of the test results. *Id.* at 5.

On February 12, 2014, Ms. Moss underwent EMG/Nerve Conduction Testing to evaluate for myopathy and polyneuropathy. Ex. 8 at 16. The findings note severe axonal sensorimotor polyneuropathy of the lower extremities with marked active and chronic denervation changes. *Id.* The findings were consistent with moderate to severe bilateral L3-L4 lumbar radiculopathies with both active and chronic degenerative changes. *Id.* Further nerve conduction velocity and needle electromyographic studies of the upper extremities were recommended to delineate the extent of the sensorimotor polyneuropathy. *Id.* at 17.

On February 19, 2014, Ms. Moss underwent EMG/Nerve Conduction Testing to evaluate for bilateral ulnar neuropathy. Ex. 8 at 20. The results of the electrical study were abnormal. There was electrophysiologic evidence for predominantly motor neuropathy which was asymmetric and multifocal and had mixed axonal and demyelinating features. *Id.*

On March 3, 2014, Ms. Moss returned to Dr. Ellstein again complaining of continued pain and weakness in both hands (left greater than right), an inability to use silverware while eating, and often dropping objects. Ex. 6 at 6. Dr. Ellstein noted that her EMG/NCV testing results showed an abnormal electrical study but overall evidence of predominantly motor neuropathy which is asymmetric and multifocal with mixed axonal and demyelinating features. *Id.* at 7. Dr. Ellstein's assessment was multifocal motor neuropathy, bilaterally. *Id.* He referred Ms. Moss back to her neurologist and recommended occupational therapy. *Id.*

On March 4, 2014, Ms. Moss again saw Dr. Gudesblatt at South Shore Neurological Associates. Ex. 8 at 25. Her history of present illness was recorded as follows:

> 1. polyneuropathy
> The symptoms are reported as being incapacitating. The symptoms occur daily. She states the symptoms are unstable. 85-year-old woman with progressive multilocal root-sensory polyneuropathy. She reports increasing difficulty over years which has resulted in accelerated problems more recently. She describes frustration related to increased physical disability. She describes difficulty with short-term memory. She reports increased difficulty with energy during the daytime. She reports increased flatulence. She reports increased weakness of the hands. She is [sic] also increased weakness in her legs and inability to ambulate any distance.

Id. A neurological exam revealed "Rapid hand movements slowed. Motor strength 5/5 deltoid, biceps, triceps, and wrist extension with finger abduction 4/5. upper extremities. Hip flexion 3+/5, knee extension 5-/5, dorsiflexion 1/5. Knee jerks absent. Motor tone is normal sitting. Non-ambulatory. Vibration reduced distal lower extremities." *Id.* at 29. After reviewing the results of her extensive testing, Dr. Gudesblatt assessed Ms. Moss with multifocal motor neuropathy with some axonal and sensory involvement. *Id.* at 30. His assessment included polyneuropathy and CIDP. *Id.* Ms. Moss's autoimmune testing demonstrated no marker, and at her age CSF analysis was deferred. *Id*. Dr. Gudesblatt recommended a course of IVIG treatment in an attempt to stabilize

and perhaps improve the progressive course of Ms. Moss's condition. "If she is unable to tolerate or is not a candidate for IVIG, then a course of pulse steroids might be arranged." *Id*.

On March 19, 2014, Ms. Moss started her initial round of IVIG treatments and received her first of four doses of Gamunex 30grams. Ex. 8 at 35. Doses two through four were administered over the next three consecutive days. *Id.* at 38, 40, 42.

On April 21, 2014, Quest Diagnostics reported the results of a lumbar puncture performed on April 8, 2014. Ex. 8 at 44. The results showed two well defined gamma restriction bands in the CSF and corresponding serum sample, but some bands in the CSF were more prominent. *Id.* According to Quest: "This pattern is associated with Guillain-Barre syndrome, peripheral neuropathy or increased permeability of the blood-brain barrier secondary to infection or trauma."[33] *Id*. Her myelin basic protein level was less than 2.0, which is interpreted as a negative result. *Id.* at 45.[34]

On April 21, 2014, Ms. Moss appeared at St. Joseph's Hospital for XR modified barium swallow testing. Ex. 8 at 51. The findings revealed mild oral dysphagia, no penetration or aspiration, normal pharyngeal stage, and mild gastroesophageal reflux. *Id.* An AP Chest x-ray revealed the heart and mediastinal contours were normal. *Id*. The lungs were clear without pleural effusion or congestion. *Id*. The visualized osseous structures were intact, and bilateral humeral heads were high riding likely related to underlying rotator cuff arthropathy. *Id*. "Degenerative changes and disc space narrowing visualized the cervical spine. Upper cervical spine hardware intact." *Id*. The overall impression was clear lungs, mild oral dysphasia and mild gastroesophageal reflux. *Id.*

On April 28, 2014, Ms. Moss started her second round of IVIG treatments and received her first of four doses of Gamunex 30grams. Ex. 8 at 52. Doses two through four were administered over the next three consecutive days. *Id.* at 54, 56, 58. At her second appointment, Ms. Moss complained of a headache due to fast IVIG treatment but indicated that this dissipated. *Id.* at 56.

On April 30, 2014, Head Over Heals wrote to Dr. Allen to inform him that Ms. Moss was being discharged from physical therapy "due to discontinuing therapy at this time." Ex. 4 at 57. Over the course of her treatment, her disability decreased from 84% to 75%. *Id.* Ms. Moss stated that she would participate in a home exercise program focusing on stretching, exercises, MFR, and internal work. *Id.*

On May 13, 2014, Ms. Moss returned to Dr. Gudesblatt at South Shore Neurological Associates, PC. Ex. 8 at 60. Her history of present illness was recorded as follows:

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[33] "The clinical significance of a numerical band count, determined by Isoelectric Focusing has not been definitively defined. The data should be interpreted in conjunction with all pertinent clinical and laboratory data for this patient." Ex. 8 at 44.

[34] "The test and its performance characteristics were developed by Quest Diagnostics Nichols Institute. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary." Ex. 8 at 45.

> 1. CIDP - polyneuropathy
> The symptoms are reported as being incapacitating. The symptoms occur daily. She states the symptoms are unstable since last visit. She reports increased difficulties. She describes frustration related to physical disability. She has had complaints of shortness of breath and fatigue while speaking. She reports increased difficulty with swallowing and occasional choking episodes. She reports increased weakness of her arms, but she is in uncertain about this. She reports occasional hand tremors. She finds her leg strength has worsened to the point where she is unable to stand or transfer. She is unable to ambulate even with a walker. She also has complaints of headaches since IVIG.

Ex. 8 at 60. A neurological exam revealed "Rapid hand movements slow. Motor strength 5/5 upper extremities with finger abduction 4/5. Hip flexion 2/5, knee extension 4-/5, OC flexion 1/5. Knee jerks absent. Motor tone is normal sitting. Nonambulatory. Pinprick and vibration reduced distal lower extremities." *Id.* at 65. Dr. Gudesblatt assessed Ms. Moss with polyneuropathy (symptomatic) and CIDP (symptomatic). *Id*. He noted progressive multifocal motor and sensory axonal and demyelinating polyneuropathy and multifocal motor neuropathy. *Id*.

Dr. Gudesblatt noted that although autoimmune testing was negative, Ms. Moss's spinal fluid demonstrated elevated protein,[35] elevated neuron specific enolase, and serum and spinal fluid oligoclonal bands. Ex. 8 at 66. Dr. Gudesblatt remarked that Petitioner had not demonstrated "clear improvement or stabilization with two months of IVIG." *Id.* Dr. Gudesblatt increased Petitioner's IVIG dose. *Id*. If there was still no improvement or stabilization after the increase, he recommended hospital admission for plasma exchange followed by Rituximab, then resuming IVIG treatments. *Id*. He stated that her shortness of breath and difficulty swallowing were secondary to her current disease progression, and that physical therapy should be continued for stabilization and for transfer training to maintain independence. *Id.*

On May 27, 2014, Ms. Moss started her third round of IVIG treatments and received her first of four increased doses of Gamunex 40grams. Ex. 8 at 67. Doses two and three were administered over the next two days. *Id.* at 69, 71.

On May 29, 2014, Ms. Moss was admitted to North Shore Long Island Jewish Health System with complaints of nausea, vomiting and headache that began one hour after her IVIG treatment earlier that day. Ex. 17 at 45. Her daughter reported that Ms. Moss began feeling generalized body weakness and a severe tension-like headache and that Ms. Moss usually had the same complaints after treatment but never this severe. *Id.* Ms. Moss was noted as being wheelchair bound, having chronic slurred speech, and chronic numbness/tingling in her lower extremities secondary to CIDP. *Id.* The treating physician, Dr. Ravindra Bhachawat spoke to Ms. Moss's family about the possible use of steroid treatment; however, Ms. Moss had underlying skin problems with steroids. *Id.* at 19. Dr. Bhacawhat contacted Dr. Gudesblatt to report that secondary to Ms. Moss's age, he did not believe plasmapheresis would be of any benefit and he recommended

[35] Although Dr. Gudesblatt noted that Petitioner had elevated protein in the spinal fluid, this test does not appear in Petitioner's medical records.

physical therapy. *Id.* at 97. Dr. Bhachawhat's notes state that Dr. Gudesblatt agreed with his recommendation. *Id.*

Ms. Moss was discharged from St. Joseph's on May 31, 2014. Ex. 17 at 44. Her principal discharge diagnosis was CIDP and a lower dose of IVIG treatment was recommended going forward. *Id.* at 14. Her secondary discharge diagnoses were hyponatremia (likely pseudohyponatremia secondary to IVIG), HTN, depression, coronary artery disease, CHF, and hyperlipidemia. *Id.* at 43.

On July 23, 2014, Ms. Moss saw an ENT. Ex. 10 at 1. Her history of present illness states that she presented in an electric wheelchair with progressive neurologic disorder and bilateral hearing aids. *Id*. She reported having problems with fluid and water intake but was okay with solids and thicker consistencies. *Id*. She was assessed with sensorineural hearing loss, cerumen impaction, and dysphasia. *Id*.

On July 30, 2014, Ms. Moss presented to North Shore Long Island Jewish Health System Emergency Department via EMS in respiratory distress. Ex. 17 at 8. Ms. Moss complained of fatigue the day before and difficulty breathing as of 5am that morning. *Id.* She reported no chest pain and no fever. *Id.* at 13. While admitted, her progress notes state that Ms. Moss was more anxious than short of breath. *Id.* at 15. She was discharged the same day with a principal diagnosis of dyspnea.[36] *Id.*

On August 21, 2014, Ms. Moss returned to Dr. Gudesblatt. Ex. 8 at 74. Her history of present illness was recorded as follows:

> 1. CIDP - polyneuropathy
> 86-year-old woman seen for progressive neuropathy. She has been treated with IVIG and despite adjustment of dose after not tolerating increasing dosage she has had progressive disability. She reports increased weakness, difficulty speaking and increased weakness of her legs. She is no longer able to ambulate. She reports fatigability of her head and weakness of her hands. She reports increased depression and frustration. She has had increased daytime sleepiness.

