

In the United States Court of Federal Claims  
OFFICE OF SPECIAL MASTERS

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KEVIN RADFORD, \*  
\*  
Petitioner, \* No. 18-704V  
\* Special Master Christian J. Moran  
\*

v. \*  
\* Filed: February 22, 2023

SECRETARY OF HEALTH \*  
AND HUMAN SERVICES, \* entitlement, significant aggravation,  
\* flu vaccine, CIDP, theory  
\* Respondent. \*

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*Laura Levenberg*, Muller Brazil, Dresher, PA, for petitioner;  
*Tyler King*, United States Dep’t of Justice, Washington, DC, for respondent.

**PUBLISHED DECISION DENYING COMPENSATION<sup>1</sup>**

Kevin Radford suffered from chronic inflammatory demyelinating polyneuropathy (“CIDP”) before he received an influenza (“flu”) vaccine in September 2015. He alleges that the flu vaccination significantly aggravated his CIDP. The Secretary disputes this claim.

Mr. Radford, one of his treating doctors, a neurologist Mr. Radford retained, and a neurologist the Secretary of Health and Human Services (“Secretary”) retained all testified at a hearing. Based upon the testimonial and documentary evidence, Mr. Radford is not entitled to compensation. Mr. Radford’s claim suffers from two independent flaws. First, he has not established with preponderant evidence how a flu vaccine can cause CIDP to worsen. Second, Mr.

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<sup>1</sup> The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. The posting of this decision will make it available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Radford has not persuasively shown that his CIDP was meaningfully worse after the vaccination. Thus, the Clerk's Office is instructed to dismiss Mr. Radford's petition.

I. **Facts**<sup>2</sup>

A. **Before Vaccination**

Mr. Radford was born in 1963. Tr. 10. Before the relevant vaccination, he worked on a full-time basis directing counselors who worked with injured Federal employees. Id. at 10-11, 96. He could perform the basic activities of daily living and household chores such as taking out the trash. Id. at 16.

In December 2012, Mr. Radford began a series of appointments with a podiatrist, Jeffrey Miller. Mr. Radford complained about bilateral heel pain and plantar fasciitis. Exhibit 8 at 2; Tr. 17-18. Dr. Miller diagnosed Mr. Radford as suffering from tarsal tunnel syndrome. Exhibit 8 at 2. Other appointments occurred on February 4, 2013, and March 11, 2013. Id. A neurologist whom the Secretary retained, Dr. Brian Callaghan, opined that tarsal tunnel syndrome is "incredibly rare" and it is unlikely that Mr. Radford suffered from tarsal tunnel syndrome. Tr. 269.

In addition to having pain in his feet for which Mr. Radford sought care from a podiatrist, Mr. Radford also had pain and numbness in his hands. For these problems, Mr. Radford sought care from a neurologist, Stephen Sacks, on March 20, 2014. Exhibit 11 at 6; Tr. 22-23. Dr. Sacks performed a nerve conduction study and an EMG that Dr. Sacks interpreted as being consistent with carpal tunnel syndrome. Exhibit 11 at 7-8.

Both the neurologist whom Mr. Radford retained, Dr. Maria Chen, and the Secretary's expert, Dr. Brian C. Callaghan, agreed that the EMG did not show carpal tunnel syndrome. Instead, both experts opined that the March 20, 2014 EMG showed that Mr. Radford was suffering from CIDP. Tr. 129, 151, 174, 263. Because of these opinions, Mr. Radford eventually alleged that a flu vaccination significantly aggravated his previously undiagnosed CIDP.<sup>3</sup>

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<sup>2</sup> The parties generally agreed that the medical records accurately describe events occurring around the time that the medical records were created. Although Mr. Radford testified, he recognized the accuracy of the medical records. See, e.g., Tr. 70, 83.

<sup>3</sup> The neurologist who eventually diagnosed Mr. Radford's CIDP, Jacob Kaufman, was less confident in placing the onset of CIDP in the spring of 2014. Tr. 191-92.

On April 3, 2014, Mr. Radford then visited his orthopedist, Dr. John Nuvelis, and presented with a “mild aching, burning” pain in his right wrist since five months prior, as well as numbness and tingling in his hand. Exhibit 12 at 12-13. He also had mild chronic aching in his hips. Id. at 13. He was diagnosed with carpal tunnel syndrome and hip pain. Id. at 14.

Over one month later, Mr. Radford had a follow up appointment with Dr. Nuvelis on May 28, 2014. Exhibit 12 at 9-11. During the visit, Dr. Nuvelis injected Mr. Radford with a steroid (cortisone). Id. at 11.

In October 2014, Mr. Radford was experiencing pain in his left lower extremity, which he rated as a 6/10. Exhibit 6 at 10; Tr. 68-70. He, therefore, sought care from his primary care physician, Mignon DeLeon. Id. Mr. Radford also told Dr. DeLeon that he banged his elbow on a wall at work and had left elbow pain. Dr. DeLeon prescribed ibuprofen. Exhibit 6 at 10.

