

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 17-1132V

Filed: August 24, 2020

PUBLISHED

AARON TOMSKY,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Special Master Horner

Decision; Ruling on the Written  
Record; Cervical Radiculopathy;  
Bell's Palsy; Chronic  
Inflammatory Demyelinating  
Polyneuropathy (CIDP); Influenza  
(flu) vaccine

*Shealene Priscilla Mancuso, Muller Brazil, LLP, Dresher, PA, for petitioner.*  
*Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.*

### **DECISION**<sup>1</sup>

On August 22, 2017, petitioner, Aaron Tomsky, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that he suffered chronic inflammatory demyelinating polyneuropathy (“CIDP”) caused-in-fact by an influenza (“flu”) vaccine administered on September 19, 2014. For the reasons set forth below, I conclude that petitioner is not entitled to an award of compensation.

#### **I. Applicable Statutory Scheme**

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal*

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

*link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient’s injury was “caused-in-fact” by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;” the logical sequence must be supported by “reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Althen*, 418 F.3d at 1278; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the “causation-in-fact” standard, as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between

vaccination and injury. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

*Althen*, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner’s causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id.* at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Id.* at 1280.

Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a pre-existing condition, the petitioner must establish three additional factors. See *Loving v. Sec’y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three *Whitcotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); see also *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test.). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee’s condition prior to the administration of the vaccine, (2) the vaccinee’s current condition, and (3) whether the vaccinee’s current condition constitutes a “significant aggravation” of the condition prior to the vaccination. *Id.*

In this case, petitioner has alleged that the flu vaccine caused him to suffer CIDP. Since CIDP is not listed on the Vaccine Injury Table relative to the flu vaccine, petitioner must satisfy the above-described *Althen* test for establishing causation-in-fact. Additionally, although petitioner did not plead any claim for significant aggravation, respondent contends that the symptoms of his CIDP pre-dated the vaccination at issue in this case. Accordingly, a further question is whether petitioner may alternatively satisfy the *Loving* test for establishing a significant aggravation.

## **II. Procedural History**

This case was originally assigned to Special Master Sanders on August 23, 2017. (ECF No. 4.) Petitioner filed some of his medical records and an affidavit with his petition (Exs. 1-6), but also sought and received authorization for several subpoenas to obtain further records. (ECF Nos. 7-16.) Petitioner filed a statement of completion on December 1, 2017, after filing additional medical records marked as Exhibits 7-9. (ECF Nos. 18, 20, 23-24.)

On May 10, 2018, respondent filed a Rule 4 report recommending against compensation. (ECF No. 29.) In particular, respondent noted that the symptoms of petitioner’s alleged CIDP predated the vaccination at issue. (*Id.* at 8.) Additionally, although petitioner did not plead a significant aggravation claim, respondent disputed that petitioner would be able to meet his burden under a significant aggravation test.

(*Id.* at 9.) Shortly thereafter, Special Master Sanders held a Rule 5 conference on May 16, 2018. (ECF No. 30.) Petitioner's counsel confirmed that petitioner did not intend to amend his petition to add a significant aggravation claim and indicated that instead he would present an expert report distinguishing petitioner's CIDP from other neurological conditions present (including Bell's Palsy) and opining that the CIDP was a later consequence of petitioner's flu vaccination. (*Id.*)

Subsequently, petitioner filed an expert report by neurologist Lawrence Steinman on November 27, 2018. (ECF No. 33-2; Ex. 10.) Respondent filed a responsive report by neurologist Eric Lancaster on March 1, 2019. (ECF No. 37-1; Ex. A.) Additionally, each expert submitted a supplemental report in turn. (ECF No. 39-2; Ex. 11 and ECF No. 41-1; Ex. D.)

Thereafter, the case was reassigned to me on August 29, 2019. (ECF No. 43.) On September 3, 2019, I ordered petitioner to file a joint status report indicating how the parties wished to proceed. (Order (Non-PDF), 9/3/2019.) On October 3, 2019, respondent filed a status report on behalf of the parties. (ECF No. 49.) The status report indicated that petitioner would be filing additional medical records, but that the parties otherwise "believe that the record will be complete and propose a briefing schedule following petitioner's statement of completion of filing records, after which the parties anticipate that the case will be submitted for decision, unless the Court determines that it would prefer to hold an entitlement hearing." (*Id.*)

Petitioner filed his amended statement of completion on November 4, 2019, after filing additional records marked as Exhibits 12-16. (ECF Nos. 48, 50-53.) Subsequently, I set a briefing schedule for a ruling on the written record.<sup>2</sup> (ECF No. 54.)

On January 6, 2020, petitioner filed his motion for a ruling on the written record. (ECF No. 56.) Specifically, petitioner requested "a ruling determining that petitioner has provided evidence that satisfied his burden of proof, establishing that he suffered Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP") caused by the influenza vaccine, received on September 19, 2014, and is therefore entitled to compensation." (*Id.* at 1.)

Respondent filed his response on February 21, 2020. (ECF No. 58.) He indicated that "[w]hile respondent does not oppose the Court ruling on entitlement on the record as it now stands, petitioner has failed to establish by preponderant evidence that an influenza (flu) vaccination caused his chronic inflammatory demyelinating polyneuropathy (CIDP). Accordingly, the result of a ruling on the record must be the dismissal of this claim." (*Id.* at 1.)

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<sup>2</sup> Although the suggestion of resolving this case on the written record arose from an agreement of the parties, I note that I have also separately determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this case without a hearing. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record.").

On March 15, 2020, petitioner filed a reply reiterating his view that he has established by preponderant evidence that his CIDP was caused-in-fact by his influenza vaccine in accordance with the applicable *Althen* test. (ECF No. 62.) Accordingly, the parties' respective presentations are complete, and this case is now ripe for a ruling determining whether petitioner is entitled to compensation.

### **III. Medical History**

#### **a. Prior to Petitioner's September 29, 2014 Flu Vaccination**

Before August of 2014, petitioner was a relatively healthy thirty-six-year-old male, though he had anxiety and attention deficit disorder. (*E.g.*, Ex. 2, p. 150-51 (problem list as of 8/26/2014).) Petitioner received the flu vaccination at issue in this case on September 19, 2014; however, his pertinent medical history begins several weeks prior. (Ex. 1, p. 1; Ex. 2, p. 281.)

On September 3, 2014, petitioner was seen by his primary care physician, Dr. Dennis Joel Abraham. (Ex. 2, p. 158.) At that visit he complained of severe bilateral pain, more right than left, extending from his hands to his shoulders. (*Id.* at 158.) He rated the pain a "6" and described it as "sharp, cramping, and shooting aches." (*Id.* at 158-59.) The pain had been occurring for three weeks, first occasionally, but continuously during the prior two weeks. (*Id.* at 159.) Petitioner reported a remote neck injury from a motor vehicle accident but indicated no recent traumas. Dr. Abraham felt his complaints were consistent with radiculopathy; however, on exam petitioner had normal range of motion in both the neck and his arms, no tenderness of the cervical spine, and movement did not increase his symptoms. (*Id.* at 159-60.) Deep tendon reflexes were normal, but there was some increased paresthesia and some decreased sensation in several fingers. (*Id.* at 160.) Dr. Abraham suspected cervical disc disease and nerve root compression and recommended a follow-up MRI. (*Id.* at 161.) An MRI study was completed on September 8, 2014. (Ex. 2, p. 182.) It showed a "minimal" disc bulge at C4-C5 without stenosis and a mild, right-sided foraminal stenosis due to a minimal, asymmetric disc bulge at C6-C7. (*Id.*)

Subsequently, petitioner presented to the emergency department on September 11, 2014. (Ex. 2, p. 214.) His chief complaints were "generalized body aches" and anxiety. (*Id.*) Petitioner described "intermittent pains," but that "in the last 24 hours he has been having more pain that moves between his bilateral shoulder and upper flank with some intermittent numbness in his bilateral hands." (*Id.*) In contrast to his visit with Dr. Abraham on September 3, he now attributed his pain to throwing out his back while roofing about two to three weeks prior. (*Id.*) He reported that "[t]oday he has also been having a severe sharp pulling pain in his left leg, which is new for him;" however, he reported being able to complete his activities of daily living. (*Id.*) At this visit he was "extremely anxious." (*Id.* at 216.) His discharge diagnoses were "anxiety reaction" and "pain, uncertain cause (acute)." (*Id.* at 229.)