Id. A neurological evaluation revealed "Rapid hand movements slowed. Motor strength 5-/5 upper extremities. Hip flexion 1-/5, knee extension 2/5, dorsiflexion 0/5. Knee jerks absent. She is non-ambulatory. Motor tone is normal sitting. Vibration absent at the feet. Pinprick preserved." *Id.* at 78. Dr. Gudesblatt assessed her with polyneuropathy (symptomatic), weakness (symptomatic), and CIDP (symptomatic). Dr. Gudesblatt recommended an increased dose of IVIG and increased frequent infusions. *Id*. If the increased dose did not improve her condition, Dr. Gudesblatt encouraged hospitalization for plasma exchange if the family was interested and cardiac clearance could be obtained. *Id*. Dr. Gudesblatt recommended the use of Ambien symptomatically for sleep, although he warned the family about concerns regarding reduced ventilation and oxygenation at

[36] Dyspnea is defined as breathlessness or shortness of breath; difficult or labored respiration. Dorland's, https://www.dorlandsonline.com/dorland/definition?id=15277&searchterm=dyspnea (last visited May 18, 2021).

night due to her neuromuscular cage weakness. *Id.* at 79.

On January 7, 2015, Ms. Moss was admitted to Hospice Inn. Ex. 16 at 1. Her admitting diagnosis was CIDP, aspiration pneumonia – dysphasia. *Id.* at 8. Ms. Moss was admitted with a DNR and had a life expectancy of six months or less. *Id.* at 4. The history of her condition states that Ms. Moss had a past medical history of CIDP, hypertension, hyperlipidemia, and CAD, that she had not been walking for several months secondary to CIDP, and that she had developed progressive dysphasia. *Id.* at 8. The record indicates that Ms. Moss was given Rituxan treatments and IVIG for CIDP a few weeks ago which did help her symptoms at first; however, it was short lived. *Id.* She was hospitalized on January 3, 2015 with worsening dysphagia and recurrent aspiration resulting in respiratory distress. *Id.* at 6. In the ER she was found to be very hypoxic and hypotensive and was placed on Bi Pap. After meeting with a palliative team on January 5, 2015, the family decided to keep Ms. Moss comfortable and to forgo any additional aggressive measures. *Id.* at 32. On January 8, 2015, Ms. Moss passed away peacefully. *Id.*

III. Fact Evidence (Petitioner's Affidavit)

Petitioner's affidavit avers that she is the daughter of Marylyn Moss, and that she was appointed Executor of the estate following Ms. Moss's death on January 8, 2015. Ex. 2 at 1. Petitioner states that her mother's symptoms began in October of 2013, and that during the course of her illness, her mother suffered from problems with speech, balance, swallowing, breathing, numbness and weakness. *Id*. Petitioner states that she watched her mother suffer both physically and emotionally from October of 2013 "to the time of her death from chronic inflammatory demyelinating polyneuropathy." *Id*.

IV. Expert Reports and Testimony

A. Petitioner's Expert, Dr. Marcel Kinsbourne

Dr. Kinsbourne offered three expert reports opining that the flu vaccine exacerbated Ms. Moss's pre-existing CIDP. Expert Report, filed on April 25, 2017, as Ex. 19 ("First Kinsbourne Rep."); Supplemental Expert Report, filed on July 26, 2018, as Ex. 20 ("Second Kinsbourne Rep."); Second Supplemental Expert Report, filed on July 28, 2019, as Ex. 21 ("Third Kinsbourne Rep.").

1. Qualifications

Petitioner did not file a curriculum vitae for Dr. Kinsbourne; however, he frequently testifies in vaccine program cases and his qualifications were summarized in *Strong v. Sec'y of Health & Hum. Servs.*:

> Dr. Marcel Kinsbourne is board certified in pediatrics. He received his medical degree in England, and he has been licensed to practice medicine in North Carolina since 1967. *Id*. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including

> professorships in pediatrics, neurology, and psychology. *Id*. at 2. His clinical experience includes serving as a senior staff physician in Ontario from 1974–1980, and a clinical associate in neurology at Massachusetts General Hospital from 1981–1991, although (as noted in other cases) many years have passed since he regularly saw patients. *Pope v. Sec'y of Health & Hum. Servs.*, No. 14–078V, 2017 WL 2460503, at 8 (Fed. Cl. Spec. Mstr. May 1, 2017). He has not personally studied the immunologic issues raised by theories claiming vaccine causation and lacks specialization in the field of peripheral neuropathies (although his general neurologic expertise rendered him competent to discuss such matters).

No. 15-1108V, 2018 WL 1125666 at 6 (Fed. Cl. Spec. Mstr. Jan. 12, 2018).

2. Opinion

It is Dr. Kinsborne's opinion that Ms. Moss had pre-existing CIDP, which was significantly aggravated by her influenza vaccination of September 25, 2013. Second Kinsbourne Rep. at 2.

a. *Diagnostic Criteria*

Dr. Kinsbourne claimed that "there is no consensus on the minimal clinical and electrodiagnostic features that justify the diagnosis of CIDP." Second Kinsbourne Rep. at 2. Dr. Kinsbourne stated that at least nine sets of clinical criteria for CIDP have been proposed, most of which were designed to maximize specificity for research purposes, possibly at the expense of sensitivity. *Id*.; C.L. Koski et al., *Derivation and Validation of Diagnostic Criteria for Chronic Inflammatory Demyelinating Polyneuropathy*, 277 J. NEUROL SCI 1-2, 2 (2009) (filed as Ex. U) (hereinafter "Koski"). Koski along with 13 other neurologists derived simple diagnostic criteria in which "a patient with a chronic polyneuropathy with progression for more than eight weeks . . . would be classified as having CIDP if he or she had either a certain pattern of electrophysiologic abnormalities or a distinct clinical presentation." *Id*.

Koski's diagnostic criteria allow "either electrophysiologic or clinical criteria to establish the diagnosis of CIDP" – not both as generally required by previously published criteria. Third Kinsbourne Rep. at 1; Koski at 6. This elective diagnostic option is crucial to Dr. Kinsbourne's opinion as he conceded that the results of Ms. Moss's repeated electrodiagnostic testing did not satisfy the Koski's electrodiagnostic criteria. As such, his analysis of Ms. Moss's condition relied solely on her clinical symptoms:

> A patient with a chronic polyneuropathy with progression for more than eight weeks . . . would be classified as having CIDP if the patient exhibited:
>
> 1. Symmetric onset or symmetric exam, and
> 2. Weakness in all four limbs, and
> 3. At least one limb with proximal weakness

Second Kinsbourne Rep. at 1; Koski at 5.

Dr. Kinsbourne argued that extracts from the medical records "show that these criteria were satisfied by the time Ms. Moss's disorder had sufficiently advanced." Second Kinsbourne Rep. at 1. Although he did not establish the date of onset, Dr. Kinsbourne stated that the onset was symmetric in her legs, followed by proximal and distal weakness in her lower extremities as recorded by Dr. Gudesblatt on January 15, 2015. *Id*. By February 10, 2014, Dr. Kinsbourne noted that Ms. Moss exhibited weakness in all four limbs, reporting that she had diminished strength in both hands and was dropping objects. *Id*. at 2; Ex. 6-7.

In further support of this diagnosis, Dr. Kinsbourne highlighted that Ms. Moss's treating physician, Dr. Marc Allen, diagnosed her with CIDP based on Dr. Gudesblatt's investigation into her condition; that Ms. Moss did respond to IVIG treatment (although she could not tolerate an increased dose);[37] that she had an elevated level of cerebral spinal fluid protein; and serum and CSF oligoclonal bands – both indicative of neuroinflammation. Second Kinsbourne Rep. at 1.

Dr. Kinsbourne explained that CIDP "most frequently starts insidiously and evolves slowly, either in a slowly progressive (more than 60% of patients) or in a relapsing manner (approximately one-third of patients), with partial or complete recovery between recurrences." First Kinsbourne Rep. at 6; R.A. Lewis, *Chronic Inflammatory Demyelinating Polyradiculoneuropathy Clinical Presentation*, MEDSCAPE, https://emedicine.medscape.com/article/1172965-clinical (last updated June 13, 2018) (filed as Ex. 19-F) (hereinafter "Lewis"). Dr. Kinsbourne presumably classified Ms. Moss as having had a relapsing/remitting course of CIDP as he posited that Ms. Moss's CIDP had been active without diagnosis for a lengthy period of time, extending back to at least October 2010, although her neurological impairments were never recorded as increasingly severe, addressed with any treatments, or prompted referral to a neurologist. First Kinsbourne Rep. at 4, 6. Dr. Kinsbourne claimed that the absence of any reference to polyneuropathic symptoms between May 2013 through September 2013 demonstrates that her condition had stabilized and perhaps remitted at the time she received her influenza vaccination on September 25th of that year. *Id*. at 4-5.

b. *Alternative Diagnoses*

Dr. Kinsbourne criticized Dr. Donofrio's use of the unduly restrictive diagnostic criteria designed for research purposes to rule out CIDP as the explanation for Ms. Moss's condition and dismissed Dr. Donofrio's alternative diagnoses as mere comorbidities that are prevalent in old age. Second Kinsbourne Rep. at 2.

B. Respondent's Expert, Dr. Peter Donofrio

Dr. Donofrio offered three expert reports and also testified at hearing. Expert Report, filed on July 27, 2017, as Ex. A ("First Donofrio Rep."); Supplemental Expert Report, filed on October 1, 2018, as Ex. S ("Second Donofrio Rep."); and a Second Supplemental Expert Report, filed on November 26, 2019, as Ex. W ("Third Donofrio Rep.").

[37] Dr. Kinsbourne's second report contradicts his first report in which he stated that Ms. Moss's CIDP was unresponsive to multiple infusions of IVIG. First Kinsbourne Rep. at 5.

1. Qualifications

Dr. Donofrio testified at hearing that he recently retired in June of 2021, and that he is now a professor emeritus at Vanderbilt and no longer sees patients. Tr. at 41. Before his retirement, Dr. Donofrio was a Professor of Neurology at Vanderbilt University Medical Center. He served as the Chief of the Neuromuscular Section and Director of the EMG lab. Some of his other duties included the Directorship of the MDA (Muscular Dystrophy Association) Clinic and the ALS Clinic at Vanderbilt. He is a member of the Medical Advisory Committee of the GBS/CIDP International Foundation; Vanderbilt University Medical Center is a certified Center of Excellence for the GBS/CIDP International Foundation. He is board certified in Neurology, Internal Medicine, EMG and Neuromuscular Disorders.

Dr. Donofrio has experience in evaluating a spectrum of neuropathies such as Guillain-Barré syndrome (GBS) and CIDP and the related condition of Miller Fisher Syndrome (MFS). He testified that he has treated several hundred patients with CIDP. Tr. at 33. He also has experience in caring for patients with multiple sclerosis (MS), ADEM and transverse myelitis. He has published in the areas of GBS, CIDP, and other neuropathies. He has experience reviewing the literature and data on vaccine-related GBS, CIDP, transverse myelitis, MS, and other neurologic conditions. He is the author of the textbook entitled: The Textbook of Peripheral Neuropathy published in April 2012 by Demos Medical. First Donofrio Rep. at 1.