After October 2014, Mr. Radford continued to have pain. Pet., ¶¶ 5-8; Tr. 73, 265. Due to pain in his heel and plantar fascia, Mr. Radford returned to Dr. Miller on December 11, 2014. Exhibit 8 at 2. Dr. Miller’s impression remained unchanged, in other words, Mr. Radford’s diagnosis remained chronic plantar fasciitis and tarsal tunnel syndrome. Dr. Miller recommended stretching and orthotics and prescribed Mobic. Id.

In December 2014, Mr. Radford was having sharp pain in his thigh and left calf. This pain made walking quickly difficult and prevented him from attending his office’s holiday party. Tr. 26, 74; see also Exhibit 7 at 1.

Mr. Radford reported his problems with walking when he saw Dr. Sacks again on January 13, 2015. Exhibit 7 at 1-2; Tr. 71. Dr. Sacks performed another NCS and EMG. Exhibit 7 at 4. He indicated that the clinical and electrophysiological evidence supported a diagnosis of bilateral tarsal involvement of the medial plantar nerves and recommended follow-up care with an orthopedist and podiatrist. Id. However, again, Dr. Chen and Dr. Callaghan interpreted the electrophysiological evidence differently from Dr. Sacks. In the opinion of Dr. Chen and Dr. Callaghan, the EMG was consistent with CIDP. Tr. 131, 263, 269, 306, 311.

Around this time, Mr. Radford moved from his home in Norristown, Pennsylvania to Atlanta, Georgia because his wife’s job had switched. Tr. 31. Mr. Radford’s employer allowed him to telework some days and Mr. Radford often flew back and forth. Id. at 31-33.

For his carpal tunnel problem, Mr. Radford underwent a bilateral release on February 6, 2015. Exhibit 12 at 2. The surgeon was Dr. Nuvelis. Dr. Nuvelis saw Mr. Radford for a follow-up on February 18, 2015 and recommended activities to improve Mr. Radford's "grip strength and range of motion." Id. at 4.

In the winter and spring of 2015, Mr. Radford was still having trouble walking due to pain in his thigh. He also stopped exercising in a gym. Tr. 30.

In February 2015, Mr. Radford visited Dr. Miller who noted he was experiencing "heel pain bilaterally." Exhibit 8 at 2; see also id. at 3 (showing that in March 2015, Mr. Radford revisited Dr. Miller and again discussed that he was having "heel pain bilaterally").

On March 16, 2015, Mr. Radford visited Penn Specialty Care Valley Forge Sports Medicine Center because he was experiencing "back pain" and was treated by Dr. Michael Christopher Schettino. Exhibit 2 at 73-74 (noting Mr. Radford was experiencing low back pain, left leg paresthesia, left leg weakness, abnormal reflex, left lumbar radiculopathy, and an antalgic gait). At the end of visit, Dr. Schettino instructed Mr. Radford to "obtain x-rays . . . [and a] MRI of [his] L/S spine." Id. at 74.

An MRI of Mr. Radford's lumbar spine showed that he had spinal stenosis due to epidural lipomatosis. Id. at 11.<sup>4</sup> "Epidural lipomatosis" means that Mr. Radford had an excess amount of fat within his spinal cord. Tr. 214-15. This excessive amount of fat compresses the nerve roots in the spinal cord, causing an axonal injury. Id. at 215. While epidural lipomatosis is uncommon, the condition sometimes requires surgery. Id. at 270. The location of the epidural lipomatosis (L4 to S1) means that this condition could not be causing the problem that Mr. Radford was experiencing in his hands. Id.

The location of the epidural lipomatosis was consistent with problems in Mr. Radford's lower extremities. Tr. 156-57, 216, 290. Around this time, Mr. Radford was using a cane to help him walk. Exhibit 2 at 71; Tr. 79.

Mr. Radford's use of a cane was part of the history a neurosurgeon, Timothy Lucas, obtained on April 1, 2015. Exhibit 2 at 71. Dr. Lucas diagnosed him with spinal stenosis of the lumbar region. Id.

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<sup>4</sup> Dr. Chen pointed out that the MRI did not image Mr. Radford's cervical spine. Tr. 315.

In April 2015, Mr. Radford had episodes of foot drop and he fell several times. He also had difficulty walking up stairs. Id. at 68.

For these reasons, Dr. Lucas operated on Mr. Radford's herniated lumbar disc on April 17, 2015. Exhibit 2 at 68. This operation was appropriate because Mr. Radford had a structural problem in his spinal cord. Tr. 155, 178, 196. As part of the recovery from the operation Dr. Lucas prescribed 60 mg of prednisone for five days. Exhibit 2 at 48; see also Tr. 289.

After Mr. Radford started taking prednisone, he felt better. Id. In his recovery, Mr. Radford spent time at a rehab clinic where he stopped using his cane. Tr. 31. He missed more than two months of work and when he returned to work, he teleworked on a full-time basis. Id.

When Mr. Radford returned to Dr. Lucas for postoperative care on June 11, 2015, Mr. Radford reported he had no pain, but he had numbness and tingling along his lower leg. Exhibit 14 at 26. Mr. Radford also reported his balance was improved. Id.

Mr. Radford testified that in summer of 2015, he was traveling back and forth between Philadelphia and Atlanta. Tr. 34. While he said he had no trouble with the traveling, he also reported that he used a wheelchair in the airport. Tr. 80.