Following his emergency department visit, petitioner was seen, as a referral, by orthopedist Dr. Paresh Ghodge for “neck pain” on September 18, 2014. (Ex. 2, pp. 169, 267.) Petitioner reported neck pain radiating down his right arm with tingling in his right thumb. (*Id.* at 267.) He clarified that he cannot recall a specific injury, but that the pain started after roofing his father’s house. (*Id.* at 266.) Upon exam, petitioner had normal strength and tone, his sensation was intact, and his reflexes and deep tendon reflexes were normal. (*Id.* at 267.) An examination of his cervical spine was largely normal, but with a positive Spurling test on the right. (*Id.*) Upon review of his prior MRI, his diagnosis was right-sided neck pain and cervical radiculopathy. (*Id.*) He was referred to physical therapy. (*Id.* at 268.)

Notably, however, following his exam with Dr. Ghodge, petitioner called the office back to request additional guidance. He indicated that in addition to discussing a pinched nerve, “[h]e told him that the other symptoms, the lip issues – unable to smile, are neurological.” (*Id.* at 277.) The extent of Dr. Ghodge’s notation regarding his neurological exam was that petitioner was “negative for weakness, dizziness, or paresthesia.” (*Id.* at 267.)

The next day, on September 19, 2014, petitioner was seen by Dr. Anoshirvan Mazhari for, *inter alia*, left-side facial droop, which he reported had been present for three to four days. (*Id.* at 282-83.) His lips had previously been numb, but that symptom subsided, and he now could not wink his left eye or smile with the left side of his mouth. (*Id.* at 282.) Petitioner’s prior complaints of limb pain were not discussed. He was diagnosed with Bell’s Palsy and fatigue and was administered the flu vaccination that forms the basis of this petition. (*Id.* at 282-89.)

#### **b. After Petitioner’s September 19, 2014 Flu Vaccination**

Less than a week later, petitioner began physical therapy on September 25, 2014. (Ex. 2, p. 297.) Upon initial evaluation, the physical therapist noted that “[p]atient has a complex presentation. With cervical exam has diffuse/unclear dermatomal sensory reported changes. Unable to demonstrate ability to centralize symptoms through positional exam today. He has newer onset L facial palsy, and also some concurrent low back complaints/LE complaints. Plan on cervical and facial interventions. May be appropriate for work up with neurologist if symptoms fail to improve.” (*Id.*) Petitioner reported right-sided neck pain occurring for one and a half months. He indicated that the pain radiated into both of his hands, right more than left. He also described about one to two weeks of left-sided facial Bell’s Palsy as well as “some shooting pains in the legs at times with some history of intermittent back pain.” (*Id.* at 298.) Petitioner reported that his symptoms are constant and “seem to be getting worse.” (*Id.*)

On October 6, 2014, petitioner’s physical therapist e-mailed his doctors to recommend that he be referred to a neurologist. (Ex. 2, p. 173.) She wrote:

Patient's facial palsy is seeming to be improved, blurriness in L[eft] vision improving. He will follow up with eye doctor next week. He does continue to have upper and lower, bilateral extremity complaints, along with diffuse, not appearing to be solely dermatomal<sup>3</sup> sensory changes reported in the B[ilateral] [lower and upper extremities]. He has made some change in R[ight] [upper extremity] symptoms with cervical positioning. He is also noting some plantar foot changes, in addition to reports of balance difficulties when in crowded areas. Along with continued PT he may be appropriate for referral to neurology to follow up with multiple system complaints and coordinate further cares. He is making some progress in PT but has some more involvement I would like looked at.

(*Id.*) Dr. Ghodge made the referral based on the physical therapist's recommendation. (Ex. 2, p. 351.)

Petitioner presented to neurologist Masood Ghazali, M.D., on October 15, 2014. (Ex. 3, p. 27.) His chief complaint was "face, foot and hand numbness and paresthesia." (*Id.*) Petitioner reported to Dr. Ghazali that he had experienced radiating pain down his right arm with tingling in the right thumb that began in early September after he had been roofing for his father. Dr. Ghazali noted Dr. Ghodge's findings of mild right-sided foraminal stenosis at C6-C7 with minimal disc bulge at C4-C5 and a positing Spurling sign on the right. However, he also noted petitioner's report to his primary care doctor that he had facial weakness<sup>4</sup> and numbness in the lips as well as the physical therapist's observation of concurrent low back pain and lower extremity symptoms. (*Id.*) Petitioner indicated his facial symptoms were about 85% improved, but also noted that he was experiencing tingling and numbness in his feet bilaterally with unsteady balance. He denied significant weakness or knee buckling. (*Id.*) On physical exam, petitioner had absent reflexes symmetrically at the knees and ankles and reduced sensation between the toes and knuckles. (*Id.* at 30.) Dr. Ghazali listed separate diagnoses of Guillain-Barre Syndrome ("GBS"), Bell's palsy, and cervical disc degeneration, but characterized petitioner's condition in his notes as "acute inflammatory demyelinating polyradiculoneuropathy" (or "AIDP"). (*Id.*) He recommended hospitalization and additional diagnostic testing. (*Id.*)

Petitioner was hospitalized from October 15-19, 2014. (Ex. 9, pp. 3-4.) On admission he was noted to have had "about 6 weeks of neurologic symptoms, including

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<sup>3</sup> Dermatome rule is defined as "the theory that visceral pain is referred to the dermatomes supplied the posterior roots through which the visceral afferent impulses reach the spinal cord." *Dermatome Rule*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=104605> (last visited June 8, 2020). Dermatome is defined as "the area of skin supplied with afferent nerve fibers by a single spinal nerve. Called also dermatomic area." *Dermatome*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=13359> (last visited June 8, 2020).

<sup>4</sup> Dr. Ghazali incorrectly recorded that petitioner's facial weakness began two days after his flu vaccination. (Ex. 3, p. 27.) In fact, as described above, petitioner was vaccinated at the very appointment wherein he sought treatment for a three to four day history of facial weakness. (Ex. 2, pp. 281-87.)

right arm pain and finger numbness.”<sup>5</sup> (*Id.* at 3.) During his hospitalization petitioner underwent a lumbar puncture which showed elevated protein of 314 mg/dL but was otherwise normal. He had an electromyography (“EMG”) exam that showed multifocal demyelination. During hospitalization he experienced some autonomic instability. He was treated with IVIG and was seen by both physical and occupational therapists. (*Id.* at 4.) His symptoms improved, but did not resolve, during hospitalization and he was observed to have some issues with occipital headache and neck pain that were “likely somewhat musculoskeletal.” (*Id.*) During his hospitalization, petitioner received a PT assessment. (*Id.* at 30.) Petitioner indicated that he “had been seeing a physical therapist for a cervical disk herniation, which he thought was causing a majority of his pain/mobility concerns.” (*Id.*) His discharge diagnosis was AIDP with cranial nerve involvement. (*Id.* at 3.)

On October 28, 2014, petitioner started physical therapy at Courage Kenny Rehabilitation Mercy Hospital for his AIDP. (Ex. 9, p. 50.) Petitioner reported “onset of various neurological symptoms starting around labor day weekend or before which he saw various doctors for but was told it was a pinched nerve in the neck.” (*Id.*) Petitioner’s treatment was planned for twice a week for 12 weeks. (*Id.* at 63.)