2. Opinion

a. *Diagnostic Criteria*

Dr. Donofrio utilizes the diagnostic criteria developed by the 2010 European Federation of Neurological Societies and Peripheral Nerve Society (EFNS/PNS), which represent a consensus statement on good practices for diagnosing CIDP not aimed at maximizing specificity for research purposes. Second Donofrio Rep. at 2; *European Federation of Neurological Societies/Peripheral Nerve Society Guideline on Management of Chronic Inflammatory Demyelinating Polyradiculoneuropathy. Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society – First Revision*, 15 J. PERIPHER NERV SYST, 1-9 (2010) (filed as Ex. F) (hereinafter "EFNS/PNS"). Dr. Donofrio stated that the EFNS/PNS Consensus Statement is a well-accepted guide for diagnosing and managing CIDP on the grounds that it ensures one is dealing with patients who actually have CIDP, rather than patients who are borderline or do not have a true diagnosis. First Donofrio Rep. at 9. Dr. Donofrio testified that almost everyone he knows uses the EFNS/PNS criteria. Tr. at 18. These criteria were published in 2011. *Id.*

The diagnostic criteria proposed by the Consensus Statement rely upon a combination of electrodiagnostic and laboratory results. EFNS/PNS at 2. The authors of the statement noted that the while the Koski criteria provided the option of diagnosing CIDP when electrodiagnostic criteria were not fulfilled, "all prior criteria sets included electrodiagnostic criteria." Thus, the Consensus Statement was reluctant to adopt the Koski approach. EFNS/PNS at 2. In stark contrast to Koski, the Consensus Statement indicated that "[e]lectrodiagnostic tests are mandatory." EFNS/PNS at 3. The major features of electrodiagnostic criteria suggesting a diagnosis of CIDP are listed in Table

1 of the Statement and are broken down into three categories: definite, probable or possible. *Id*. If electrodiagnostic criteria are not satisfied initially, the Statement encourages repeat testing at a later date. EFNS/PNS at 3.

The Consensus Statement offers Good Practice Points for defining diagnostic criteria for CIDP beginning with a review of the clinical criteria set forth in Table 4; then, if warranted, electrodiagnostic testing, as outlined in Table 2; a review of any supportive criteria set forth in Table 5; and finally a categorization of definite, probable or possible CIDP based on the results of Steps 1-3 as outlined in Table 6. EFNS/PNS at 6.

Table 4. Clinical diagnostic criteria.

(1) Inclusion criteria
  (a) Typical CIDP
    Chronically progressive, stepwise, or recurrent symmetric proximal and distal weakness and sensory dysfunction of all extremities, developing over at least 2 months; cranial nerves may be affected; and
    Absent or reduced tendon reflexes in all extremities
  (b) Atypical CIDP (still considered CIDP but with different features) One of the following, but otherwise as in (a) (tendon reflexes may be normal in unaffected limbs):
    Predominantly distal (distal acquired demyelinating symmetric, DADS) or
    Asymmetric [multifocal acquired demyelinating sensory and motor neuropathy (MADSAM), Lewis-Sumner syndrome] or
    Focal (e.g., involvement of the brachial or lumbosacral plexus or of one or more peripheral nerves in one upper or lower limb)
    Pure motor or
    Pure sensory (including chronic immune sensory polyradiculopathy affecting the central process of the primary sensory neuron)
(2) Exclusion criteria
  Borrelia burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure probably to have caused the neuropathy
  Hereditary demyelinating neuropathy
  Prominent sphincter disturbance
  Diagnosis of multifocal motor neuropathy
  IgM monoclonal gammopathy with high titre antibodies to myelin-associated glycoprotein
  Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, diabetic and non-diabetic lumbosacral radiculoplexus neuropathy. PNS lymphoma and amyloidosis may occasionally have demyelinating features

EFNS/PNS at 6.

Table 5. Supportive criteria.

1. Elevated CSF protein with leukocyte count $<10/mm^3$ (level A recommendation)
2. MRI showing gadolinium enhancement and/or hypertrophy of the cauda equina, lumbosacral or cervical nerve roots, or the brachial or lumbosacral plexuses (level C recommendation)
3. Abnormal sensory electrophysiology in at least one nerve (Good Practice Points):
   a. Normal sural with abnormal median (excluding median neuropathy at the wrist from carpal tunnel syndrome) or radial sensory nerve action potential (SNAP) amplitudes; or
   b. Conduction velocity <80% of lower limit of normal (<70% if SNAP amplitude <80% of lower limit of normal); or
   c. Delayed somatosensory evoked potentials without central nervous system disease
4. Objective clinical improvement following immunomodulatory treatment (level A recommendation)
5. Nerve biopsy showing unequivocal evidence of demyelination and/or remyelination by electron microscopy or teased fibre analysis (Good Practice Points)

EFNS/PNS at 6.

Table 6. Diagnostic categories.

Definite CIDP
Clinical criteria 1 (a or b) and 2 with electrodiagnostic criterion 1; or
Probable CIDP + at least one supportive criterion; or
Possible CIDP + at least two supportive criteria
Probable CIDP
Clinical criteria 1 (a or b) and 2 with electrodiagnostic criterion 2; or
Possible CIDP + at least one supportive criterion
Possible CIDP
Clinical criteria 1 (a or b) and 2 with electrodiagnostic criterion 3
CIDP (definite, probable, possible) associated with concomitant diseases.

EFNS/PNS at 6.

Based on the Consensus Statement, Dr. Donofrio concluded that Ms. Moss did not satisfy the diagnostic criteria for possible, probable, or definite CIDP. First Donofrio Rep. at 9. She did not satisfy the clinical criteria in Table 4 as she did not have symmetrical proximal and distal weakness and sensory dysfunction of all four extremities in the early stages of her illness. *Id*. She did not meet the electrodiagnostic criteria for Table 1 (as conceded by Dr. Kinsbourne), and she did not display any supportive criteria for a diagnosis, namely, she did not improve following three separate courses of IVIG treatment.[38] *Id*.

Although Dr. Kinsbourne and Dr. Gudesblatt stated that Ms. Moss had an elevated cerebrospinal fluid protein, Dr. Donofrio did not find any support in the medical records for that assessment. Second Donofrio Rep. at 1. Dr. Donofrio's review of the April 21st lab results did not find Ms. Moss's CSF total protein level listed on the report. *Id.* However, he stated "that if the albumin levels were normal and the immunoglobin levels were normal, then the spinal fluid protein was not increased above normal." *Id.* at 2. Dr. Donofrio goes on to state that "the presence of two oligoclonal bands[39] in the serum does not support de novo synthesis of the two bands in the spinal fluid, a finding one would expect in GBS or CIDP." *Id.* At hearing, he clarified that the data cannot be used "to either support or refute the diagnosis of CIDP." Tr. at 31. He further highlighted that Ms. Moss's CSF IgG and IgG index CSF were not elevated which should be the case in an inflammatory polyneuropathy. Second Donofrio Rep. at 2.

Dr. Donofrio also concluded that Ms. Moss did not satisfy the Koski criteria for a diagnosis of CIDP, and he doubted the reliability of the Koski criteria once a patient such as Ms. Moss developed superimposed medical and neurologic disorders that can produce similar symptoms of proximal and distal weakness. Second Donofrio Rep. at 1.

[38] The Hospice Inn records indicate that she underwent a fourth round of IVIG treatment as well as Rituxan. treatments. Ex. 16 at 8.

[39] Oligoclonal bands are discrete bands of immunoglobulins with decreased electrophoretic mobility; their appearance in electrophoretograms of cerebrospinal fluid when absent in the serum is a sign of possible multiple sclerosis or other diseases of the central nervous system. https://www.dorlandsonline.com/dorland/definition?id=60106&searchterm=oligoclonal+bands (last visited May 18, 2021).

Regardless of whether one applies the Koski or EFNS/PNS Consensus Statement criteria, it is Dr. Donofrio's opinion that Ms. Moss did not have CIDP. First Donofrio Rep. at 10. Dr. Donofrio presented two alternative etiologies for her condition, and a host of co-morbidities that would reasonably explain the steady decline in her health from 2010 through 2015. Finally, even assuming Ms. Moss did suffer from CIDP, Dr. Donofrio does not believe that her post-vaccination condition was either caused or significantly aggravated by the influenza vaccination. *Id.* at 10-11.

b. *Alternative Diagnoses*

Dr. Kinsbourne criticized Dr. Donofrio for what he deemed to be a "slew of miscellaneous alternative diagnoses which do not have a relationship to vaccination," many of which were mere co-morbidities that are prevalent in old age. Second Kinsbourne Rep. at 2. Dr. Donofrio clarified that he offered only two alternative etiologies for Ms. Moss's polyneuropathy: idiopathic polyneuropathy and statin-induced neuropathy.

Dr. Donofrio is of the opinion that Ms. Moss developed a peripheral neuropathy or polyneuropathy beginning as early as 2010, that was likely complicated by lumbar disc disease that worsened yearly. First Donofrio Rep. at 7. He argued that a strong case can be made for a peripheral neuropathy, especially given that "none of Ms. Moss's healthcare providers mentioned the diagnosis of CIDP prior to her vaccination of September 25, 2013, and none of them tried to link [Ms. Moss's] symptoms to the flu vaccination." *Id*. "It appears," he noted, "that the relationship between the flu vaccination and the patient's symptoms was not considered until after her death. *Id*. at 8.

Dr. Donofrio stated that "more than 100 etiologies exist for peripheral neuropathy including vitamin deficiencies, connective tissue disorders, medications, chemotherapy, diabetes and alcohol abuse." First Donofrio Rep. at 8; Peter D. Donofrio, *Clinical Approach to the Patient with Peripheral Neuropathy,* TEXTBOOK OF PERIPHERAL NEUROPATHY 1-7 (Peter D. Donofrio, MD 1st ed. Demos Medical 2012) (filed as Ex. C) (hereinafter "Textbook of Peripheral Neuropathy"). Approximately 35-40% of patients suffer from idiopathic peripheral neuropathy, which simply means that no definite cause can be found. First Donofrio Rep. at 8.

Of note in this case, Dr. Donofrio highlighted neurotoxic medications such as simvastatin as a known cause of peripheral neuropathy. First Donofrio Rep. at 9. Dr. Donofrio cited to an article in Prescrire International which reports that several cases of peripheral neuropathy have been attributed to a statin (cholesterol-lowering drug), including sensory or sensorimotor polyneuropathy with signs of sensory impairment, and a decrease or sometimes a suppression of osteotendinous reflexes. *Id.*; *Peripheral neuropathy and statins*, 16 PRESCRIRE INT. 92, 247-48 (2007) (filed as Ex. P); *See also* M.B. Jacobs, *HMG-CoA reductase inhibitor therapy and peripheral neuropathy,* 120 ANN INTERN MED 11, 970 (1994). (filed as Ex. L). Some patients also experienced "a marked reduction in muscle strength in the affected limb(s)." *Id*.