By July 4, 2015, Mr. Radford was again having leg pain, which prevented him from walking briskly. Tr. 37. Mr. Radford told Dr. Lucas that his "gait was very disturbed." Exhibit 14 at 33; see also Tr. 81. Dr. Lucas later memorialized a complaint that Mr. Radford was having recurrent foot drops around this time. Exhibit 2 at 48 (noting that "in 7/2015 . . . [Mr. Radford's] numbness became continuous again and he began to have trouble walking due to recurrent foot drops."). Dr. Callaghan linked Mr. Radford's severe weakness in his ankles to Mr. Radford's undiagnosed CIDP. Tr. 275.

In August 2015, Mr. Radford visited his podiatrist Dr. Miller twice, and at both appointments, Mr. Radford reported that he continued to have heel pain. Exhibit 8 at 3. Dr. Miller prescribed naproxen on August 14, 2015. Id. Naproxen is an anti-inflammatory and nerve block that will relieve pain regardless of whether the pain comes from plantar fasciitis or CIDP. Tr. 242-43. Dr. Chen and Dr. Callaghan opined that the pain in Mr. Radford's heels was traceable to CIDP. Id. at 301, 312.

Mr. Radford returned to Dr. Lucas, the neurosurgeon, on September 3, 2015, and this record from Dr. Lucas is one of the critical medical records in determining whether Mr. Radford's CIDP worsened after the flu vaccination. Mr. Radford told Dr. Lucas that the numbness that Mr. Radford had been experiencing before the operation had returned. Exhibit 14 at 32-33. Dr. Lucas also memorialized that Mr. Radford reported having daily falls. Id.; see also Tr. 83.

Dr. Lucas tested Mr. Radford's strength in various muscle groups. Neurologists report their findings on a five-point scale with a three indicating the person can barely move their leg against gravity. Tr. 271. Details about Dr. Lucas's evaluation of Mr. Radford's strength as well as Mr. Radford's reflexes and sensation are set out below.

In the September 3, 2015 appointment, Dr. Lucas did not diagnose Mr. Radford with CIDP, although Dr. Lucas was smart enough to realize that re-growing fat could not explain all of Mr. Radford's problems. Id. at 172, 270. Through his expert, Dr. Chen, Mr. Radford emphasized that before he received the vaccination, no doctor diagnosed Mr. Radford with CIDP. Id. at 130, 155-56, 160, 288. Likewise, before the vaccination, Mr. Radford had not received any immunotherapy purposely directed at CIDP. Id. at 131. On the other hand, the Secretary's expert, Dr. Callaghan, viewed Mr. Radford as suffering a relapsing-remitting course of CIDP in which flares and symptoms recur. Id. at 265-66.

## **B. Vaccination through March 2016**

Mr. Radford received the allegedly harmful flu vaccination on September 11, 2015, at a Rite Aid near his apartment. Exhibit 1 at 1; Tr. 38. Mr. Radford testified that after the vaccination, he had more difficulties. For example, he recalled that shopping in a supermarket was difficult because he needed to use a cart to go through the store. Tr. 57.

Because he was concerned about his situation and unhappy with his previous primary care physician, Mr. Radford sought a new doctor. Id. at 41-42, 100. He called Robyn Salky on September 22, 2015 and reported numbness and tingling in his legs and shooting pain. Exhibit 3 at 17; Tr. 40-41, 132.

The appointment with Dr. Salky occurred on October 4, 2015. He presented to her as a new patient and gave a history consistent with the above. Exhibit 3 at 17. Mr. Radford was using a cane as needed for an antalgic gait. Id.; but see Tr. 101 (Mr. Radford's testimony that he does not remember whether he was using a cane). Dr. Salky's exam revealed tenderness in his lower lumbar spine, but her

neurologic exam produced normal results. Exhibit 3 at 17.<sup>5</sup> Dr. Salky recommended continuing to take gabapentin, losing weight, and seeing a neurologist. Id.; Tr. 42.

The neurologist to whom Dr. Salky referred Mr. Radford was Dr. Jacob L. Kaufman, but there was a delay before Dr. Kaufman could see Mr. Radford. Tr. 43. During this time, Mr. Radford was driving to work. At work, his supervisor saw him lose his balance and almost fall into a filing cabinet. So, the supervisor suggested that Mr. Radford tele-commute full-time. Id. at 45. In Mr. Radford's view, he thought of himself as going downhill quickly as his symptoms worsened—he began walking with the assistance of a cane and had to drag himself up and down the stairs. Id. at 44-45.

Dr. Kaufman saw Mr. Radford on November 11, 2015. Exhibit 13 at 22. This visit is another important source of evidence in determining whether Mr. Radford's CIDP worsened after the September 11, 2015 flu vaccination and was the subject of a great deal of testimony from Dr. Kaufman, Dr. Chen, and Dr. Callaghan.