Petitioner returned to the emergency department and was admitted on December 5, 2014 for “evaluation of weakness.” (*Id.* at 141.) Petitioner noticed progressively worse weakness in his lower extremities and had a hard time walking. (*Id.* at 142.) Petitioner’s neurologic workup was within normal limits. (*Id.* at 144.) Petitioner’s chart indicated that petitioner noted facial numbness and weakness two days after receiving a flu shot in September.<sup>6</sup> (*Id.* at 162.) His neurological exam revealed a slight downturn to left mouth consistent with Bell’s palsy and slight dysarthria. Petitioner’s lumbar puncture on December 6, 2014 showed an elevated CSF protein at 662 mg/dL, supportive of probable chronic inflammatory demyelinating polyneuropathy. (*Id.* at 163.) Petitioner was discharged on December 15, 2014. (*Id.* at 141.)

Petitioner received a consultation from Dr. Elizabeth H. Beck on December 18, 2014. (Ex. 9, p. 256.) Dr. Beck reported that petitioner had significant pain. She noted that it is unclear whether “current admission represents new weakness or possibly failure to improve. Either way, the time course (longer than 8 weeks) of a somewhat relapsing remitting course raises the question of a more chronic process (CIDP or one of its variants).” (*Id.*) Additionally, petitioner received a neurology consultation from Dr. Ronald M. Tarrel for his lower extremity weakness on the same day. Dr. Tarrel noted that petitioner first experienced symptoms at the end of August 2014 and had sudden onset of left-sided facial droop and numbness in early September 2014. (Ex. 9, pp. 1293-94.) Petitioner reported experiencing bilateral numbness in his feet two days after

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<sup>5</sup> Respondent notes that this places onset on September 3, 2014, which predates petitioner’s vaccination of September 19, 2015. (ECF No. 58, n.1.) Also of note, however, September 3 is also the date on which petitioner first presented with symptoms diagnosed as cervical disc degeneration, which is also a neurologic condition. (Ex. 2, p. 158.)

<sup>6</sup> According to the prior records, this is incorrect. Petitioner experienced lip numbness and facial droop prior to his flu vaccination on September 19, 2014.



his flu shot. Dr. Tarrel noted that petitioner was admitted to the emergency department with symptoms consistent with multifocal demyelinating polyradiculoneuropathy with cranial nerve involvement. (*Id.* at 1294.) Dr. Tarrel assessed petitioner with GBS with “near classic presentation of ascending sensory deficits followed by muscle weakness.” (*Id.* at 1297.) Dr. Tarrel considered CIDP and wanted a repeat EMG to “possibly distinguish from GBS [and] would be treated with steroids (as opposed to plasmapheresis/IVIG).” (*Id.* at 1298.)

From December 23, 2014 to January 21, 2015, petitioner received inpatient rehabilitation at Courage Kenny Rehabilitation Unit Abbott Northwestern Hospital for CIDP. (Ex. 9, pp. 322-39.) He received steroids and IVIG for the three weeks during his admission and was discharged with instructions to use a power wheelchair. (*Id.* at 333-35.) Additionally, petitioner received pool therapy, which he tolerated well. (*Id.* at 505.) On February 7, 2015, petitioner visited Dr. Tarrel for a re-evaluation of his CIDP. (Ex. 7, p. 7.) Petitioner experienced worsening symptoms after attempting to decrease his steroid. Dr. Tarrel indicated that petitioner had decreased bulk and tone throughout all four extremities and wanted petitioner to proceed with more aggressive therapy and another full round of IVIG.

Petitioner continued having physical, occupational, recreational, and speech language therapy for his condition throughout 2015 to 2017. (See Ex. 9; Ex. 13.) Petitioner also continued visiting the Noran Neurological Clinic to manage his condition. (See Ex. 8.) He has a personal care assistant and aside from using his wheelchair, petitioner wears ankle braces to help ambulate. (Ex. 7, p. 51; Ex. 8, p. 18.) Petitioner also established primary care at CentraCare Health in 2015 with Dr. Christopher J. Thompson. (Ex. 4, p. 16.) Petitioner also saw Dr. Xiaofang Sheng-Tanner, who recorded that petitioner was diagnosed with CIDP after receiving his flu shot. (*Id.* at 20, 24.)

Petitioner suffered a fall in August of 2016 that resulted in a fracture, causing him to be admitted into the hospital with recommendations of surgery and nursing facility for rehabilitation in light of his CIDP. (Ex. 8, pp. 8-21.) During his visit with Dr. Clifford Michael Matushin on July 6, 2017, it was noted that petitioner “shows slow progression of his disease and has been able to maintain his normal activities of daily living without significant compromise.” (*Id.* at 125.)

On August 30, 2018, petitioner had a new patient consult with Dr. Eric Kirchner at Lester River Medical Clinic at St. Luke’s Hospital. (Ex. 16, p. 148.) Petitioner was referred to St. Luke’s Neurology Associates by his PCP, Dr. Kirchner for a neurology consultation with Dr. Rebecca Meyerson. (Ex. 16, p. 140.) Dr. Meyerson noted that petitioner “developed symptoms [of CIDP] in September of 2014 somewhat abruptly after receiving a flu shot he developed weakness and paresthesias of both upper and lower extremities.” (*Id.*) After being wheelchair bound for over two years, petitioner was reported to be ambulating independently, but has been experiencing balancing difficulties. (*Id.*)

Petitioner was referred to St. Luke's Physical Medicine & Rehab Associates by Dr. Meyerson for further treatment of bilateral foot drop, sensory ataxic gait, impaired balance, and increased fall risk. (Ex. 16, p. 114.) He had a follow up appointment on March 22, 2019 and part of petitioner's history of present illness indicated that petitioner developed GBS after receiving a flu shot, which then progressed to CIDP. Upon assessment, Dr. Leslie Cavazos reported that petitioner had extremity weakness, bilateral foot drop, neuropathy, fall risk, impaired gait, mobility and ADLs. (*Id.* at 118.) In August 2019, petitioner came into the emergency department at St. Luke's hospital with abdominal pain. (Ex. 16, pp. 18-28.) The cause of his symptoms were unknown, but his labs indicate evidence of an inflammatory/infectious condition and was presumptively treated for tick-borne disease. (*Id.* at 28, 60.)

### **c. Affidavit**

Petitioner affirmed that in August 2014 before receiving the flu vaccination at issue in this case, petitioner "threw out [his] back working as a roofer," and "experienced intermittent back pain and right thumb and index finger tingling and numbness," as a result. (Ex. 6, p. 1.) He described the pain as immediate and constant like a "typical work injury." (*Id.*) Petitioner noted that while seeking treatment for his work injury, he started developing sharp pain in his legs. Petitioner recalled that "on or about September 15, 2014 [he] experienced some left side facial droop and lip numbness." (*Id.* at 2.) He received the flu vaccination on September 19, 2014 and affirmed that approximately two weeks after the vaccination, petitioner started feeling "new symptoms of weakness and numbness in [his] hands and feet." Petitioner indicated that these symptoms were unlike the pain he felt related to his work injury. (*Id.*) Petitioner represented that the he continues to experience the symptoms of CIDP. (*Id.* at 3.)

## **IV. Expert Opinions**

### **a. Petitioner's Expert, Lawrence Steinman, M.D.**

Dr. Steinman received his medical degree from Harvard in 1973. He is currently a professor of the department of neurology at Stanford University. (Ex. 10.3, p. 1.) Dr. Steinman has treated patients, both adults and children, who suffered from various forms of neuroinflammatory diseases and inflammatory neuropathy including Bell's palsy, GBS, CIDP, transverse myelitis, ADEM, and others. (Ex. 10, p. 1-2.) Dr. Steinman's research focuses on how the immune system attacks the nervous system and has published on the subject of molecular mimicry. He holds over 50 American and European patents, including several U.S. patents relating to vaccines. (*Id.* at 3.)