Dr. Donofrio cited several studies supporting the theory that long-term exposure to statins may substantially increase the risk of polyneuropathy. First Donofrio Rep. at 10; Jeppesen et al., *Statins and peripheral neuropathy*, 54 EUR J CLIN PHARMACOL 11, 835-38 (1999) (filed as Ex. M); W.V. Brown, *Safety of statins*, 2008 CURR OPIN LIPIDOL. 19, 558-62 (2008) (filed as Ex. Q); 16

PRESCRIRE INT. 92, 247-48 (2007) (filed as Ex. P). Dr. Donofrio's review of the medical records revealed that Ms. Moss regularly took simvastatin from 2010 through 2015. First Donofrio Rep. at 9. Based on his research, Dr. Donofrio concluded that Ms. Moss's nerve conduction studies and EMG were more consistent with simvastatin-induced neuropathy. *Id*.

c. *Co-morbidities*

Dr. Donofrio defended his recitation of Ms. Moss's numerous co-morbidities to explain the worsening of her symptoms. Dr. Donofrio posited that her host of co-morbidities would have placed a heavy toll on an 86-year-old woman and would likewise explain her progressive deterioration of health over the last 15 years of her life. First Donofrio Rep. at 1.

Alternatively, her co-morbidities may have been the cause of some of her symptoms. For example, weakness is a symptom of both Vitamin D deficiency and deconditioning such as Ms. Moss experienced after she broke her left ankle and was prohibited from participating in weight bearing activities. First Donofrio Rep. at 8-9. In connection with her advanced age, the progression of her symptoms does not imply [that Ms. Moss] had CIDP or any other superimposed neuropathy." Second Donofrio Rep. at 1.

V. Legal Standard

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Hum. Servs.,* 35 Fed. Cl. 1, 7 (1996) (quoting H.R. No. 908 at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6287, 6344).

A petitioner bears the burden of establishing his or her entitlement to compensation from the Vaccine Program. The burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). A petitioner may prevail by proving either that (1) the vaccinee suffered an injury listed on the Vaccine Injury Table with onset beginning within a corresponding time period following receipt of a corresponding vaccine (a "Table Injury"), for which causation is presumed or that (2) the vaccinee suffered an injury that was actually caused by a vaccine. Under either method, however, the petitioner must also show that the vaccinee "suffered the residual effects or complications of the illness, disability, injury, or condition for more than six months after the administration of the vaccine." Section 11(c)(1)(D)(i).

In the present case, Petitioner does not allege a Table injury, thus, she bears the burden of establishing actual causation. Furthermore, Petitioner alleges that Ms. Moss suffered an off-table significant aggravation of a pre-existing CIDP as a result of receiving the influenza vaccination on September 25, 2013. Pet. at 1.

The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). In *Loving*, the United States Court of Federal

Claims established the governing six-part test for off-Table significant aggravations. Petitioner must prove by a preponderance of the evidence:

> (1) The person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving v. Sec'y of Health & Hum. Servs., 86 Fed. Cl. 135, 144 (2009); *see also W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (adopting this as the proper legal standard for significant aggravation claims brought under the Vaccine Act). *Loving* prongs four, five, and six are derived from the Federal Circuit's test for off-Table actual causation cases. *Althen v. Sec'y of Health & Hum. Servs.*, 17 F.3d 374 (Fed. Cir. 1994).

In *Sharpe,* the Federal Circuit clarified the *Loving* prongs and what is required by petitioners to successfully demonstrate a causation-in-fact significant aggravation claim. *Sharpe v. Sec'y of Health & Hum. Servs.,* 2020 WL 3564251, 964 F.3d 1072 (Fed. Cir. 2020). *Loving* prong three only requires a comparison of a petitioner's current, post-vaccination condition with her pre-existing pre-vaccination condition. *Sharpe* at 1082; *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099 (Fed. Cir. 1996). A petitioner is not required to demonstrate an expected outcome or that her post-vaccination condition was worse than such an expected outcome. *Sharpe* at 5.

Under *Loving* prong four, a petitioner need only provide a "medical theory causally connecting [petitioner's] significantly worsened condition to the vaccination." *Sharpe* at 7; *see also Loving*, 86 Fed. Cl. at 144. In other words, petitioner is required to present a medically reliable theory demonstrating that a vaccine "can cause a significant worsening" of the condition. *Sharpe* at 7 (citing to *Pafford ex. rel. Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1356-57 (Fed. Cir. 2006). A petitioner may be able to establish a prima facie case under *Loving* prong four without eliminating a pre-existing condition as the cause of her significantly aggravated injury. *Id.*; citing *Walther v. Sec'y of Health & Hum. Servs.*, 485 F. 3d 1146, 1151 (Fed. Cir. 2007) (noting that "the government bears the burden of establishing alterative causation. . . . once petitioner has established a prima facie case").

Loving prong five requires a petitioner to show "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." *Loving*, 86 Fed. Cl. at 144. In other words, petitioner must show that the vaccinations "did" cause a worsening of [petitioner's underlying disorder]. *Id.*

In determining whether a petitioner is entitled to compensation, a special master must consider the entire record and is not bound by any particular piece of evidence. § 13(b)(1) (stating that a special master is not bound by any "diagnosis, conclusion, judgment, test result, report, or

summary" contained in the record). Furthermore, a petitioner is not required to present medical literature or epidemiological evidence to establish any *Althen* prong. The special master essentially must weigh and evaluate opposing evidence in deciding whether a petitioner has met their burden of proof. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009); *see also Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95). In Vaccine Program cases, these factors are used in the weighing of the scientific evidence actually proffered and heard. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. *See, e.g.*, *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009).

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

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

VI. Analysis

A. CIDP Generally

CIDP is a neurological disorder that involves an autoimmune response against peripheral nerve myelin. Brostoff et al., *Post-influenza vaccine chronic inflammatory demyelinating polyneuropathy*, 37 AGE AGEING 3, 229-30 (2008) (filed as Ex. I) (hereinafter "Brostoff"). It is "an acquired autoimmune peripheral symmetrical neuropathy, characterized by histologic and electrodiagnostic findings consistent with demyelination and occasional remyelination." Sanz et al., *Chronic inflammatory demyelinating polyradiculoneuropathy in a patient with systemic lupus erythematosus and good outcome with rituximab treatment*, 32 RHEUMATOL INT 12, 4061-63 (2012) (filed as Ex. H) (hereinafter "Sanz"). Brostoff further describes CIDP as "characterized by motor or sensory dysfunction in more than one limb for more than 2 months with hyporeflexia and characteristic CSF and electrodiagnostic test results." Brostoff at 229. Proximate more than distal weakness is commonly observed. Donofrio, *Clinical Approach to the Patient with Peripheral Neuropathy*, Textbook of Peripheral Neuropathy, Demos Medical 2012, Chapter 1 at 4 (filed as Exhibit C). Some patients experience a disease that is slowly progressive while others have a relapsing-remitting course. Lewis at 1. "Most experts consider the necessary duration of symptoms to be greater than 8 weeks for the diagnosis of CIDP to be made." *Id.*

B. Petitioner has not Presented Preponderant Evidence that Ms. Moss Suffered from CIDP Prior to her Influenza Vaccination

The Petition alleges that Ms. Moss suffered a significant aggravation of her CIDP after receiving an influenza vaccine on September 25, 2013. Pet. at 1. Respondent argues that Ms. Moss likely suffered from peripheral neuropathy or polyneuropathy that was aggravated by a host of co-morbidities and her advanced age, and that there was no causal relationship between the vaccination of September 25, 2013 and Ms. Moss's medical condition. First Donofrio Rep. at 10-11.

At the outset, I note that no diagnosis of CIDP exists in the medical records until May 13, 2014, more than seven months after Ms. Moss's influenza vaccination. Ex. 8 at 66. Thus, one key issue to be addressed is whether Ms. Moss's medical history supports a finding that she suffered from CIDP prior to vaccination. For the reasons discussed below, I find that the evidence does not preponderantly establish that Ms. Moss suffered from CIDP prior to the receipt of the influenza vaccine.

1. Expert Witness Persuasiveness

If a petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. *See Broekelschen*, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."). In this case, both experts are neurologists and are qualified to offer an opinion. Dr. Donofrio, however, has clinical experience that is significantly more up-to-date and more directly relevant to the issues in this case than Dr. Kinsbourne. Dr. Donofrio's background

in studying and writing about disorders of the peripheral nervous system, including GBS and CIDP, make him a better fit to opine on the issues of Ms. Moss's condition. He has published extensively in his field, to include several articles that specifically concern the diagnosis and treatment of CIDP. Donofrio CV at 13-20. He is the author of a textbook on peripheral neuropathy. *Id.* at 21. In addition to being board certified in neurology, Dr. Donofrio is also board certified in electrodiagnostic medicine and neuromuscular medicine. *Id.* at 2. Dr. Donofrio recently retired from clinical practice in June of 2021. Tr. at 41. Before that time, he treated several hundred patients with CIDP. *Id.* at 33.

Dr. Kinsbourne, on the other hand, is a pediatric neurologist who does not specialize in peripheral neuropathies, and who has not seen patients in approximately 30 years. In *Ellis*, the special master discussed this issue, noting that "[t]he concerns about Dr. Kinsbourne's lack of current practice … are neither novel nor, according to appellate authorities, arbitrary." *Ellis v. Sec'y of Health & Hum. Servs.*, No. 13-336V, 2018 WL 4846547, at *25 (Fed. Cl. Spec. Mstr. Sept. 6, 2018). The special master in *Ellis* cited to a decision from more than 20 years ago where a different special master explained that she could not rely upon Dr. Kinsbourne because, in part, he "has had no clinical experience in ten years." *Flanagan v. Sec'y of Health & Hum. Servs.*, No. 90-1126V, 2000 WL 1207256, at *13 (Fed. Cl. Spec. Mstr. Aug. 4, 2000), *mot. for rev. denied*, 48 Fed. Cl. 169, 173-74 (2000), *aff'd sub nom. Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1338-39 (Fed. Cir. 2001). Dr. Kinsbourne has never diagnosed a patient with CIDP pursuant to the Koski criteria because these criteria were proposed in 2009, after he stopped seeing patients. Tr. at 15. Throughout my analysis of this case, I have found that Dr. Donofrio was more persuasive in diagnosing CIDP and in interpreting the contemporaneous medical records both before and after Ms. Moss's vaccination.

2. EMG/NCS Testing does not Support a Diagnosis of CIDP

"Electromyography (EMG) is a critical test to determine whether the disorder is truly a peripheral neuropathy and whether the neuropathy is demyelinating." Richard A. Lewis, MD, *Chronic Inflammatory Demyelinating Polyneuropathy*, MEDSCAPE at 2, https://emedicine.medscape.com/ article/1172965-overview (2018) (filed as Ex. 19) (hereinafter "Lewis"). Dr. Donofrio noted that "[p]atients with CIDP have characteristic nerve conduction study abnormalities consistent with multifocal demyelination." First Donofrio Rep. at 8. Dr. Donofrio is board certified in electrodiagnostic medicine and neuromuscular medicine and thus is especially well qualified to discuss and interpret Ms. Moss's EMG testing. Dr. Donofrio testified during the hearing that Ms. Moss's EMG/NCS studies did not support a diagnosis of CIDP.