As part of Dr. Kaufman's evaluation of Mr. Radford, Dr. Kaufman reviewed the March 2014 EMG and the January 2015 EMG, which had been interpreted as supporting carpal tunnel syndrome and tarsal tunnel syndrome. Dr. Kaufman disagreed with these interpretations. Exhibit 13 at 22.<sup>6</sup> Dr. Kaufman also obtained a history from Mr. Radford in which Mr. Radford said that he worsened in July. Id.; see also Tr. 277. This history does not mention the flu vaccination. Tr. 184.

Like Dr. Lucas, Dr. Kaufman conducted a neurologic evaluation, testing Mr. Radford's strength, reflexes, and sensation. The details are presented below. Based upon this information Dr. Kaufman suspected that Mr. Radford had CIDP. Exhibit 13 at 22; Tr. 174.

Dr. Kaufman ordered another EMG, which took place on November 17, 2015. The EMG showed “[s]evere, distal-predominant, sensorimotor, demyelinating polyneuropathy, exceeding EFNS/PNS Joint Task Force criteria for ‘definite’ [CIDP].” Exhibit 4 at 19. Dr. Kaufman also stated: “While this study does not exclude concomitant effects of lumbar epidural lipomatosis, that condition

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<sup>5</sup> With respect to Dr. Salky's determination that Mr. Radford's neurologic system was normal, Dr. Chan and Dr. Callahan placed little stock in her assessment. Tr. 302, 314.

<sup>6</sup> In Dr. Kaufman's testimony, he softened his criticism, explaining that as a younger doctor he was overconfident. Tr. 189.

alone would not produce absent lower extremity sensory responses or demyelinating features.” Id.

Dr. Kaufman sent Mr. Radford to the hospital immediately. In the hospital, Mr. Radford received a course of IVIG and steroids. Exhibit 2 at 48. After starting a 5-day course of IVIG, Mr. Radford’s leg strength improved, and he could move around the hospital without using a cane. Id.; Tr. 49-50, 192-93, 201. This prescription for IVIG was the first treatment specifically intended to address CIDP. Tr. 237. He was discharged from the hospital on November 26, 2015 with the diagnosis of CIDP. Exhibit 2 at 49.

When Mr. Radford saw Dr. Kaufman during a follow-up on January 4, 2016, Mr. Radford no longer needed a cane. Exhibit 13 at 49; Tr. 85, 202. Mr. Radford was participating in physical therapy and told Dr. Kaufman that his right hand and bilateral ankle weakness had resolved. Exhibit 13 at 52. When asked about Mr. Radford’s improvement, Dr. Kaufman stated that the improvement does not provide any helpful information about either the cause of Mr. Radford’s CIDP or the reason Mr. Radford’s CIDP worsened. Tr. 213. The January 4, 2016 appointment with Dr. Kaufman was the last visit for Mr. Radford because he then moved to the Atlanta, Georgia area full-time. Id. at 103.

### **C. After March 2016<sup>7</sup>**

After Mr. Radford permanently re-located in Georgia, he found new doctors to care for him. Albert Cook, a neurologist, first saw Mr. Radford on February 29, 2016. Exhibit 25 at 62; Tr. 51. Dr. Cook has periodically seen Mr. Radford through approximately March 2019. See Exhibit 25, passim. Dr. Cook arranged for a nurse to come to Mr. Radford’s house to provide IVIG treatments once per month. Tr. 52.

In May 2019, Mr. Radford sought a second opinion regarding his worsening gait and worsening balance from a different neurologist, Julian Bragg. Exhibit 17 at 59. Dr. Bragg has cared for Mr. Radford through at least May 2020. See id., passim.

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<sup>7</sup> Because the recent events in Mr. Radford’s life do not contribute to determining whether the 2015 flu vaccination harmed him, this evidence is presented summarily.

Besides these two neurologists, Mr. Radford also has a primary care physician, Karita Gone. On October 13, 2016, a physician's assistant in Dr. Gone's office gave Mr. Radford another flu shot. Exhibit 18 at 66-67.

Dr. Gone has followed Mr. Radford through a variety of problems including a potential vitamin B12 deficiency. In this context, Mr. Radford told her that he was pursuing a claim in the Vaccine Program. Id. at 32; see also Tr. 86-87. Dr. Gone did not comment on whether she thought the flu vaccine could have caused a worsening of his neurologic problems. See Tr. 87.

In his oral testimony, Mr. Radford described his daily life. He explained that he cannot walk his dog. Tr. 61. He has trouble going up and down stairs. Id. at 64. He has missed out on family events around holidays. Id. at 61. Although his employer, the Federal government, allows him to telecommute, Mr. Radford offered a view that his health problems have hindered his ability to be promoted at work. Id. at 63. While he has not returned to his former self, Mr. Radford hopes to get to that state someday. Id.

## **II. Procedural History**

Originally, Mr. Radford alleged that the flu vaccination caused him to suffer CIDP. Pet., filed May 18, 2018. Over the next few months, he submitted medical records and affidavits. Exhibits 1-13.

The Secretary reviewed these materials and recommended that compensation be denied. Resp't's Rep., filed Apr. 9, 2019. The Secretary maintained that based upon Dr. Kaufman's records, Mr. Radford experienced the onset of CIDP years before the allegedly causal flu vaccination. Id. at 10. The Secretary further asserted that the medical records did not support a finding that the flu vaccine significantly aggravated Mr. Radford's CIDP. Id.