Upon his review of petitioner's medical records, Dr. Steinman stated that petitioner had Bell's palsy prior to his vaccination, but suffered CIDP after his vaccination. Dr. Steinman indicated that petitioner's spinal fluid analysis taken on October 15, 2014 was consistent with an inflammatory polyneuropathy. (Ex. 10, p. 7.) Dr. Steinman indicated that petitioner had an "[a]cute onset of what was initially diagnosed as [GBS], but ultimately became CIDP," sometime between September 19

and October 6, 2014. Dr. Steinman also noted that, based on Dr. Tarrel's assessment on February 7, 2015, petitioner's Bell's palsy was no longer present. (*Id.*) Dr. Steinman opined that petitioner's Bell's palsy "had an entirely different trajectory than the CIDP."<sup>7</sup> (*Id.* at 1.) Dr. Steinman indicated that onset of abnormalities in petitioner's arms and legs was noted within 17 days of receiving the flu vaccination, which is consistent with the timing found for onset of inflammatory neuropathy after influenza vaccine.

Dr. Steinman opined that the specific components of the 2014-15 influenza vaccine, which included an H1N1-like virus, is capable of triggering an autoimmune response to antigens that are associated with axonal neuropathy and with CIDP. (Ex. 10, pp. 7-8.) Specifically, he indicated that prior studies have shown H1N1-containing influenza vaccines induce anti-ganglioside antibodies. (Ex. 10, p. 8.) Gangliosides, in turn, have been associated with the pathogenesis of inflammatory polyneuropathy. (Ex. 10, p. 9.) He also suggested that contactin and neurofascin are detected in CIDP. (Ex. 10, p. 10.) Dr. Steinman opined that the components of the 2014-2015 seasonal influenza vaccine share structural homology with gangliosides and/or with contactin or neurofascin, which through molecular mimicry, can trigger inflammatory neuropathy. (*Id.* at 10-12.)

Based on his own published research identifying and experimenting with amino acids and triggering encephalomyelitis and neuroinflammation, Dr. Steinman opined that 2014-2015 influenza vaccine could induce CIDP via triggering autoimmunity to axonal and myelin antigens. (*Id.* at 13-16.) Through his research he "found some highly relevant molecular mimics in the vaccine components," including identifying "5 of 12 amino acids and even 4 of 11 amino acids was sufficient to trigger experimental encephalomyelitis." (*Id.* at 12-13.) Dr. Steinman noted that immunity to nervous system antigens is rather widespread in normal individuals. However, it is not possible to test petitioner for such immunity. (*Id.* at 17-18.)

In his supplemental expert report, Dr. Steinman responded to Dr. Lancaster's report and maintained that petitioner's September 19, 2014 influenza vaccination triggered his CIDP. (Ex. 11.) Dr. Steinman opined that petitioner's Bell's palsy was distinct from his inflammatory neuropathy, and reiterated that the Bell's palsy was largely resolved by the time the inflammatory neuropathy was first noted. Although there is a case report pertaining to Bell's palsy and GBS, "unilateral facial involvement is exceptionally rare in GBS, though bilateral facial involvement – not seen in this case – is seen on occasion in GBS." (*Id.* at 2.) Additionally, Dr. Steinman provided additional data to support his theory, stating that the "BLAST searches and corresponding hits on

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<sup>7</sup> It is clear from Dr. Steinman's report that he had concluded that petitioner's Bell's palsy-like symptoms abated prior to the onset of inflammatory neuropathy. (Ex. 10, p. 7, 19; Ex. 11, pp 1-2.) On that specific basis he opined that petitioner's facial weakness symptoms constituted a separate Bell's palsy and that the course of that Bell's palsy was incompatible with facial weakness due to CIDP. (*Id.*) However, with his citation to Dr. Tarrel's February 7, 2015 encounter record, Dr. Steinman highlights that petitioner's Bell's palsy-like symptoms were not confirmed as absent up to that point. As discussed in Section III(a), below, petitioner's prior medical records confirm that his Bell's palsy-like facial weakness persisted until at least December of 2014, which is well after the onset of his inflammatory neuropathy and months into the course of his CIDP.

the Influenza Database showing that immune responses to these fragments of influenza in Petitioner's vaccine can actually be found in humans," further supporting petitioner's theory. (*Id.* at 11.)

**b. Respondent's Expert, Eric Lancaster, M.D. Ph.D.**

Dr. Lancaster received his doctorate degree in neuroscience from the University of Maryland in 2002 and his medical degree from University of Maryland School of Medicine in 2003. (Ex. B.) Dr. Lancaster currently serves as an assistant professor of neurology at the University of Pennsylvania. (Ex. A.) He is board certified in neurology. Dr. Lancaster has experience in interpreting EMG/NCS studies and has published in various articles focusing on autoimmune neurological disorders, including CIDP. (*Id.* at 1.)

Dr. Lancaster likewise agreed that petitioner was correctly diagnosed with CIDP. Specifically, he explained that petitioner "had a severe sensory-motor neuropathy that persisted and caused disability of a period of years. His spinal fluid protein was highly elevated on two studies. The time to peak disability from the onset of symptoms was more than 4 weeks, and there was probably a need for immune therapy over a period of years." (Ex. A, p. 13.) Based on these factors, Dr. Lancaster indicated he had "about 80%" confidence in the diagnosis of CIDP, though he noted the lack of any EMG/NCS data and further suggested that several other conditions, such as POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy and M-spike) and DADS (distal acquired demyelinating symmetric) neuropathy, were not ruled out. (*Id.* at 13-14.)

Dr. Lancaster opined that onset of the upper extremity symptoms petitioner described to Dr. Abraham on September 3, 2014 likely represents the onset of his CIDP. (*Id.* at 14-15.) These symptoms included sharp, cramping or shooting, or aching shoulder pain extending from the shoulders to the hands along with numbness and tingling. (*Id.* at 14.) According to Dr. Lancaster, petitioner's symptoms of numbness and tingling progressed and can be viewed in hindsight as the initial symptoms of his CIDP. Based on petitioner's report at the time that the symptoms had been present for two weeks, this places onset of the condition around August 20, 2014. (*Id.*)

Additionally, Dr. Lancaster opined that facial weakness is a well-recognized presenting symptom in some cases of CIDP. (*Id.* at 13.) According to Dr. Lancaster, this facial weakness presents similarly to Bell's palsy. (*Id.*) This represents the second manifestation of petitioner's CIDP and also preceded the vaccination at issue. (*Id.* at 17.) Dr. Lancaster clarified that facial weakness is not diagnostic for CIDP, but it is also not an exclusion criteria for making the diagnosis of CIDP. (Ex. D, p. 1.) Dr. Lancaster emphasized that facial weakness was not petitioner's only neurological symptom of CIDP prior to vaccination and therefore, petitioner's vaccination did not cause CIDP, but rather "CIDP was already occurring prior to vaccination." (*Id.*)

With regard to general causation, Dr. Lancaster opined that "[t]here is no reliable evidence that vaccines cause CIDP. CIDP, unlike GBS, is not post-infectious in

general.” (Ex. A, p. 18.) Dr. Lancaster also questioned Dr. Steinman’s methodology for seeking the homologies that support his opinion, suggesting that the degree of incomplete homology Dr. Steinman found (sequences of 3-5 out of 20 amino acids per protein) is not rigorous enough to eliminate chance matches, which are statistically inevitable by pure chance based on the number of comparisons being made. (*Id.* at 18-19.)

Dr. Lancaster also suggested that, although some CIDP patients do have antibodies for neurofascin and contactin, this petitioner does not “precisely fit” that profile because those patients responded to rituximab and not IVIG. (*Id.* at 19.) He noted that such antibodies are detectable by a simple blood test and a negative test result would refute Dr. Steinman’s theory. (*Id.*)

## **V. Issues to Be Decided**

In this case, there is no dispute that petitioner was correctly diagnosed with CIDP. The parties do, however, differ significantly on their interpretation of the medical records. While petitioner contends that he suffered CIDP following his vaccination along with unrelated Bell’s palsy and cervical radiculopathy pre-dating his vaccination, respondent contends that petitioner’s pre-vaccination neurological symptoms are all attributable to his CIDP.