Dr. Donofrio briefly discussed the first EMG from November 18, 2013. He noted that this study showed evidence of a lumbar radiculopathy. Tr. at 22. He also testified that the raw data from this study supported a peripheral neuropathy, but did not support CIDP. *Id.* Specifically, he noted that Ms. Moss's absent peroneal and tibial motor responses, absent F waves, and reduced sural sensory responses are consistent with an axonal neuropathy but are "unlikely to be a demyelinating neuropathy." *Id.* at 24. Furthermore, the needle exam in this study was normal. This finding "would not be expected in someone with any type of neuropathy, including CIDP." *Id.*

Ms. Moss's EMG of the upper extremities performed in November of 2013 indicated bilateral moderate to severe median neuropathy at the wrist and cervical radiculopathy. Ex. 4 at 64. Dr. McMonigle assessed Petitioner with carpal tunnel syndrome. *Id.* at 8. This assessment was reiterated by Dr. Ellstein. *Id.* at 53. Dr. Donofrio also opined that "The symptoms of numbness and weakness in the hands and painful wrists are easily explained by carpal tunnel syndrome, diagnosed by Dr. Ellstein." First Donofrio Rep. at 10. I find the collective opinions of Drs. McMonigle, Ellstein, Donofrio to be persuasive that Ms. Moss experienced numbness and weakness in her hands and wrists as a result of carpal tunnel syndrome.

The findings from Ms. Moss's February 12, 2014 EMG/Nerve Conduction Testing were consistent with severe axonal sensorimotor polyneuropathy of the lower extremities with marked active and chronic denervation changes. Ex. 8 at 16. The findings were also consistent with moderate to severe bilateral L3-L4 lumbar radiculopathies with both active and chronic degenerative changes. *Id.* Dr. Donofrio testified about these results, noting that the testing did not demonstrate a demyelinating neuropathy, which "would definitely be against CIDP." Tr. at 23.

Dr. Donofrio conducted an extensive analysis of the raw data from Ms. Moss's final EMG, performed on February 19, 2014. *See* Ex. 8 at 22-24; Tr. at 24-29. The electromyographer's impression was "There is electrophysiologic evidence for predominantly motor neuropathy which is asymmetric and multifocal and has mixed axonal and demyelinating features." Ex. 8 at 20. Dr. Donofrio disagreed with this interpretation and noted that he has performed nerve conduction studies for 45 years and based on this experience, he "not only look[s] through the report, but [he] go[es] through every piece of raw data [him]self." Tr. at 22. He opined that "[t]here was absolutely no evidence for demyelination, little, if any, evidence for axon loss, maybe in the right median sensory nerve, as well as a tiny bit of spontaneous activity on needle exam." *Id.* at 30. He testified that he did not understand how the electromyographer came to the conclusion that the study showed demyelinating features. *Id.*

Dr. Donofrio opined that in a case of CIDP, he would expect that the testing would show:

> prolonged distal latencies, flowing of conduction velocity, prolonged or absent F wave latencies, and spontaneous activity on needle examination. If you use the EFNS criteria, you have to have a certain degree of slowing of conduction velocity and a certain degree of increased distal latency to make the diagnosis of CIDP. And this study, which was the fifth study and the last study done in this patient, doesn't even come close to making the cut. In fact, this lady had a remarkably good-looking study.

Id. at 30.

After providing his detailed analysis of the raw data, Dr. Donofrio testified that "these are remarkably good looking, almost normal studies, and this was the last EMG done on a patient with presumed CIDP. Really, it would be untenable to make the diagnosis based upon this data." Tr. at 29. Dr. Kinsbourne testified that he did not review the raw data from any of Ms. Moss's EMGs. *Id.* at 16. Further, he did not comment on Dr. Donofrio's extensive testimony concerning the raw data. I find that Ms. Moss's final EMG suggests that she did not have CIDP. In arriving at this

conclusion, I have determined that Dr. Donofrio's testimony was more persuasive than the opinion of the electromyographer who performed Ms. Moss's final study as well as the opinion of Dr. Kinsbourne.

3. Ms. Moss did not Respond to IVIG

According to Lewis, close to 90% of patients with CIDP respond to initial immunosuppressive therapy. Lewis at 14. In this case, Ms. Moss received three courses of IVIG and did not improve after this treatment.[40] In fact, her clinical course worsened. This is evidenced by Dr. Gudesblatt's notes in Ms. Moss's medical records. On May 13, 2014, Dr. Gudesblatt wrote that "she has not had clear improvement or stabilization with 2 months of IVIG." Ex. 8 at 66. On August 12, 2014, he noted that Ms. Moss "has been treated with IVIG and despite adjustment of dose after not tolerating increasing dosage she has had progressive disability." *Id.* at 74. Dr. Gudesblatt also documented "progressive neuropathy despite IVIg with increasing disability." *Id.* at 79.

Dr. Donofrio opined that this medical record evidence clearly documented that Ms. Moss did not respond to IVIG. First Donofrio Rep. at 2; Second Donofrio Rep. at 1; Third Donofrio Rep. at 3; Tr. at 35. Dr. Kinsbourne also acknowledged that Ms. Moss did not improve after IVIG treatment. Tr. at 9. The EFNS criteria note the importance of a positive response to IVIG in their supportive criteria, which lists "[o]bjective clinical improvement following immunomodulatory treatment" as one factor that supports a diagnosis of CIDP. EFNS/PNS at 6. The fact that Ms. Moss did not respond to IVIG is additional evidence that she did not have CIDP.

4. There is not Preponderant Evidence that Ms. Moss had Elevated CSF Protein Levels

Lewis et al. noted that elevated protein levels in the cerebrospinal fluid are seen in 80% of patients with CIDP. Lewis at 2. Dr. Donofrio testified that approximately 90% of patients with CIDP have an elevated spinal fluid protein. Tr. at 50.

On May 13, 2014, Dr. Gudesblatt noted in Ms. Moss's medical record that "spinal fluid demonstrates elevated protein". Ex. 8 at 66. However, there is no record that Ms. Moss's spinal fluid did in fact have elevated protein. A lumbar puncture was performed on April 8, 2014. *See id.* at 46. The spinal fluid revealed two white blood cells, no red cells, and a normal albumin and total IgG. *Id.* Nowhere in these test results did it indicate that Ms. Moss had elevated protein. Further, Dr. Donofrio opined that the spinal fluid protein is primarily composed of the albumin and immunoglobulin levels. Tr. at 32. Because these levels were normal, Dr. Donofrio testified that even though total protein was not reported, these normal levels suggest that Ms. Moss's total protein levels were also normal. *Id.*

[40] I have considered the Hospice Inn record, which notes that Ms. Moss "was given Rituxan treatments and IVIG for CIDP a few weeks ago which did help her symptoms at first[,] however it was short lived." Ex. 16 at 8. This note is not supported by medical record evidence.

Dr. Kinsbourne agreed that he "didn't see any elevated levels for those substances" but opined that CIDP has "enormous variability" and that the levels may have been normal "because the tests were done in a rather late stage of the disease." Tr. at 11. Ultimately, he concluded that he did not "think one can conclude anything positive or negative from the absence of those particular markers." *Id.*

I find there is preponderant evidence that Ms. Moss's CSF protein levels were not elevated. Although Dr. Gudesblatt stated that they were, his note in the medical records is belied by the CSF testing itself. Elevated protein is observed in 80-90% of patients with CIDP and Ms. Moss did not have elevated protein. This fact also suggests that Ms. Moss did not have CIDP.

5. Ms. Moss had Other Features of her Illness that are Unusual in Patients with CIDP

The medical records document that Ms. Moss had mild slurring of her speech, a low voice, and dysphagia (difficulty swallowing) which Dr. Donofrio opined are not consistent with CIDP. Tr. at 20; First Donofrio Rep. at 10. Dr. Steig also noted that Ms. Moss's slurred speech was a separate concern from her issues with her lower extremities. Ex. 4 at 38. Dr. Steig recommended that she stop taking Diovan to improve her throat symptoms and to stop taking Oxycodone and Ambien to improve her slurred speech. *Id.* at 36.

Dr. Kinsbourne disputed this position, noting that CIDP and GBS are closely related diseases and that there are variants of GBS that cause dysphagia. Tr. at 12. Specifically, Dr. Kinsbourne testified that

> Now, there are variants of GBS which, in fact … have dysphagia as one component of the disability, and also a problem with the hypoglossal nerve causing slurred speech, which she also complained of. So there's a thing called the Miller-Fisher variant, which has that, and the pharyngeal variant, which has a weakness of the pharynx, which is pertinent to swallowing and dysphagia.

Id. Dr. Kinsbourne further noted that "these features can rarely also occur in CIDP." *Id.* In support of his position, Dr. Kinsbourne filed a case report authored by Teramoto. *See* Teramoto et al., *Relapse with Dysphagia in a Case of Chronic Inflammatory Demyelinating Polyradiculoneuropathy*, 54 INTERN MED 1791-93 (2015) (filed as Ex. 22) (hereinafter "Teramoto"). Teramoto described the case of a 69 year-old woman who met the EFNS/PNS criteria for definitive CIDP who also developed slight dysphagia. The patient in this case report did not have difficulty with speech or voice and did respond to treatment with IVIG.[41] Teramoto at 1792. Teramoto noted that "CIDP with involvement of [cranial nerves] IX and/or X is infrequent, with clinical features reported in three cases." *Id.*

[41] Of note, the Teramoto case report indicated that IVIG is an effective treatment for CIDP with dysphagia. The fact that Ms. Moss's condition (to include her dysphagia) worsened after IVIG treatment further suggests that she did not have CIDP.

While Dr. Kinsbourne's testimony coupled with the Teramoto case report do suggest that CIDP can include dysphagia, both note this finding is infrequent. Dr. Donofrio testified that in his 45 years of practice, he has never seen dysphagia, dysarthria (slurring of speech), or hypophonia (reduction in the volume of voice) occur in a case of CIDP. Tr. at 33. The fact that Ms. Moss experienced dysphagia, dysarthria, and hypophonia suggest that these signs were not caused by CIDP, but instead were the result of a different condition.

6. Diagnostic Criteria: EFNS/PNS

Dr. Donofrio testified that the EFNS/PNS are the appropriate diagnostic criteria to diagnose CIDP because these criteria "are meant to eliminate people who don't have CIDP and to include people who have CIDP." Tr. at 18. In fact, Respondent filed a research paper which studied the different criteria used in diagnosing CIDP. *See* Rajabally et al., *Validity of diagnostic criteria for chronic inflammatory demyelinating polyneuropathy: a multicentre European study*, 80 J NEUROL NEUROSURG PSYCHIATRY 1364-68 (2009) (filed as Ex. Y) (hereinafter "Rajabally"). Rajabally found that the Koski criteria had a sensitivity of 63% and a specificity of 99.3%, while the EFNS/PNS criteria had a sensitivity of 81.3% and a specificity of 96.2%. Rajabally at 1364. This means that the Koski criteria correctly identified 63% of CIDP patients while the EFNS/PNS criteria correctly identified 81.3%. Rajabally concluded "the EFNS/PNS criteria were the most sensitive and allowed identification of a [] significantly greater number of patients than Koski et. al.'s criteria." *Id.* I have credited Dr. Donofrio's testimony that the EFNS/PNS criteria are the criteria more appropriately used to diagnose CIDP than the Koski criteria.