In a May 10, 2019 status conference, Mr. Radford announced an intention to present a report from an expert. To assist with the development of expert opinions, the undersigned proposed a set of instructions. Order, issued May 10, 2019. The parties did not comment on the proposed instructions.

Mr. Radford submitted a report from his neurologist, Dr. Chen, on July 30, 2019. Dr. Chen agreed with Dr. Kaufman that Mr. Radford was suffering from CIDP before his vaccination. Exhibit 15 at 6. She, therefore, offered an opinion that the flu vaccine aggravated Mr. Radford's CIDP. Id. at 6-9.

The Secretary, in turn, filed a report from a neurologist, Dr. Callaghan, on December 30, 2019. Dr. Callaghan, too, agreed that Mr. Radford manifested symptoms of CIDP before the flu vaccination. Exhibit A at 4. However, Dr. Callaghan questioned both of Dr. Chen's opinions that the flu vaccine can aggravate CIDP and that Mr. Radford's CIDP worsened following the vaccination. Id.

Mr. Radford determined that a supplemental report from Dr. Chen was not needed. Pet'r's Status Rep., filed Jan. 14, 2020. Accordingly, the next step was for the parties to argue their cases through briefs. See Order, issued Mar. 17, 2020.

In advance of a potential adjudication, Mr. Radford updated his medical records. Exhibits 17-19, 22-23. After multiple enlargements of time, Mr. Radford presented his brief on August 18, 2020. However, the brief did not comply with all aspects of the order for briefs. See Order, issued Sept. 17, 2020. Thus, Mr. Radford submitted a revised brief on Nov. 9, 2020.

The Secretary addressed Mr. Radford's arguments in his brief, which the Secretary filed on May 24, 2021. Mr. Radford submitted a reply brief on July 8, 2021.

The undersigned determined that receiving oral testimony would be helpful. Order, issued July 22, 2021. In the ensuing status conference, the parties discussed whether doctors who treated Mr. Radford should testify. The parties planned for a hearing to be held over two days, April 21-22, 2022. Order, issued Aug. 18, 2021.

In the months leading to the hearing, Mr. Radford expressed an interest in having Dr. Kaufman testify. Pet'r's Status Rep., filed Nov. 22, 2021. Through the use of a subpoena, Mr. Radford secured Dr. Kaufman's attendance at the hearing. Pet'r's Mot. to Issue Subpoena, filed Jan. 7, 2022. Mr. Radford submitted Dr. Kaufman's curriculum vitae as Exhibit 30.

The hearing was held, as scheduled, on April 21-22, 2022 via videoconferencing. Mr. Radford testified about his health and movingly conveyed how living with CIDP has affected his life. Dr. Chen and Dr. Callaghan testified more or less in accord with their reports. Dr. Kaufman testified and his testimony was greatly appreciated.

Because the testimony did not raise any unexpected issues, briefs were not requested. See Arctic Cat Inc. v. Bombardier Rec., 876 F.3d 1350, 1372 (Fed. Cir. 2017) (ruling that a district court did not abuse its discretion in trebling damages without asking for briefs). Accordingly, the case is ready for adjudication.

### III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing the special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec’y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty).

In a case such as this, in which a petitioner seeks compensation for the worsening of an injury not listed on the Vaccine Table, the Federal Circuit has defined the elements of petitioner’s case. As confirmed in W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013), the elements of an off-Table significant aggravation case were stated in Loving. There, the Court blended the test from Althen v. Sec’y of Health & Hum. Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005), which defines off-Table causation cases, with a test from Whitecotton v. Sec’y of Health & Hum. Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resulting test has six components. These are:

- (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 significantly 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, 86 Fed. Cl. at 144.

#### **IV. Analysis**

Mr. Radford alleges that the flu vaccination significantly aggravated his CIDP. Pet., at 1. Mr. Radford has both failed to provide a persuasive medical theory and to show with preponderant evidence that his condition significantly worsened due to the vaccination. Two prongs from Loving are discussed in the order of importance, beginning with the more important element (theory). Accordingly, Mr. Radford has failed to meet the required elements of Loving and therefore is denied compensation.

##### **A. Theory / Loving Prong 4**

In the hearing, two neurologists, Dr. Chen and Dr. Kaufman, both opined that a flu vaccine can cause (or aggravate) CIDP. However, neither doctor's testimony on this point was persuasive.

Dr. Kaufman's testimony regarding potentially harmful consequences of the flu vaccine was shorter than Dr. Chen's and, therefore, is evaluated first. Although Dr. Kaufman treated Mr. Radford after he received the allegedly causal vaccination, Dr. Kaufman was not aware that Mr. Radford was recently vaccinated. Tr. 184. This lack of knowledge explains the lack of discussion about vaccine-induced aggravation in Dr. Kaufman's medical records.