Petitioner further contends, and respondent disputes, that he has satisfied the *Althen* test for demonstration of causation-in-fact. Importantly, however, respondent’s competing view of the record raises significant factual questions regarding petitioner’s pre-vaccination state of health, in particular which, if any, of petitioner’s neurological symptoms arose before his September 19, 2014 flu vaccine and which of those, if any, were symptoms of the CIDP that petitioner alleges to have had onset post-dating his vaccination. Moreover, even if petitioner failed to demonstrate that his CIDP was initially caused by his vaccination, he could still potentially demonstrate that his CIDP was significantly aggravated by his vaccination.

Accordingly, I will first discuss my findings of fact as to the presence and onset of three relevant conditions: cervical radiculopathy, Bell’s palsy (or facial weakness), and CIDP. Based on those findings of fact, I will assess petitioner’s causation-in-fact allegation by applying the *Althen* test. Finally, in the interest of completeness, though it was not pled by petitioner, I will briefly address the potential for a significant aggravation claim.

## **VI. Findings of Fact**

In light of the parties’ contentions in this case, the state of petitioner’s pre-vaccination health is the most significant aspect of the analysis in this case. As noted above, petitioner contends that he had post-vaccinal onset of CIDP preceded by unrelated, pre-vaccination onset of both cervical radiculopathy and Bell’s palsy. Respondent, in contrast, argues that all of petitioner’s pre-vaccination neurological

symptoms can be attributed to his later diagnosed CIDP. I will discuss each of the three alleged conditions separately.

#### **a. Cervical radiculopathy**

First, upon my review of the entire record, including petitioner's medical records and the expert presentations of both parties, I find that there is preponderant evidence that petitioner experienced cervical radiculopathy unrelated to his later diagnosed CIDP. I further find that there is preponderant evidence that the first manifestation of petitioner's cervical radiculopathy occurred in August of 2014, and that petitioner's cervical radiculopathy likely explains petitioner's upper extremity symptoms prior to his September 19, 2014 flu vaccination.

Specifically, petitioner was first suspected of having a cervical radiculopathy by his primary care physician and that suspicion was later confirmed and diagnosed by an orthopedic specialist, Dr. Paresh Ghodge, on September 18, 2014. (Ex. 2, pp. 266-68.) That diagnosis was supported by objective findings, albeit mild, upon an MRI of the cervical spine without contrast on September 8, 2014. The findings were consistent with petitioner's complaints of bilateral, but right more than left, arm pain radiating on the right to his thumb. (*Id.* at 181-82.) Although respondent's expert, Dr. Lancaster suggested the mild MRI findings, especially the lack of stenosis, suggested the upper extremity symptoms were more consistent with CIDP, petitioner's treating physician, Dr. Ghodge, made his diagnosis of cervical radiculopathy in full awareness of the MRI findings. This was also contemporaneously evaluated by Dr. Ghazali, the first neurologist to evaluate petitioner's full presentation of facial weakness and upper and lower extremity symptoms. In his assessment Dr. Ghazali maintained petitioner's prior cervical disc degeneration diagnosis while also separately assessing the presence of AIDP and sending him for hospitalization. (Ex. 3, p. 27.)

Additionally, petitioner's physical therapist, whose observations triggered the investigation eventually leading to petitioner's CIDP diagnosis, distinguished between his symptoms of cervical radiculopathy and other neurological symptoms. Her observation that physical therapy was aiding only the symptoms of cervical radiculopathy (noting right upper extremity symptoms change with cervical positioning), and not other sensorineural symptoms which had spread to all four extremities, was what led to her suggestion that petitioner be referred for a separate neurologic diagnosis. (Ex. 2, p. 173.) However, although she distinguished between upper extremity sensory symptoms that were dermatomal versus sensory changes that were not solely dermatomal, she did not separately discuss the onset of these different upper extremity symptoms.<sup>8</sup> (*Id.*)

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<sup>8</sup> Notably, although for reasons discussed below I do not credit petitioner's recollection as to the timing, petitioner did describe in his affidavit that his experience of upper extremity symptoms he related to his cervical condition was distinct from the onset of weakness, numbness, and tingling that progressed into his CIDP. (Ex. 6.)

Respondent's expert is not incorrect that in hindsight the upper extremity symptoms are potentially consistent with his later CIDP diagnosis. (Ex. A, pp. 14-15 (citing Ex. 2, pp. 159-60, 182, 214-26).) Moreover, over the long-term upper extremity involvement was unquestionably a part of his later, post-diagnosis, CIDP neurologic presentation. (E.g., Ex. 4, p. 22 (noting nearly two years after diagnosis a neurologic exam including decreased muscle tone and dystrophy of the upper and lower extremities). However, petitioner's medical records on the whole reflect that his treating physicians also believed that he did experience symptoms of cervical radiculopathy prior to his vaccination and maintained that impression even as they came to the realization that he was experiencing additional symptoms consistent with demyelinating polyneuropathy. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("medical 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). Thus, on this record it is not possible to separately attribute, by a preponderance of the evidence, any of petitioner's pre-vaccination upper extremity symptoms to his CIDP in preference to his contemporaneously diagnosed cervical radiculopathy.

#### **b. Bell's Palsy vs. Facial Weakness**

In this case it is undisputed that petitioner experienced symptoms consistent with Bell's palsy and that the onset of those symptoms occurred about three to four days prior to petitioner's September 19, 2014 flu vaccination. (Ex. 2, pp. 282-85, 277-78.) The parties differ, however, on whether petitioner's facial weakness should be attributed to his later diagnosed CIDP or considered separately as Bell's palsy. Upon my review of the entire record, including petitioner's medical records and the expert presentations of both parties, I find that petitioner's facial weakness beginning on or about September 16, 2014, was a manifestation of petitioner's later diagnosed CIDP.

"Bell's palsy is a form of temporary facial paralysis resulting from damage or trauma to the 7<sup>th</sup> cranial nerve, one of the facial nerves . . . [However,] several other condition can cause facial paralysis that might be diagnosed as Bell's palsy." (National Institute of Neurological Disorders and Stroke, *Bell's Palsy Information Page*, <https://www.ninds.nih.gov/Disorders/All-Disorders/Bells-Palsy-Information-Page> (accessed on Jan. 30, 2019) (Ex. 10.1-1).) Dr. Lancaster explained that a subset of patients with CIDP exhibit facial weakness. (ECF No. A, p. 13 (citing Heber Varela & Devon I. Rubin, *Facial and Trigeminal Neuropathies as the Initial Manifestation of Chronic Inflammatory Demyelinating Polyradiculopathy*, 10 CLIN. NEUROMUSCULAR DISEASE 194 (2009) (Ex. A, Tab 5).) Specifically, facial weakness due to cranial nerve involvement is present in about 15% of CIDP cases. (C.L. Koski et al., *Derivation and Validation of Diagnostic Criteria for Chronic Inflammatory Demyelinating Polyneuropathy*, 277 J. NEUROLOGICAL SCIENCES 1, 4 (2009) (Ex. A, Tab 6, p. 4); Varela & Rubin, *supra* at Ex. A, Tab 5, p. 4.) Additionally, one study suggests that facial

weakness is significantly more common among CIDP patients than among patient groups of other chronic polyneuropathies. (Koski et al., *supra* at Ex. A, Tab 6, p. 3.)

In this case, petitioner's treating physicians ultimately concluded that petitioner's facial weakness was a part of the clinical picture for his CIDP. When petitioner was discharged from his first hospitalization in October of 2014, his discharged diagnosis was AIDP with cranial nerve involvement. (Ex. 9, pp. 3-4.) Moreover, unlike petitioner's cervical radiculopathy, petitioner's initial preliminary diagnosis of Bell's palsy was never supported by any objective findings or response to treatment that could distinguish a separate Bell's palsy from petitioner's later diagnosed CIDP.