Dr. Donofrio testified that "One of the major criteria in the EFNS PNS are the results of the nerve conduction studies." Tr. at 18. Dr. Donofrio concluded that Ms. Moss did not satisfy the diagnostic criteria for possible, probable, or definite CIDP. First Donofrio Rep. at 9. She did not satisfy the clinical criteria in Table 4 as she did not have symmetrical proximal and distal weakness and sensory dysfunction of all four extremities in the early stages of her illness. *Id*. She did not meet the electrodiagnostic criteria for Table 1, and she did not display any supportive criteria for a diagnosis, namely, she did not improve following three separate courses of IVIG treatment. *Id*.

Dr. Kinsbourne agreed that Petitioner did not meet the EFNS/PNS criteria. *See* Third Kinsbourne Rep. at 1 (noting that Ms. Moss's electrodiagnostic testing results were "not quantifiable according to CIDP electrodiagnostic criteria."). He further stated that "physicians would always, if they can, use conduction studies". Tr. at 10. He argued that because Ms. Moss was "near death" and that her case of CIDP was so far advanced, her conduction studies were not useful in rendering a diagnosis. *Id.* at 9-10. In advancing this position, Dr. Kinsbourne described the EMG NCS results as "really horrifying" noting that several of the nerves that were tested did not conduct at all. *Id.* at 9. This, in turn, according to Dr. Kinsbourne, made the electrodiagnostic criteria impractical. *Id.*

Although Dr. Kinsbourne did not specify which EMG he was referencing, Dr. Donofrio assumed it was the test from November 18, 2013. This test revealed that Ms. Moss's peroneal and tibial nerves were not recordable. Ex. 4 at 68. However, Ms. Moss's treating physician, Dr. McMonigle indicated that her impression of Ms. Moss's abnormal study was "lumbar radiculopathy." *Id.* at 62. This assessment was also endorsed by Dr. Stieg, one of Ms. Moss's

treating neurologists. Ex. 4 at 37. Further, Dr. Donofrio agreed that these findings could be seen in a lumbar radiculopathy. Tr. at 40. I do not find Dr. Kinsbourne's position advocating against the use of the EFNS/PNS criteria in this case to be persuasive. The November 2013 EMG indicated that Ms. Moss had a lumbar radiculopathy, not that she was so far advanced in her purported CIDP that such testing would be unfruitful.

Although I find the EFNS/PNS criteria are the appropriate criteria to diagnose CIDP, and that Petitioner has not presented preponderant evidence that Ms. Moss met these criteria, I will also assess whether there is preponderant evidence that Ms. Moss met the Koski criteria.

7. Koski Criteria

Dr. Kinsbourne testified at hearing that Ms. Moss did not meet the Koski criteria prior to her vaccination. Tr. at 6. He stated that Ms. Moss's CIDP had been ongoing for several years, and that this progression is typical for CIDP. *Id.* at 7. In his opinion, the vaccination caused her slowly progressing CIDP to dramatically worsen and caused her to develop symptoms which met the Koski criteria several months *after* her receipt of the flu vaccine. *Id.* at 6-7.

a. *Symmetric Onset*

With respect to the first criterion, symmetric onset, Dr. Kinsbourne claims that the onset of Ms. Moss's symptoms was symmetric in her legs. Second Kinsbourne Rep. at 1. Ms. Moss first complained of numbness in both of her feet in June of 2012. Ex. 15 at 123. The medical records evidence that her symptoms satisfied the first Koski criterion.

b. *Weakness in all Four Limbs*

The second Koski criterion requires weakness in all four limbs. Koski at 5. There is no evidence of weakness in Ms. Moss's upper extremities prior to her vaccination. In fact, at the time she was discharged from Huntington Hills in September of 2013, she was able to perform two sets of 10 wheelchair push-ups in physical therapy. Ex. 12 at 576. Even on January 15, 2014 (nearly four months after vaccination), the medical record indicates "She is not reporting arm weakness and is able to self-propel the wheelchair." Ex. 4 at 44. According to Dr. Donofrio, the fact that Ms. Moss showed good strength in her upper extremities during this visit "in and of itself, would eliminate the Koski criteria because you have to have weakness in all four limbs." Tr. at 20. Although Ms. Moss does report hand weakness that began "lately" during an October 23, 2013 appointment (Ex. 4 at 20), her treating physicians have attributed this pain and weakness to carpal tunnel syndrome.

Dr. Donofrio testified persuasively that Ms. Moss did not meet this second criterion because her symptoms can be better explained by another condition. In this case, Ms. Moss had symptoms in her hands that were better explained by CTS. Further, she had a prior history of neck and lower back problems that, according to Dr. Donofrio, better explain her upper extremity weakness, which Ms. Moss reported on February 10, 2014. *See* Ex. 6 at 4. For these reasons, the evidence does not preponderantly establish that Ms. Moss met the second Koski criterion.

c. *At Least One Limb with Proximal Weakness*

The third Koski criterion requires that at least one limb have proximal weakness. Koski at 5. Dr. Kinsbourne cited medical records from March 4, 2014 to support this criterion. These record note Petitioner's hip flexion as 3+/5. Ex. 8 at 29. Ms. Moss did experience proximal weakness at this appointment, more than five months after vaccination and approximately four years after her purported CIDP began, and accordingly met this criterion. During his testimony, Dr. Donofrio noted the importance of using common sense when applying the Koski criteria, to include this criterion. He testified, "[I]f there's another or better explanation for proximal weakness, such as pathology in the neck and lower back, that would trump the use of the Koski criteria." Tr. at 36.

More significant than the application of the Koski criteria to various complaints contained in Petitioner's medical records over the course of several years is the fact that Petitioner's overall clinical picture is not consistent with a CIDP diagnosis. Dr. Donofrio opined:

> The other thing that is really implied in the Koski criteria is you … shouldn't use it if the patient's had five EMGs and none of them have shown evidence for demyelination. So in other words, you can't make the diagnosis of CIDP based upon the clinical findings when everything else points away from the diagnosis.

Tr. at 37. I have evaluated the evidence presented concerning Petitioner's diagnosis. Ultimately, I find Dr. Donofrio persuasively opined that Ms. Moss did not have CIDP prior to her vaccination.

8. Treating Physicians

In weighing evidence, special masters are expected to consider the views of treating doctors. *Cappizano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Prior to vaccination, none of Ms. Moss's treating physicians had diagnosed her with CIDP. Her problems with her legs were attributed to lumbar stenosis, lumbar radiculopathy, degenerative sacral and facet joint disease, lymphedema, venous insufficiency, vertiginous syndrome, vascular disease, claudication, neuropathy, and myopathy. She had a pre-existing neuropathy, which was attributed to lumbar radiculopathy. Dr. Rebello noted that Ms. Moss's symptoms were related to spinal, cardiac and venous etiologies. Dr. Rebello's assessments are particularly persuasive in this case, as he had been Petitioner's treating physician since as early as 2010 and had direct interaction with Ms. Moss an average of once per month for a period of at least three years prior to vaccination.

More than five months after vaccination, on March 4, 2014, Dr. Gudesblatt diagnosed Ms. Moss with both CIDP and polyneuropathy.[42] Ex. 8 at 30. He repeated that diagnosis on May 13,

[42] Dr. Donofrio testified about these diagnoses, noting that he was confused and surprised that Dr. Gudesblatt would diagnose both polyneuropathy and CIDP. Tr. at 48.

2014. Ex. 8 at 66. Although Dr. Gudesblatt noted that Petitioner had elevated spinal fluid protein, this test does not appear in Petitioner's medical records.

In Dr. Donofrio's review of the record he did not find Ms. Moss's CSF total protein listed in her lumbar puncture results. Second Donofrio Rep. at 1. However, he interpreted these results as normal based on her normal albumin and immunoglobulin levels. *See* Ex. 8 at 46; Second Donofrio Rep. at 1. Because approximately 90-95% of patients with CIDP have an elevated spinal fluid protein, that fact that Ms. Moss's levels were normal suggests that she did not have the condition. First Donofrio Rep. at 8.

In addition, Dr. Donofrio opined that two oligoclonal bands in the CSF and in the corresponding serum does not support a diagnosis of CIDP (stating that "the presence of two oligoclonal bands in the serum does not support de novo synthesis of the two oligoclonal bands in the spinal fluid, a finding one would expect in GBS or CIDP.") Second Donofrio Rep. at 1-2.

Other than the lumbar puncture results, Dr. Gudesblatt did not articulate how Ms. Moss satisfied either the Koski criteria or the EFNS/PNS criteria. Dr. Kinsbourne has conceded that "Ms. Moss had repeated electrodiagnostic testing, revealing multiple severe abnormalities, but with many responses absent, and therefore not quantifiable according to the CIDP electrodiagnostic criteria." Third Kinsbourne Rep. at 1.

Finally, Dr. Gudesblatt's diagnosis is called into question by Ms. Moss's lack of response to IVIG treatments. Dr. Donofrio reported that most CIDP patients commonly improve after the first or second infusion of IVIG. First Donofrio Rep. at 9. Ms. Moss underwent four treatments of IVIG, yet her condition showed no improvement, as recorded in Dr. Gudesblatt's own contemporaneous notes. An adverse reaction during the third course of treatment resulted in a trip to the emergency room and a recommendation by the attending physician that she not undergo plasmapheresis. Ex. 17 at 97. As such, there is no persuasive evidence that Ms. Moss exhibited objective clinical improvement following immunomodulatory treatment. *See* First Donofrio Rep. at 9; ENF/PNS Table 6.

Ultimately, I have considered Dr. Gudesblatt's CIDP diagnosis in arriving at my determination that there is not preponderant evidence that Ms. Moss had CIDP prior to her vaccination. For the reasons articulated in this decision, I am not persuaded by the opinions of Dr. Gudesblatt and Dr. Kinsbourne, and instead have credited the opinions of Ms. Moss's other treating physicians and Dr. Donofrio.

9. Ms. Moss's Death Certificate

Petitioner claims that Ms. Moss ultimately died as a result of the influenza vaccine significantly aggravating her pre-existing CIDP. Pet. at 4. On January 3, 2015, Ms. Moss was rushed to the Emergency Department at North Shore Long Island Jewish Health System in respiratory distress after choking on her food at dinner. Ex. 16 at 46. Upon arrival, she was hypoxic and hypotensive and placed on BIPAP. *Id*. She was admitted to the ICU and started on IV antibiotics. *Id*. Her condition appears to have stabilized as she was alert and awake for several consultations on January 4, 2015. *See* Ex. 16 at 65-93.

An assessment by one of the treating physicians in the ER noted that Ms. Moss had CIDP which led to dysphasia. Ex. 16 at 65-66. After a bedside swallow assessment, Ms. Moss was diagnosed with severe oropharyngeal phase dysphagia and ordered nothing by mouth. *Id.* at 84. While in the ICU she developed aspiration pneumonia, and a Certificate of Terminal Illness was issued on January 6, 2015. *Id.* at 138. Ms. Moss was transferred to Hospice Inn where she went into cardiac arrest and passed away on January 8, 2015. *Id.* at 30-31. Her death certificate lists Cardiopulmonary Arrest as the immediate cause of death due to or as a consequence of CIDP. Ex. 1.