In his oral testimony, Dr. Kaufman discussed whether a flu vaccine can aggravate a neurologic condition. When Mr. Radford's attorney asked whether Dr. Kaufman believe[d] "it [wa]s possible that a flu vaccine could cause an aggravation of preexisting CIDP?," Dr. Kaufman responded "[u]nquestionably." Tr. 185. To explain the basis of his opinion, Dr. Kaufman analogized CIDP to GBS. Tr. 217. In this context, Dr. Kaufman stated: "I don't think we understand CIDP well enough to really attribute things like causality, you know. But there's no question that flu vaccines can exacerbate CIDP." Id. Dr. Kaufman also recognized that no cause of CIDP has been determined. Id. at 218.

With respect to the narrow question on whether a flu vaccine can cause or aggravate CIDP, Dr. Kaufman's testimony is not illuminating. To start, a question based upon what is "possible," does not, by itself, help a petitioner establish a proposition of what is likely. See Paterek v. Sec'y of Health & Hum. Servs., 527

F. App'x 875, 883 (Fed. Cir. 2013). The remainder of Dr. Kaufman's testimony is confusing in that he simultaneously asserted (1) that a cause of CIDP is not known, and (2) a flu vaccine can cause an aggravation. See Tr. 217-18. This ambiguous testimony does not carry Mr. Radford's burden. Therefore, the opinions from Dr. Chen must be considered.

As a doctor whom Mr. Radford retained for purposes of this litigation, Dr. Chen disclosed her opinions regarding causation in advance of the hearing. Dr. Chen essentially presented an opinion that the flu vaccine can cause (or aggravate) CIDP via molecular mimicry. Exhibit 15 at 7. Although her report uses the term "bystander effect," Dr. Chen's testimony clarified that "bystander effect is . . . the concept behind molecular mimicry." Tr. 134; accord id. at 225-26. The theory of molecular mimicry posits that if components of the flu vaccine have enough similarity to components of a person's nervous system, then the immune system of a recipient of a flu vaccine attacks the nervous system. Id. at 225-26; see also id. at 134 (Dr. Chen), 278 (Dr. Callaghan's discussion about molecular mimicry).

Dr. Chen did not present any articles linking flu vaccine to CIDP specifically. Tr. 233. Dr. Callaghan averred that he was not aware of any studies about flu vaccine and CIDP and further maintained that due to his participation in organizations for neurologists, that if any literature did exist, he would be aware of it. Id. at 259-62, 278. This lack of literature weakens Dr. Chen's opinion. Although literature is not required, Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274 (Fed. Cir. 2005), "a scientific theory that lacks any empirical support will have limited persuasive force." Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 134 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012).

In the absence of any direct literature, Dr. Chen cited three articles to support her opinion, which she and Dr. Callaghan discussed. Exhibit 15 at 6-7; Tr. 229.<sup>8</sup> They are reviewed in turn.

The first article is by Kuitwaard.<sup>9</sup> Here, researchers composed a set of questions that they mailed to 461 people with neurologic disorders. Some questions asked whether the person had received a vaccination within eight weeks before the person developed GBS or CIDP. Exhibit 16-K at 311. It appears that

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<sup>8</sup> Before the hearing, Mr. Radford identified other potentially relevant articles. Pet'r's Revised Br. at 14-16. However, those other articles were not discussed during the hearing. In any event, a review of those articles does not suggest that any of them meaningfully advance the theory that a flu vaccine can aggravate CIDP. Thus, those articles are not discussed here.

<sup>9</sup> Krista Kuitwaard et al., "Recurrences, Vaccinations and Long-Term Symptoms in GBS and CIDP," 14 J. Peripheral Nervous Sys. 310 (2009) (filed as Exhibit 16-K).

researchers did not confirm the information recipients provided as the “retrospective nature of part of the questionnaires could have introduced recall bias. It is difficult to draw firm conclusions from a questionnaire in which patients report their recurrences after vaccinations themselves.” Id. at 315.

Of the 461 people surveyed, 323 patients (70%) responded. Of this group, 76 people stated that they suffered from CIDP, although, again, each diagnosis was not confirmed. Id. at 312. Eight people with CIDP stated they received a vaccination within eight weeks of vaccination. Id. The most received vaccine in the entire group was the flu vaccine. Id. “Of the 24 patients who received a flu vaccination (range 1-17 times) after being diagnosed with CIDP, five reported an increase in symptoms after one or more vaccinations.” Id.

With respect to their findings about preceding vaccinations, the researchers seemed not to draw any conclusions. They stated:

Our study indicates that the risk of developing another GBS episode after a flu vaccination is small. This confirms a recent study that found no evidence of an increased risk of GBS after seasonal influenza vaccination (Stowe et al., 2009). Another study has also suggested a low risk following vaccination, where only 4% (11/311) of GBS patients and 8% (5/65) of CIDP patients experienced a recurrence of symptoms following a vaccination (Pritchard et al., 2002).

Id. at 313.

When questioned about this article, Dr. Chen stated that a sample size of twenty-four people is small. Tr. 146-47. Dr. Callaghan agreed that the sample size was small and discussed the methodological problems that reduce the study’s value. Id. at 282-83. Thus, Dr. Callaghan asserted that Kuitwaard might prompt another study. Id.