Thus, respondent persuasively contends that petitioner's Bell's palsy cannot be discerned from his CIDP, but instead the facial weakness is a presenting symptom of CIDP. (ECF No. 58, p. 15.) Both parties have submitted case reports presenting facial weakness as an initial symptom of CIDP. (Varela & Rubin, *supra*, at Ex. A, Tab 5; J.M Brostoff, Y. Beitverda & J. Birns, *Post-Influenza Vaccine Chronic Inflammatory Demyelinating Polyneuropathy*, 37 *Age and Ageing* 229 (2008) (Ex. 10.13).) Dr. Lancaster stated that "[t]he alternative hypothesis, that the CIDP and facial weakness are unrelated, would require Petitioner to have two different inflammatory nerve disorders entirely by coincidence in a period of a couple of weeks. This is implausible." (Ex. A, pp. 15-16.)

Petitioner contends that the course of petitioner's Bell's palsy began before his influenza vaccination and had an entirely different trajectory than the CIDP, which followed vaccination. (ECF No. 56, p. 10.) However, contrary to Dr. Steinman's assertion that petitioner's alleged Bell's palsy largely resolved prior to onset of inflammatory neuropathy (Ex. 10, p. 19), petitioner's medical records indicate that as of December 5, 2014, he still had evidence of a slight downturn to the left side of his mouth potentially consistent with Bell's palsy (Ex. 9, p. 163).<sup>9</sup> Nor has Dr. Steinman substantiated his assertion that facial weakness must follow the same trajectory as other symptoms to be consistent with petitioner's CIDP.

Petitioner's expert also contends that facial weakness is not diagnostic of CIDP. Dr. Steinman indicated that "unilateral facial involvement is exceptionally rare in GBS, though bilateral facial involvement – not seen in this case – is seen on occasion in GBS." (Ex. 11, pp. 1-2.) However, Dr. Lancaster is persuasive in explaining that a symptom does not have to be diagnostic of a condition to be a manifestation of that

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<sup>9</sup> Dr. Steinman relies on a notation from petitioner's October 15, 2014 encounter with Dr. Ghazali. (Ex. 10, p. 5-6; Ex. 3, p. 27.) During that encounter petitioner reported that he felt his facial weakness "is about 85% better." (Ex. 3, p. 27.) Importantly, however, petitioner confirmed ongoing numbness and reduced movement at that time and Bell's palsy remained a part of his assessment. (*Id.* at 27, 30.) Petitioner was similarly observed to have seen overall improvement in his CIDP throughout his hospitalization, which began October 15, 2014. (Ex. 9, p. 3.) Bell's palsy was observed again on December 4, 2014, and later confirmed absent on February 7, 2015. (Ex. 9, p. 163; Ex. 7, p. 7.) By the time petitioner's medical records suggest his facial weakness may have been resolved, it had already been noted in December of 2014 that his overall CIDP presentation may be consistent with a relapsing, remitting course. (Ex. 9, p. 256.)



condition and Dr. Steinman did not dispute that cranial nerve involvement is sometimes seen in CIDP. (Ex. D, p. 1; Ex. 11, p. 3.) See e.g., *R.K. v. Sec'y of Health & Human Servs.*, No. 03-632V, 2015 WL 10936124, at \*67 (Fed. Cl. Spec. Mstr. May 23, 2016) (recognizing that “there is a difference between engaging in diagnosis and recognizing with the benefit of hindsight that certain signs or symptoms are indicative of a subsequently diagnosed condition.”), *mot. for rev. denied* 125 Fed. Cl. 57, *aff'd* 671 Fed. Appx. 792.

In consideration of all of the above, I conclude that it is more likely than not that petitioner’s facial weakness symptoms represented a manifestation of his later diagnosed CIDP. The onset of petitioner’s facial weakness occurred approximately three to four days prior to his flu vaccination.

### **c. Pre-Vaccination CIDP Symptoms**

Finally, the remaining question is whether petitioner’s pre-vaccination symptoms establish by preponderant evidence that his undisputed CIDP pre-dated the vaccination at issue in this case. As described above, I find that the symptoms of facial weakness were more likely than not a manifestation of petitioner’s CIDP. However, even setting that finding aside, I further find upon my review of the entire record that petitioner additionally experienced neurological symptoms in his lower extremities which are not connected by preponderant evidence to petitioner’s cervical radiculopathy and which are consistent with the diagnostic criteria for CIDP.<sup>10</sup>

In discussing petitioner’s medical history, Dr. Steinman initially indicated that “[a]cute onset of what was initially diagnosed as Guillain Barre, but ultimately became CIDP began sometime between the immunization on Sept. 19 and October 6, 2014 when a note in Ex 2, p. 345 from PT/OT indicated both leg pain and hand pain.” (Ex. 10, p. 7.) Respondent’s expert, Dr. Lancaster, similarly opined that the symptoms of arm and hand paresthesia as well as generalized muscle aches, intermittent pains in shoulders and upper flank, and sharp pulling left leg pain, in hindsight, were manifestations of CIDP. (Ex. A, pp. 15, 17.) In discussing GBS, AIDP, and CIDP generally, Dr. Lancaster stressed that pain is often a “prominent,” though not “core,” part of clinical diagnosis. (*Id.* at 12.)

Although it is impossible for the reasons discussed in Section VI(a) above to distinguish potential upper extremity symptoms from petitioner’s documented cervical radiculopathy, petitioner first complained of lower extremity symptoms of severe sharp pulling pain in his left leg on September 11, 2014, in the context of generalized body aches when he was admitted to the emergency department. (Ex. 2, pp. 214-16.) Petitioner also pursued further follow up when he visited Dr. Mazhari on September 16,

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<sup>10</sup> To be clear, the presence of facial weakness and lower extremity pain and sensory symptoms do not represent the end of the diagnostic analysis; however, petitioner’s ultimate CIDP diagnosis is not disputed in this case. This discussion focuses only on whether these symptoms of petitioner’s later diagnosed CIDP pre-dated his vaccination.

2014 with chief complaints of pain in his leg and anxiety. (Ex. 2, p. 245.) These pains were never otherwise attributed to any other condition by petitioner's treating physicians and both Dr. Lancaster and Dr. Steinman opined that pain, not just sensory symptoms, are symptomatic of CIDP.<sup>11</sup> (Ex. A, p. 12; Ex. 10, p. 7.) Thus, although the experts agree that petitioner's lower extremity pain was a manifestation of his later diagnosed CIDP, Dr. Steinman is incorrect in placing onset of that symptom post-vaccination.

However, in discussing the timing of onset of petitioner's CIDP, Dr. Steinman also referenced "abnormalities" of the arms and legs more broadly. (Ex. 10, p. 7.) He seemed to indicate that it was the specific presence of neuropathy in the arms and legs that determined onset. (*Id.* at 19.) Abnormal sensation may also be a presenting symptom of CIDP. (National Institute of Neurological Disorders and Stroke, *NINDS Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Information Page*, [www.ninds.nih.gov/disorders/cidp/cidp.htm](http://www.ninds.nih.gov/disorders/cidp/cidp.htm) (last modified Jan. 14, 2016) (Ex. 10.2).) Specifically, CIDP can be identified clinically by "tingling or numbness (beginning in the toes and fingers), weakness of the arms and legs, loss of deep tendon reflexes (areflexia), fatigue, and abnormal sensations." (*Id.*)

By that metric, Dr. Steinman is still likely incorrect as to the timing. It is true that petitioner's symptoms were better documented in post-vaccination records. Additionally, some of petitioner's symptoms, such as limb weakness, were not evidenced until after vaccination. However, the record as a whole does indicate that petitioner's lower extremity sensory symptoms did pre-date his vaccination. When petitioner first reported to physical therapy one week following the vaccination at issue, he reported not only shooting pains in his legs, but was also observed to have sensory changes in his lower extremities as well as his upper extremities. Onset of lower extremity symptoms was noted to be "concurrent" with his facial weakness. (Ex. 2, p. 297-302.) In follow up, when petitioner was first diagnosed with GBS/AIDP, Dr. Ghazali also confirmed that petitioner's lower extremity symptoms leading to that diagnosis began at the same time as his facial weakness. (Ex. 3, p. 27.) This places onset of lower extremity sensory symptoms no later than September 16, 2014, which predates his vaccination.