I first note that both the North Shore Long Island records and the Hospice Inn records state that Ms. Moss's family reported to her caregivers that CIDP had caused Ms. Moss to develop bilateral weakness of upper and lower extremities, dysphagia, and dysarthria. Ex. 16 at 137. There does not appear to have been an independent assessment of Ms. Moss's CIDP diagnosis. Having found that Ms. Moss did not suffer from CIDP, the issue of whether CIDP caused her to develop dysphasia is moot. However, I further note that Ms. Moss complained of dysphasia prior to her vaccination, and that scant evidence has been presented to show that CIDP is a known cause of dysphasia.

I also note that Petitioner has not presented evidence that CIDP is a cause of cardiac disease. Dr. Donofrio opined that CIDP does not cause cardiac disease. First Donofrio Rep. at 10. He specifically testified that "CIDP is an inflammatory peripheral neuropathy. It doesn't affect the heart at all." Tr. at 33. Dr. Kinsbourne generally agreed. *See id.* at 12-13. Dr. Donofrio also pointed out that Ms. Moss was an 86 year-old woman, and that she "probably had a heart attack." *Id.* at 34. In fact, Ms. Moss had a history of coronary artery disease and congestive heart failure. She suffered a prior myocardial infarction in June of 2013. Ex. 17 at 147. Based on the above, I find that Petitioner has not presented preponderant evidence that CIDP causes cardiopulmonary arrest. Accordingly, while I have considered Ms. Moss's death certificate in arriving at my conclusions in this case, I do not find it persuasive in connecting her death to her purported CIDP.

For all these reasons, I find that Petitioner has not established, by a preponderance of the evidence, that Ms. Moss had CIDP prior to September 25, 2013. Although this finding means that Petitioner cannot prevail in her case, I will briefly analyze the *Loving* prongs. *Broekelschen*, 618 F.3d at 1349.

C. *Loving* Prong One: Ms. Moss's Condition Prior to the September 25, 2013 Vaccination

Prior to her influenza vaccination, Ms. Moss had been diagnosed with restless leg syndrome, neuropathy, gastroesophageal reflux, polymyalgia rheumatica, hyperlipidemia, fibromyalgia, cervical spinal stenosis, hypertension. myopathy, hypertension ("HTN"), gastroesophageal reflux disease ("GERD"), spinal stenosis, and osteopenia, vertigo, severe lumbar stenosis at L2-L3 and L3-L4 with right lumbar radiculopathy, foraminal encroachment at multiple levels as a result of bulging discs, facet degenerative changes, venous insufficiency lymphedema vertiginous syndrome peripheral vascular disease, coronary artery disease, congestive heart failure ("CHF"), COPD, depression, myalgia, osteoarthritis, high cholesterol, combined systolic and

diastolic acute or chronic heart failure, acute chronic bronchitis, and acute non-ST elevation myocardial infarction. Ex. 15 at 1, 2, 10, 53, 72, 84, 85, 126, 129, 244, 250, 272; Ex 17 at 146-47. Neither Dr. Kinsbourne nor Dr. Donofrio disputed the accuracy of any particular pre-vaccination diagnosis.

Ms. Moss complained to Dr. Rebello, Dr. Stein, and Dr. Eskenazi of dizziness, gait disturbance, headaches, incoordination, loss of balance, numbness in her feet and toes, and dysphasia prior to her vaccination. With respect to her lower extremities, Ms. Moss regularly complained of pain in her low back, hips and right leg which her treating physicians attributed to lumbar and cervical stenosis and possible nerve root inflammation following her unsuccessful lumbar laminectomy in October of 2011. Her degenerative disc and joint disease are well documented by a CAT scan performed in 2011; MRIs performed on November 17, 2011, January 3, 2012, July 26, 2012, and August 17, 2012; as well as a whole-body bone scan February 27, 2012.

Ms. Moss's problems with her lower extremities were complicated by symptoms of edema and/or vascular issues, and the contemporaneous medical records consistently note swelling in her lower legs and feet and treatment with compression stockings, low salt diet, calf exercises and limb elevation. The medical records from 2010 note neuropathy and severe loss of balance. When she began to experience numbness and tingling in her feet in June of 2012, Dr. Rebelllo assessed her with neuropathy. Subsequently, Ms. Moss suffered three falls, the last of which resulted in a serious compound ankle fracture, and while she was in rehab she developed dropfoot on her right side. Thus, by the time she visited Dr. Allen on September 25, 2013, she was already having significant issues with her lower limbs and presented for this appointment in a wheelchair.

Dr. Donofrio is of the opinion that Ms. Moss developed a peripheral neuropathy or polyneuropathy (which has more than 100 etiologies) as early as 2010 that worsened yearly. First Donofrio Rep. at 7-8. Given that her clinical symptoms did not meet the criteria for CIDP, I find Dr. Donofrio's opinion to be persuasive.

D. *Loving* Prong Two: Ms. Moss's Condition after the September 25, 2013 Vaccination

After vaccination, Ms. Moss complained of the same issues of feeling unbalanced and experiencing numbness in her legs, now further complicated be her left ankle fracture and right footdrop. She personally placed the onset of her problems well before vaccination; in 2010, she had severe loss of balance; in October and November of 2012 she began falling, and reported her symptoms as progressively worsening. She also reported increased difficulty walking over the past three years during a medical visit on January 15, 2014. Ex. 4 at 44. Although she initially continued to participate in physical therapy for her ankle, her ability to walk continued to decline until she became non-ambulatory.

Diagnostic testing continued to confirm her degenerative disc and joint disease as evidenced by an MRI on January 27, 2014, and EMG/Nerve Conduction Testing on February 12, 2014 revealing evidence consistent with moderate to severe bilateral L3-L4 lumbar radiculopathies with both active and chronic degenerative changes.

Ms. Moss began to experience weakness in her hands close in time to her October 23, 2013 medical appointment. Ex. 4 at 20. I am persuaded by the medical record notes from Dr. Ellstein as well as the opinion of Dr. Donofrio that this hand weakness is a result of carpal tunnel syndrome. Ex. 4 at 54; Tr. at 22. On January 15, 2014, Dr. Gudesblatt noted that "she is not reporting arm weakness and is able to self-propel the wheelchair." Ex. 4 at 44. He assessed her motor strength as 5/5 in her upper extremities. *Id.* at 49. In December of 2013, she was diagnosed with bilateral carpal tunnel syndrome. Ex. 4 at 52. On February 10, 2014, Ms. Moss reported diminished strength in the upper extremities. *See* Ex. 6 at 4.

Pursuant to Dr. Gudesblatt's recommendation, Ms. Moss began IVIG treatment in March of 2014 in an attempt to stabilize and perhaps improve the progressive course of her condition. Unfortunately, the treatments were unsuccessful, and her condition continued to decline, as Dr. Gudesblatt reported on August 21, 2014, "She has been treated with IVIG and despite adjustment of dose after not tolerating increasing dosage she has had progressive disability." Ex. 8 at 74.

Dr. Donofrio persuasively opined that Ms. Moss had a progressive peripheral neuropathy that worsened every year with many superimposed comorbidities that contributed to her declining health. First Donofrio Rep. at 10. Dr. Donofrio noted that most polyneuropathies are progressive, and that the progressive nature of Ms. Moss's disease does not suggest that she had CIDP. Second Donofrio Rep. at 1. He further stated

> It would be expected for most polyneuropathies to move from the distal lower extremities to the hip region and from the fingers to the shoulder region particularly over 4 or more years. If the onset of the petitioner's neuropathy was 2010 or earlier, it is not surprising she experienced progression over time to the point that she was weak proximally when evaluated by Dr. Gudesblatt in 2014.

Third Donofrio Rep. at 2.

I find, consistent with the medical records, and Dr. Donofrio's opinion, that Ms. Moss had a steady downward decline beginning in 2010, which continued after vaccination.

E. *Loving* Prong Three: Did Ms. Moss Experience a Significant Aggravation of her Condition?

Ms. Moss's deterioration is consistent with the Vaccine Act's definition of significant aggravation resulting in markedly greater disability, pain, or illness accompanied by substantial deterioration of health. § 33(4). Therefore, this leaves the question of whether that significant aggravation was vaccine-related.

F. *Loving* Prong Four (*Althen* Prong One): Petitioner has established a Reliable and Reputable Theory of How the Influenza Vaccination can Cause the Significant Aggravation of CIDP

Under *Loving* prong four/*Althen* prong one, the causation theory must relate to the injury alleged. Thus, a petitioner must provide a "reputable" medical or scientific explanation, demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). It must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Dr. Kinsbourne's causation theory relies on the parallels between CIDP and GBS, an "on-Table" autoimmune disorder that the Vaccine Program acknowledges can result from seasonal flu vaccination. 42 U.S.C.A. § 300aa-14 (2016). Citing the van Doorn article, Dr. Kinsbourne stated that GBS and CIDP "appear to be variants of one disorder, with very acute GBS patients at one end of the clinical spectrum and slowly progressive CIDP patients at the other." First Kinsbourne Rep. at 5; P.A. van Doom & MP Garssen, *Treatment of immune neuropathies*, 15 CURR OPIN NEUROL 5, 623-31 (2002) (filed as Ex. 19-Q) (hereinafter "van Doorn"). As such, Dr. Kinsbourne opined that GBS and CIDP share the same immunological mechanisms. First Kinsbourne Rep. at 5; van Doorn; *see also* R. Hughes et al., *Immunization and Risk of Relapse of Guillain–Barré Syndrome or Chronic Inflammatory Demyelinating Polyradiculoneuropathy*, 19 MUSCLE NERVE 9, 1230-31 (1996) (filed as Ex. 19-D); *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Information Page*, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, https://www.ninds.nih.gov/Disorders/All-Disorders/Chronic-Inflammatory-Demyelinating-Polyneuropathy-CIDP-Information Page (last modified, Mar. 27, 2019). Thus, Dr. Kinsbourne proposed that the far more common and thoroughly documented condition of GBS can serve as a model for CIDP, its rare and less studied chronic counterpart, with respect to immunopathogenesis in general and susceptibility to vaccine injury in particular. First Kinsbourne Rep. at 5. According to Dr. Kinbourne, "[w]hatever can cause GBS can also cause CIDP", including the influenza vaccine. *Id.* at 8.

Dr. Kinsbourne claimed that in both GBS and CIDP "circulating antiganglioside antibodies attack gangliosides residing on the surface of peripheral nerve myelin and axons. The immune attack on the gangliosides is attributable to molecular mimicry of surface epitopes of infectious organisms and of vaccines." First Kinsbourne Rep. at 6. Which disorder a patient will develop depends on certain susceptibility factors that differ between patients who manifest GBS and patients who manifest CIDP. *Id.* at 7.