The second article is by Goodridge et al.<sup>10</sup> The basic thesis was that a vaccination against one pathogen might protect against other pathogens. Exhibit 16-N at 1.<sup>11</sup> According to Dr. Chen, this article helps explain why a flu vaccine

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<sup>10</sup> Helen S. Goodridge et al., “Harnessing the Beneficial Heterologous Effects of Vaccination,” 16(6) Nat. Rev. Immunol. 392 (2016) (filed as Exhibit 16-N).

<sup>11</sup> Because Mr. Radford submitted an author manuscript, this decision cites to the PDF page, not the page appearing in the journal.

against some strains of the flu virus might protect against other strains of the flu virus. Tr. 138-39. The article highlights the benefits of vaccinations and does not mention CIDP. Id. at 149, 227-28, 279.

The last article is by Toplak and Avčin.<sup>12</sup> The authors reviewed “published data on autoimmune diseases following influenza infection and vaccination.” Exhibit 16-O at 619. Dr. Chen testified that the point of the article is to remind people that “the flu vaccine . . . is safe. It’s safer than getting the flu, but, again, the autoimmune component can be - - can be aggravated in a few select individuals.” Tr. 140. The article does not discuss CIDP. Id. at 231, 280.

In sum, the articles on which Dr. Chen relied do not meaningfully support her opinion that a flu vaccine can cause (or aggravate) CIDP. Without some undergirding for Dr. Chen’s opinion, Mr. Radford has not demonstrated that her opinion is reliable. See Tullio v. Sec’y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at \*12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (discussing appellate review of decisions involving molecular mimicry), mot. for rev. denied, 149 Fed. Cl. 448, 467-68 (2020). As such Mr. Radford has not met his burden of establishing the fourth Loving prong, which corresponds to the first Althen prong.

### **B. Significant Worsening / Loving Prong 3**

The third prong of the Loving test requires a petitioner to address “whether the person’s current condition constitutes a ‘significant aggravation’ of the person’s condition prior to vaccination.” W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013).

In considering this point, a special master should not consider the natural course of the disorder, although a special master could find that the “petitioner’s condition ‘was not affected by the vaccination.’” Sharpe v. Sec’y of Health & Hum. Servs., 964 F.3d 1072, 1082 (Fed. Cir. 2020) (quoting Locane v. Sec’y of Health & Hum. Servs., 685 F.3d 1375, 1378 (Fed. Cir. 2012)).

Here, the advocacy regarding how Mr. Radford’s CIDP did (or not change) before the hearing was superficial. The parties’ briefs would have benefitted from discussing more specific aspects of Mr. Radford’s history. For example, Mr. Radford mostly argued that because treating doctors did not recognize his symptoms as CIDP before the flu vaccination, his CIDP was “mild” and that the recognition of CIDP after the vaccination meant his CIDP was more severe.

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<sup>12</sup> Nataša Toplak & Tadej Avčin, “Influenza and Autoimmunity,” 1173 *Contemporary Challenges in Autoimmunity* 619 (2009) (filed as Exhibit 16-O).

Pet'r's Reply at 4-5. The Secretary generally contended that because Mr. Radford had (undiagnosed) CIDP before the vaccination and because Mr. Radford had (diagnosed) CIDP after the vaccination, the CIDP was the same. Resp't's Br. at 18-21.

However, the parties (particularly the Secretary) presented more nuanced positions in the hearing. The parties identified two critical records: Dr. Lucas's September 3, 2015 evaluation (Exhibit 14 at 32-38) and Dr. Kaufman's November 11, 2015 evaluation (Exhibit 13 at 22-25).

Given that Mr. Radford received the allegedly harmful flu vaccination on September 11, 2015, the records from Dr. Lucas and Dr. Kaufman allow for a comparison of Mr. Radford's CIDP before and after the vaccination. This pair of records presents information in five components: history, clinical presentation, sensory ability, reflexes, and strength.

History. The histories recorded by Dr. Lucas and Dr. Kaufman are relatively similar. Each doctor records that Mr. Radford told him that Mr. Radford's health declined in July. Exhibit 14 at 32-33; Exhibit 13 at 22. After reviewing the medical history obtained by Dr. Kaufman on November 11, 2015, Dr. Callaghan emphasized that in the history Dr. Kaufman obtained on November 11, 2015, there is no indication that Mr. Radford also told Dr. Kaufman that he worsened in September or October. Tr. 276-77. This lack of notation, especially in the context of a record in which worsening in July was mentioned, tends to suggest, but does not absolutely establish, that Mr. Radford did not worsen in September or October.

Clinical Presentation. The reports have some similarities and some differences. Dr. Lucas's review of systems states Mr. Radford had "[n]umbness / [t]ingling in [a]rms or [l]egs." Exhibit 14 at 34. The remainder of Dr. Lucas's record does not say anything about problems with Mr. Radford's upper extremities. See id. at 34-38. Dr. Lucas reports that Mr. Radford was using a cane for antalgic gain and pain. Id. at 33.

In Dr. Kaufman's review of system, he indicates "arm weakness, arm numbness, leg weakness, leg numbness and difficulty walking." Exhibit 13 at 24; accord Tr. 172. The report of "leg weakness" and "leg numbness" appears consistent with Dr. Lucas's notation about "numbness / tingling" in Mr. Radford's legs. The question is whether the more detailed information from Dr. Kaufman about problems in Mr. Radford's arms and hands marks a deterioration in Mr. Radford's health.