In his affidavit, petitioner indicates that *two weeks* after his vaccination he experienced onset of new symptoms of numbness and weakness in his hands and feet distinct from his prior symptoms, explaining that "[i]t was more of a paralyzed feeling where I actually lost sensation in my extremities." (Ex. 6, p. 2.) I accept as accurate petitioner's description of his symptoms; however, petitioner's recollection of the timing is necessarily incorrect. His physical therapy records describing such symptoms by direct observation were created earlier than he recalls having experienced their onset. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993)

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<sup>11</sup> Although petitioner repeatedly mentioned throwing out his back, this was inconsistently reported. (See Ex. 2, p. 94-95, 214.) Moreover, none of his physicians ultimately opined that his lower extremity symptoms were the result of such an injury. (See Ex. 2, p. 173; Ex. 3, p. 30; Ex. 9, pp.141-44, 256, 1293-94.)

(explaining that “[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.”).

Unlike his upper extremity symptoms, none of petitioner’s treating physicians attributed his lower extremity symptoms with any other condition such as cervical radiculopathy. In fact, the presence of these lower extremity symptoms contributed to the physical therapist’s suspicion of an unrelated condition later diagnosed as CIDP. (Ex. 2, p. 173, 296-302.) Although some of his treating physicians would later place onset of his CIDP in temporal relation to his vaccination based on petitioner’s reported history, none actually opined that his CIDP was vaccine-caused. Moreover, it is clear from petitioner’s earlier medical records that the later histories he provided were incorrect or imprecise regarding onset of his symptoms. (*E.g., supra*, at n.4, 6.) Indeed, at least some of petitioner’s physicians later cast some doubt on the accuracy of the history he provided. Dr. Tarrel noted in June of 2015 that “Mr. Tomsy is a fair historian and I do not think it is in his nature to pay attention to many details.” (Ex. 7, p. 51.) In any event, it is not unusual for patient reported histories to become less accurate over time. In prior cases it has been stressed that more contemporaneously reported histories of present illness should be credited over later, inconsistent histories. *R.K.*, 2015 WL 10936124, at \*76-77. On the whole the medical records reflect that petitioner first experienced facial droopiness as well as lower extremity pain and sensory changes prior to his September 19, 2014 flu vaccination. (Ex. 2, p. 214-16, 281-85, 296-302.)

Moreover, onset of CIDP and GBS is often characterized by initial symptoms of lower extremity weakness and numbness followed by ascending symptoms. (Ex. A, pp. 12-13 (citing Bianca van den Berg et al., *Guillain-Barre Syndrome: Pathogenesis, Diagnosis, Treatment and Prognosis*, 10 NATURE REV. NEUROLOGY 469 (2014) (Ex. A, Tab 2)).) Accordingly, if lower extremity symptoms were the first manifestation of petitioner’s CIDP, that would remain consistent with inflammatory demyelinating polyneuropathy. This is further supported by the diagnostic impressions of petitioner’s treating physicians. When petitioner first presented to Dr. Masood Ghazali, his lower extremity symptoms led to an initial diagnosis of GBS or AIDP which later gave way to his CIDP diagnosis as his clinical course progressed into a chronic, relapsing, remitting presentation. (Ex. 3, p. 27-31.) Dr. Tarrel initially assessed petitioner with GBS with “near classic presentation of ascending sensory deficits followed by muscle weakness.” (Ex. 9, p. 1297.) Petitioner’s later treatment records confirm that the overall progression of his lower extremity symptoms remained consistent with his CIDP diagnosis and were considered by his treating physicians as part of his CIDP. (Ex. 9, pp. 233-40, 256-61, 1297-98.) However, none of these physicians opined petitioner’s CIDP was vaccine-related.

Accordingly, I find that, in addition to having CIDP-related facial weakness, there is also preponderant evidence that petitioner suffered pain and sensory symptoms in his

lower extremities consistent with CIDP prior to his September 19, 2014 flu vaccination, with onset occurring no later than September 16, 2014.

## VII. Analysis under *Althen* and *Loving*

As explained above, based on his allegations, petitioner's burden is to demonstrate by preponderant evidence each of the three *Althen* prongs for determining causation-in-fact (i.e. a medical theory, a logical sequence of cause and effect, and a proximate temporal relationship). *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In this case, because of my above findings of fact, *Althen* prongs two and three are dispositive. Additionally, further analysis pursuant to the *Loving* test indicates that petitioner does not prevail under any alternative theory of significant aggravation.

### a. *Althen* Prong One

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (citations omitted). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325–26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen*, 35 F.3d at 548-49).

Although Dr. Steinman devotes significant attention in his expert reports to seeking to establish that CIDP can be causally linked to the flu vaccine via the theory of molecular mimicry, I need not reach that question. Instead, the factual questions raised by petitioner's own medical history represent more significant (and, in fact, dispositive) issues. However, some prior decisions have stressed that, although they are distinct conditions, Guillain-Barre Syndrome ("GBS") and CIDP are "related" peripheral neuropathies that have a number of overlapping symptoms and share a common pathogenesis. See *Strong v. Sec'y of Health & Human Servs.*, No. 15-1108V, 2018 WL 1125666 at \*19 (Fed. Cl. Spec. Mstr. Jan. 12, 2018); *Daily v. Sec'y of Health & Human Servs.*, 2011 WL 2174535 at \*3 (Fed. Cl. Spec. Mstr. May 11, 2011). In that regard, there is precedent agreeing that petitioner can satisfy *Althen* prong one in a case such as this. Thus, in light of the below analysis pursuant to *Althen* prongs two and three, for purposes of this decision I merely assume but do not decide that petitioner has established a medical theory causally linking the flu vaccine to CIDP.

## **b. *Althen* Prong Two**

Following on from petitioner's general theory of causation, the next area of inquiry – prong two in an *Althen* causation-in-fact analysis – seeks to examine specific causation by determining whether there is a “logical sequence of cause and effect” reflected in petitioner's own medical history demonstrating that the vaccine at issue did cause petitioner's injury. *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. In establishing that a vaccine “did cause” injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1375; *Capizzano*, 440 F.3d at 1326 (“medical 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 particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras*, 993 F.2d at 1528. However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. See, Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”).

For petitioner's cause-in-fact allegation in this case, the analysis is simple as my findings of fact are dispositive. Although I did find, consistent with petitioner's allegations, that he more likely than not suffered a cervical radiculopathy prior to vaccination, I also concluded that there is not preponderant evidence that his cervical radiculopathy explains all of his pre-vaccination neurological symptoms. More specifically, I also found that petitioner's facial weakness symptoms more likely than not manifested prior to his September 19 vaccination and further that petitioner experienced pre-vaccination neurological symptoms, including both pain and sensory symptoms, in his lower extremities that are not explained by his cervical radiculopathy.

Because I further found that these facial weakness and lower extremity symptoms are both consistent with petitioner's confirmed CIDP diagnosis and pre-dated his September 19, 2014 flu vaccination, I conclude that there is preponderant evidence that petitioner suffered onset of his CIDP *prior to* the vaccination he alleged to have caused his condition. Petitioner's own medical history is therefore fundamentally at odds with any logical sequence of cause an effect that could be proposed to demonstrate that his vaccine did *cause* his CIDP. Moreover, for the reasons discussed in Section VI(c), above, the evidence of record from petitioner's treating physicians likewise favors the conclusion that petitioner's CIDP was unrelated to his vaccination.