Dr. Kinsbourne relied on the Comi article for the theory that CIDP patients have an impaired ability to shut off ongoing immune response, thus explaining its chronic course. First Kinsbourne Rep. at 7; C. Comi, *Fas-mediated T-cell apoptosis in chronic inflammatory demyelinating polyneuropathy*, 2011 J PERIPHER NERV SYST 16, Supp. l, 45-47 (2011) (filed as Ex. 19-B). "In short, activated lymphocytes express a receptor termed Fas, which is instrumental in switching off an ongoing immune response by causing T cell apoptosis. Fas-mediated T cell apoptosis is effective in GBS, hence its monophasic course, but impaired in CIDP, hence its almost indefinite continuation." *Id.*

Dr. Kinsbourne admitted that no controlled epidemiological study of CIDP relative to vaccination risk exists in the medical literature. First Kinsbourne Rep. at 7. Dr. Kinsbourne cited to published case reports to support his theory that the influenza vaccination can cause (and

significantly aggravated) CIDP. *Id.* He cited to the McCombe study, which reported that 35 percent of their series of 92 patients with CIDP had an antecedent infection. *Id.*; McCombe et al., *Chronic inflammatory demyelinating polyradiculoneuropathy: A clinical and electrophysiological study of 92 cases*, 1987 BRAIN 110, 1617-30 (1987) (filed as Ex. 19-I); Allan H. Ropper et al, *Guillain-Barre Syndrome*, 34 CONTEMPORARY NEUROLOGY 137 (F.A. Davis Company ed., 1991) (filed as Ex. 19-M) (hereinafter "Ropper") (reporting that 20 to 30 percent of patients with CIDP had a known antecedent event).

Dr. Kinsbourne highlighted that "an immune challenge that can cause a condition could well also exacerbate it." First Kinsbourne Rep. at 7. For example, he cited to Pritchard, in which "among 46 patients with CIDP, two patients relapsed after influenza vaccination." First Kinsbourne Rep. at 7; Pritchard at el., *Risk of relapse of Guillain-Barre syndrome or chronic inflammatory demyelinating polyradiculoneuropathy following immunization*, 73 J NEUROL NEUROSURG PSYCHIATRY 3, 348-49 (2002). The Pritchard article further noted that the influenza vaccine is the vaccine "most frequently associated with a relapse of GBS and advised caution in its use in CIDP." *Id*. Finally, Dr. Kinsbourne cited to the Vellozi study, to demonstrate that the flu vaccine has been shown (in a classic "challenge-rechallenge" manner) to cause recurrence or spiking of neuropathic symptoms. First Kinsbourne Rep. at 7; Velloz et al., *Safety of trivalent inactivated influenza vaccines in adults: Background for pandemic influenza vaccine safety monitoring*, 27 VACCINE 15, 2114-20 (2009) (filed as Ex. 19-R).

Dr. Donofrio stated that there is no firm epidemiologic data that supports an association between flu vaccination and GBS after the 1976-1977 Swine flu epidemic. Second Donofrio Rep. at 2. His research turned up two case reports, Sanz and Brostoff, each concerning a single patient who developed CIDP after vaccination. First Donofrio Rep. at 9; Sanz involved a single patient with systemic lupus erythematosus (SLE) whose CIDP arose after receiving a rubella vaccination. First Donofrio Rep. at 9; Sanz at 4061. Brostoff concerned a case of CIDP arising in a patient after an influenza vaccination given just two days before the disease onset. First Donofrio Rep. at 9; Brostoff at 229-30. The Kelkar study described three patients who developed CIDP after receiving an influenza vaccination; however, similar to Brostoff, one patient experienced tingling two days after the vaccination. First Donofrio Rep. at 9; Praful Kelkar, *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) With Rapid Progression After Influenza Vaccination: A Report of Three Cases*, 8 J CLINICAL NEUROMUSCULAR DISEASE 1, 20-25 (2006) (filed as Ex. J). Dr. Donofrio stated that an interval of two days "challenges the logic of attributing the onset of the illness to an immune response," casting doubt on CIDP's relationship to the influenza vaccination. First Donofrio Rep. at 9.

Dr. Donofrio further pointed to the 2012 Institute of Medicine Report which stated: "No studies were identified in the literature for the committee to evaluate the risk of chronic inflammatory demyelinating polyneuropathy (CIDP) after the administration of influenza vaccine." First Donofrio Rep. at 9; Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality, 334 (Kathleen Stratton et al., eds., 2012) (filed as Ex. K). Based on two case reports, "the committee assesse[d] the mechanistic evidence regarding an association between influenza vaccine and CIDP as weak. *Id*. As argued by Dr. Donofrio, "[t]he report of a few patients developing CIDP after any vaccination does not show a cause and effect relationship as the CIDP may have occurred purely by chance." First Donofrio Rep. at 9.

Most of the medical literature proffered by Petitioner concerns GBS, not CIDP. Nevertheless, there is no specific category of evidence that a petitioner must offer to establish a medical theory supportive of a causation finding. *Althen*, 418 F.3d at 1280. Therefore, Petitioner's inability to marshal this kind of specific scientific proof does not mean she cannot meet the requirements of the first *Althen* prong.

Molecular mimicry theories have been accepted in other Vaccine Program cases as a general framework for explaining the development of certain autoimmune diseases (although such acceptance has not always resulted in entitlement decisions favorable to petitioners). *Tompkins v. Sec'y of Health & Hum. Servs.*, No. 10–261V, 2013 WL 3498652, at *22 (Fed. Cl. Spec. Mstr. June 21, 2013) ("[t]he molecular mimicry theory is the one most widely accepted for the agents most frequently accepted as causal"), *motion for rev. den'd, Tompkins v. United States*, 117 Fed. Cl. 713 (2014).

Dr. Kinsbourne has drawn parallels between GBS and CIDP, and there are many persuasive decisions discussing the association between GBS and the flu vaccine. *Strong v. Sec'y of Health & Hum. Servs.*, No. 15-1108V, 2018 WL 1125666, at *20 (Fed. Cl. Spec. Mstr. Jan. 12, 2018); *See e.g.*, *Stitt v. Sec'y of Health & Hum. Servs.*, No. 09–653V, 2013 WL 3356791 (Fed. Cl. Spec. Mstr. May 31, 2013); *Stewart v. Sec'y of Health & Hum. Servs.*, No. 06–777V, 2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011); *see also Barone v. Sec'y of Health & Hum. Servs.*, No. 11–707V, 2014 WL 6834557 (Fed. Cl. Spec. Mstr. Nov. 12, 2014). Furthermore, Dr. Kinsbourne has presented evidence that GBS and CIDP are related peripheral neuropathies characterized by a number of common signs and symptoms—as well as a common pathogenesis, with one having a more chronic course. Accordingly, the large and persuasive body of evidence (and well-reasoned decisions of special masters past and present) noting the reliable connection between the flu vaccine and GBS has applicability herein, if CIDP were the correct diagnosis.

As noted by Chief Special Master Corcoran in *Strong*,

> Admittedly, there is less evidence and Program case law associating CIDP with the flu vaccine—somewhat diminishing the strength of a showing that so openly relies on comparisons between CIDP and GBS. But even if that rendered this case a closer call with respect to the first *Althen* prong, compelling case law counsels special masters to decide "close cases" generally in favor of claimants, and that same admonition applies to the individualized *Althen* prongs. *Althen*, 418 F.3d 1274, at 1260.

2018 WL 1125666, at *20. I therefore find that Petitioner has established that the flu vaccine can cause a significant aggravation of CIDP.

G. *Loving* Prong Five (*Althen* Prong Two): Petitioner has not Established a Logical Sequence of Cause and Effect between the Influenza Vaccination and the Significant Aggravation of Ms. Moss's Purported CIDP.

Loving prong five/*Althen* prong two requires the Petitioner to demonstrate a logical

sequence of cause and effect that the vaccination did cause a worsening of Ms. Moss's pre-existing condition. *Althen,* 418 F.3d at 1278; *Andreu,* 569 F.3d at 1375–77; *Capizzano,* 440 F.3d at 1326; *Grant,* 956 F.2d at 1148.

As discussed earlier in this decision, I have determined that the evidence in this case does not preponderantly establish that Ms. Moss had CIDP prior to her vaccination. This finding inherently means that Petitioner has not demonstrated that the flu vaccine "did cause" a significant aggravation of Ms. Moss's CIDP. The same evidence that I discussed in arriving at that determination also supports the position that the flu vaccine did not result in a significant aggravation of Ms. Moss's illness.[43]

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. *Andreu,* 569 F.3d at 1367; *Capizzano,* 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting *Althen,* 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Capizzano,* 440 F.3d at 1325. Instead, petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. *Id.* at 1325-26.

None of Ms. Moss's treating physicians linked her condition to her flu vaccine. I have considered this point in arriving at my conclusion that Petitioner has not presented preponderant evidence establishing a "logical sequence of cause and effect" between the receipt of the influenza vaccine and a significant aggravation of Ms. Moss's condition following the vaccine.

H. *Loving* Prong Six (*Althen* Prong Three): Petitioner has not Established an Appropriate Temporal Relationship between the Influenza Vaccine and the Significant Aggravation of Ms. Moss's Purported CIDP

The final *Loving* prong requires Petitioner to establish a "proximate temporal relationship" between the significant aggravation of Ms. Moss's condition and the influenza vaccine. *Loving* at 144; *see also Althen,* 418 F.3d at 1281. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008).

[43] For example, the fact that Ms. Moss's EMG studies did not evidence demyelination is confounding to her claim that the flu vaccine caused a significant aggravation of her condition. Ms. Moss had an EMG/nerve conduction study performed on February 12, 2014, nearly five months after vaccination. *See* Ex. 8 at 16. Dr. Donofrio's examination of the raw data indicates "the results approach normalcy for an 85-year-old patient as changes occur from aging in amplitudes, latencies, and conduction velocities above the age of 50 years." Second Donofrio Rep. at 1.

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

Dr. Kinsbourne opined that "the temporal interval between the influenza vaccine and the onset of Ms. Moss's polyneuropathy of less than four weeks is medically reasonable for neuroimmune disorders such as polyneuropathies." First Kinsbourne Rep. at 8. Dr. Kinsbourne repeats this assertion at the end of his first report, stating, "The vaccination-aggravation interval of several weeks is medically reasonable for an influenza-vaccination related injury." *Id.* at 9. Dr. Kinsbourne did not cite to any particular authority in support of this position.

Assuming this temporal interval is medically acceptable, Petitioner has not established that the "significant aggravation" of Ms. Moss's condition occurred in this period of time (fewer than four weeks after vaccination). In fact, it is unclear when Ms. Moss's condition became significantly aggravated. She presented to Dr. Allen for her flu vaccine in a wheelchair after sustaining the third of three falls which caused her to fracture her ankle. On October 23, 2013, one month after vaccination, Ms. Moss told Dr. McMonigle that she was in her usual state of health until she began falling two years prior. Ex. 4 at 20. Ms. Moss reported having a low voice for "several months", as well as wrist pain, and weakness and numbness in her hands. *Id*. She denied any fasciculations other than her legs occasionally feeling restless and needing to get out of bed at night. *Id.* Ms. Moss reported that the course of her symptoms had been progressively worsening. *Id*. This description does not paint the picture that Ms. Moss's significant aggravation of her condition began within four weeks of her vaccination.

Further, as of January 15, 2014, nearly four months after vaccination, Ms. Moss was "not reporting arm weakness and [wa]s able to self-propel the wheelchair." Ex. 4 at 44. In fact, Ms. Moss did not experience the onset of weakness in all four limbs, as required by the second Koski criterion, until February of 2014, five months after vaccination.

For these reasons, I find that Petitioner has not established that the significant aggravation of Ms. Moss's condition occurred in a medically acceptable timeframe, and thus has not established the sixth *Loving* prong.

VII. CONCLUSION

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, medical literature, the affidavits, as well as the experts' opinions and testimony, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under

the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[44]

IT IS SO ORDERED.

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

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