Dr. Kaufman’s identification of problems in Mr. Radford’s hands received little attention from the experts during their testimony. Dr. Chen did not base her opinion that Mr. Radford worsened on an expansion of problems to Mr. Radford’s arms and hands. See Tr. 132-33. Dr. Callaghan indicated that Dr. Lucas “was only concentrating on the legs.” Id. at 276. Although not spelled out, it seems that Dr. Callaghan might have been suggesting that Mr. Radford was having problems in his hands before the September 3, 2015 appointment. However, Dr. Lucas did not elicit any information about any problems in Mr. Radford’s upper extremities.

Dr. Kaufman recorded that Mr. Radford “walks with a cane.” Exhibit 13 at 24. Dr. Kaufman’s notation is similar to Dr. Lucas’s indication that Mr. Radford was using a case. Exhibit 14 at 33.

Sensory. The pertinent portion of Dr. Lucas’s report shows:

Sensation Exam	4/1/2015	6/11/2015	9/3/2015
Sensation symmetric to EXCEPT decreased sensation	RLE; LLE <sup>13</sup> LLE	RLE; LLE LLE	RLE LLE

Exhibit 13 at 46.

Dr. Kaufman’s report says: “Vibration sensation was absent at the right great toe and left ankle, reduced at the left great toe and right ankle. Temperature and pinprick sensation were reduced distal to the wrists and mid-shins, with an overlay of tingling and dysesthesias in the left peroneal distribution.” Exhibit 13 at 24.

Neither Dr. Chen nor Dr. Callaghan commented on whether Mr. Radford’s sensory abilities declined.

Reflexes. On this topic, Dr. Lucas’s report shows:

Reflex Exam	4/1/2015	6/11/2015	9/3/2015
Normal Reflexes	RLE; LLE	RLE; LLE	RLE; LLE

Exhibit 13 at 46.

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<sup>13</sup> “RLE” denotes right lower extremity and “LLE” denotes left lower extremity.

Dr. Kaufman's report states: "Upper extremity reflexes were absent at the biceps, 2+ at the brachioradialis and triceps. Lower extremity reflexes were absent aside from 1+ adductors." Exhibit 13 at 24.

There was some testimony about Mr. Radford's reflexes. When testifying about Dr. Lucas's record, which Dr. Kaufman had reviewed before examining Mr. Radford on November 11, 2015, Dr. Kaufman said that the report of normal reflexes "surprised" him. Tr. 199. To challenge Dr. Callaghan's overall opinion that Mr. Radford did not decline, Mr. Radford brought forward Dr. Lucas's report of normal reflexes as compared to Dr. Kaufman's report of diminished reflexes. Id. at 292 (cross-examination of Dr. Callaghan). Dr. Callaghan averred that because Mr. Radford had CIDP when Dr. Lucas examined him, "his reflexes probably were not normal." Id. Dr. Chen was not asked to comment on this aspect of Dr. Callaghan's testimony.

Strength. A final point of comparison is the two doctor's evaluation of Mr. Radford's strength. Dr. Callaghan described the strength exams as the "most important." Tr. 271. On the other hand, Dr. Chen questioned the usefulness of comparing strength results from two different evaluators. Id. at 317-19.

Dr. Lucas measured Mr. Radford's strength in five lower extremity muscles, of which two can be compared to Dr. Kaufman's later examination. For dorsiflexion, the results were L2, R3. Exhibit 14 at 36. For extensor hallucis longis, the results were L3, R4. Id.

Dr. Kaufman measured Mr. Radford's strength in those two areas as well as other muscles. For dorsiflexion, the results were L3, R4-. Exhibit 13 at 38. For greater toe extension, the results were L3, R3. Id.

Comparing the results in strength produces inconsistent results. For dorsiflexion, Mr. Radford improved from L2, R3 to L3, R4-. But for extensor hallucis longis, Mr. Radford declined from L3, R4 to L3, R3. See Tr. 276, 320, 323, 326.

Conclusion. When taken as a whole, the evidence does not support a finding that Mr. Radford met his burden of showing he declined in the months following the vaccination. Admittedly, the evidence is mixed. See Doe 11 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (indicating that the presence of contrary evidence does not make a special master's finding of fact arbitrary or capricious). For almost all points tending to show a decline, another point tends to show either no change or an improvement. For example, although

Mr. Radford walked with a cane in his visit to Dr. Kaufman in November 2015, Mr. Radford used a cane in April 2015. Exhibit 2 at 71. Overall, the evidence preponderates in finding that Mr. Radford's CIDP "was not affected by the vaccination." Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1378 (Fed. Cir. 2012).

**V. Conclusion**

Mr. Radford effectively communicated how having CIDP has taken a toll on him both before and after the flu vaccination. As such, he warrants sympathy for suffering with a difficult disease. However, the evidence that the flu vaccination worsened his course is lacking. Thus, Mr. Radford is not entitled to compensation.

The Clerk's Office is directed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including a deadline, is presented in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master