### c. *Althen* Prong Three

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1278. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* 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-in-fact.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 503 Fed. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

According to Dr. Steinman, petitioner’s CIDP represents an autoimmune demyelinating condition caused via molecular mimicry, where onset occurred within 17 days after vaccination. (Ex. 10, pp. 7-18.) Accordingly, he opines that such a condition can occur within five weeks of vaccination and up to nine or ten weeks. (*Id.* at 7 (citing Lawrence B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States 1976-1977*, 110 AM. J. EPIDEMIOLOGY 105 (1979) (Ex.10.10)).) This is consistent with prior cases which have generally identified a relevant medically reasonable period of onset for demyelinating polyneuropathies (including GBS, transverse myelitis, and CIDP). *Barone v. Sec’y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at \*13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014); *Aguayo v. Sec’y of Health & Human Servs.*, No. 12-563V, 2013 WL 441013, at \*3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013); *Corder v. Sec’y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at \*27-29 (Fed. Cl. Spec. Mstr. May 31, 2011); *Daily v. Sec’y of Health & Human Servs.*, No. 07-173V, 2011 WL 2174535, at \*9 (Fed. Cl. Spec. Mstr. May 11, 2011).

However, for the reasons discussed in Sections VI(b) and VI(c), above, I did not find Dr. Steinman persuasive in applying his opinion to the facts of this case. Rather, I concluded, contrary to Dr. Steinman’s opinion, that petitioner’s pre-vaccination facial weakness was a manifestation of his CIDP and further that Dr. Steinman misidentified the onset of petitioner’s extremity pain and neuropathy. In this case, petitioner’s CIDP manifested *in advance* of the vaccination he alleges to have caused his injury. Accordingly, there can be no medically reasonable temporal association. *E.g., L.Z. v. Sec’y of Health & Human Servs.*, No. 14-920V, 2018 WL 5784525, at \*18 (Fed. Cl. Spec. Mstr. Aug. 24, 2018) (explaining that “[p]etitioner’s direct causation claim cannot succeed, as she cannot demonstrate a vaccine ‘caused’ an illness predating vaccination.”).

#### **d. Additional Analysis Under *Loving* (Significant Aggravation)**

Finally, in the interest of completeness, although petitioner did not allege a significant aggravation claim, I note that such a claim allows for the possibility that petitioner's injury may pre-date his vaccination and still have been affected by his vaccination. Here too, however, petitioner's own medical history is at odds with such a showing, especially in light of the nature of the condition he suffers.

The Vaccine Act defines a 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 order to demonstrate that a significant aggravation has occurred a petitioner must demonstrate the factors set forth in *Loving v. Secretary of Health & Human Services*, 86 Fed. Cl. 135, 144 (2009). Petitioner must first establish (1) the vaccine's condition prior to administration of the vaccine, (2) the vaccinee's current condition (or the condition following the vaccination), and (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination. *Id.*

Under this analysis, petitioner need only compare his pre- and post- vaccination conditions. He does *not* have a burden to demonstrate that his current condition is worse than his expected outcome. *Sharpe v. Sec'y of Health & Human Servs.*, 964 F.3d 1072, 1081 (Fed. Cir. 2020). Here, I have found that petitioner's initial symptoms of CIDP pre-dated the vaccination at issue in this case. It is also clear from his medical records that his symptoms attributable to CIDP continued to worsen after his vaccination. Accordingly, there is little question that petitioner experienced a significant aggravation within the meaning of this three-part test. Importantly, however, these first three *Loving* prongs do not address whether such a significant aggravation was vaccine-related.

Although petitioner need not compare his current condition to the otherwise expected outcome of his condition, he must still demonstrate that his vaccination affected his condition and was a substantial factor in causing his injury. *Sharpe*, 964 F.3d at 1082 (citing *Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375 (Fed. Cir. 2012)). In that regard the *Loving* test also requires petitioner to meet three additional requirements that replicate the three-part *Althen* test for causation-in-fact. *Loving*, 86 Fed. Cl. at 144 (citing *Althen*, 418 F.3d at 1278). However, the *Althen* analysis contained in Sections VII (a)-(c), above, discusses petitioner's injury in the context of his allegation that onset of his injury arose *after* his vaccination. Therefore, further discussion is warranted to explain why petitioner's claim still fails (under *Althen* prong 2/*Loving* prong 5) to demonstrate a logical sequence of cause and effect showing that his vaccination did affect his pre-existing CIDP.

In both GBS and CIDP, there is a known weeks-long period of symptom progression which occurs for as many as eight weeks (or more) following onset in the case of CIDP. (Ex. A, p. 11; Koski et al., *supra*, at Ex. A, Tab 6, Fig. 2.) It is generally understood that CIDP and GBS reach a clinical nadir after about four weeks (GBS) &

more than eight weeks for (CIDP). (van den Berg et al., *supra*, at Ex. A, Tab 2, pp. 4, 9.) In this case, when petitioner received his flu vaccination on September 19, 2014, he presented with a complaint of three to four days of facial droop. (Ex. 2, p. 282-83.) He had first complained of lower extremity pain on September 11, 2014. (*Id.* at 214-16.) Consistent with the above-cited time course, petitioner first reported improvement, but not resolution, in his symptoms with treatment during his hospitalization between October 15-19, 2014, which is about five to six weeks after onset. (Ex. 9, pp. 3-4.) Petitioner was later readmitted in December of 2014, presenting with further progression of lower extremity weakness. (*Id.* at 142.) It was not clear whether this was a relapse or a failure to improve; however, it was considered consistent with a chronic relapsing, remitting course of CIDP. (*Id.* at 256.) Moreover, none of petitioner's treating physicians attributed petitioner's condition, or any of his symptoms, to his vaccination. Thus, petitioner's medical record reflects that he experienced a course of CIDP unaffected by his vaccination.

Dr. Steinman did opine in his supplemental report that, "[i]f one hypothetically chooses to consider that the rare occurrence of Bell's palsy before CIDP, as the first manifestation of what was later to become CIDP, then I would argue that the influenza immunization aggravated a mere "Bell's palsy," to such a degree, that it evolved to CIDP." (Ex. 11, p. 2.) Nonetheless, he opined that the "Bell's palsy was distinct, and I choose the more common manifestation of Bell's palsy, over the exceptionally rare initial presentation of CIDP, unless aggravation is the preferred analysis of the fact." (*Id.*) Importantly, however, Dr. Steinman's hypothetical opinion in the alternative is still at odds with the record. As described in Section VI(c) above, I found that petitioner experienced pre-vaccination lower extremity symptoms in addition to his Bell's palsy-like symptoms. Moreover, I further found in Section VI(b) that petitioner's facial weakness was already a manifestation of his CIDP and did not resolve on the timeline Dr. Steinman suggested. Accordingly, Dr. Steinman's opinion that petitioner experienced pre-vaccination Bell's palsy that evolved into CIDP following vaccination is not persuasive in establishing any vaccine-related significant aggravation.

On the whole petitioner's medical records reflect a clinical course consistent with CIDP unrelated to vaccination. Additionally, Dr. Steinman's opinion in support of petitioner's claim is premised on his incorrect assumptions regarding the onset of petitioner's symptoms. (Ex. 10, p. 7). Accordingly, neither petitioners' medical records, nor his proffered expert opinion, present a logical sequence of cause and effect showing that petitioner's vaccination affected the course of petitioner's clinical history. Therefore, even under a significant aggravation theory, there is not preponderant evidence that petitioner's vaccination was a substantial contributing factor in petitioner's injury.

## **VIII. Conclusion**

For all the reasons discussed above, after weighing the evidence of record within the context of this Program, I do not find by preponderant evidence that petitioner's injury was caused by his September 19, 2014 influenza vaccination as alleged.



Therefore, this case is **DISMISSED**. The clerk of the court is directed to enter judgment in accordance with this decision.<sup>12</sup>

**IT IS SO ORDERED.**

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

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<sup>12</sup> In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.