In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-1108V

(not to be published)

* *	Special Master Corcoran
GALEN L. STRONG, *	
*	Filed: January 12, 2018
Petitioner, *	
v. *	Entitlement; CIDP; GBS;
*	Influenza vaccine; Preexisting
SECRETARY OF HEALTH *	HIV Infection; Causation; Timing
AND HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

Alexander Laufer, Eisenhower & Laufer, P.C., Fairfax, VA, Petitioner

Sarah C. Duncan, U.S. Dep't of Justice, Washington, DC, for Respondent

DECISION DENYING ENTITLEMENT[1]

On October 1, 2015, Galen L. Strong filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Mr. Strong alleges that he experienced Guillain-Barré syndrome ("GBS") and/or chronic inflammatory demyelinating polyneuropathy ("CIDP") as the result of receiving an influenza ("flu") vaccine on September 19, 2012. Petition ("Pet.") (ECF No. 1) at 1. Petitioner filed a motion for judgment on the record on June 5, 2017. *See* Motion for Judgment on the Administrative Record, dated June 5, 2017 (ECF No. 38) ("Motion"). After considering the record as a whole, and for the reasons explained below, I find that Petitioner has not carried his burden of proof, and is accordingly not entitled to an award of damages.

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)). References to sections of the Act herein shall omit the statutory prefix.

I. Factual Background

A. *Petitioner's Pre-Vaccination Medical History*

Mr. Strong (60 years old at the time of vaccination) had some pre-vaccination health problems relevant to the determination of his claim. The medical records in this case reveal that he suffered from chronic obstructive pulmonary disease ("COPD"), hypertension, high cholesterol, recurrent bronchitis, upper respiratory infections ("URI"), and ear infections. Ex. 7 at 1-20; Ex. 11 at 1-42. (In addition, and as discussed below, in the course of treatment for the symptoms alleged as vaccine-caused in this case, Petitioner also learned he had a previously-undiagnosed infection that Respondent argues played a role in his injuries).

On July 24, 2012 (two months prior to vaccination), Petitioner saw Michael Sylvester, M.D., his primary care provider, for treatment of what he identified as five days of sinus issues, body aches, and fatigue, along with leg pain. Ex. 7 at 1. Mr. Strong was diagnosed with a URI, and thereafter sought follow-up treatment for it on July 30, August 3, and August 22, 2012, respectively. *Id*. at 4-13. In addition, on August 23, 2012, a month prior to his vaccination, a chest x-ray revealed a 4 cm mass in the right upper lobe of his lungs, and pathology was inconclusive. Ex. 9 at 14; Ex. 7 at 17-20.

B. *Vaccination and Reaction*

On September 19, 2012, petitioner saw pulmonologist Alexander Schult, M.D. At this time, he reported that aside from his pulmonary symptoms, he was experiencing "numerous joint aches and myalgias," and noting the fact that he had undergone a partial right knee replacement in 2009. Ex. 8 at 64-65. Petitioner received the flu vaccine at issue that day. *See* Exs. 1; 2; and 8 at 66.

Mr. Strong alleges (in an affidavit submitted in this action) that he experienced a vaccine reaction within the next two to three weeks (or during the first half of October 2012), characterized by fatigue, weakness and leg pain, including a burning and prickly feeling. Ex. 2 at ¶ 3.[3] However, he maintains that because his primary concern (along with physicians like Dr. Schult) was the possibility that he might have lung cancer, the significance of such symptoms was not sufficiently discussed and/or was broadly overlooked in the course of his treatment. *Id.* Nevertheless, Petitioner's pain and leg weakness was sufficiently severe to prevent him from performing routine yard work that month. To corroborate the timing of these symptoms, Petitioner noted that his sister-in-law visited the Strongs during the first week in October, and that she commented on his inability to walk short distances without great difficulty. *Id.* at ¶ 4. He also recalled a shopping trip in October to purchase a rug which he was barely able to assist his

[3] Petitioner's wife, Shelley L. Strong, also prepared an affidavit that largely echoed the same factual assertions contained in Mr. Strong's affidavit. *Compare* Ex. 2 at ¶¶ 3-4 *with* Ex. 3 at ¶¶ 3-4.

wife in transporting home due to leg pain. *Id*. at ¶ 3.

The medical records, however, do not corroborate Mr. Strong's allegations about onset of his purported reaction. Rather, they indicate that on November 15, 2012, Petitioner returned to Dr. Schult for a follow-up from his September appointment. He now reported general congestion, fatigue, and shortness of breath after exertion (although he did not provide a date on which any such symptoms began), and also that he had awakened over the prior three days with aches and pains in his legs plus a "prickly, hot feeling from the inside out." Ex. 8 at 58-59. A general exam was normal, but no neurological exam was noted. *Id.* Mr. Strong's assessment was a lung mass, COPD, and nasal discharge. *Id.* These records make no reference to the pain and leg weakness Petitioner alleges he had been experiencing in October, and also do not reference any complaints relating to a reaction to the flu vaccine.

A month later, on December 18, 2012, Mr. Strong went back to his primary care provider, Dr. Sylvester, to discuss diagnoses regarding his lung mass, and he reported continued wheezing and shortness of breath, but again nothing about the purported October weakness. Ex. 7 at 21-23. The review of symptoms was negative for paresthesias, weakness, myalgia, and arthralgias, and his neurological exam was normal. *Id.* at 22. Dr. Sylvester proposed that there might have been a reversible component or acute infectious process with respect to Mr. Strong's COPD that would explain his pulmonary symptoms, and discussed with Petitioner his concerns that the lung mass could be cancerous. *Id.* at 23. He was prescribed a prednisone taper and inhalers. *Id.* Again, no reference to ongoing or recently-experienced limb weakness or pain is set forth in these records.

C. *2013 Treatment and Initial GBS Diagnosis*

On January 9, 2013, Petitioner returned to Dr. Sylvester complaining of a cough that had persisted over the preceding three to four days, plus headaches and wheezing. Ex. 7 at 24-26. His neurologic exam was normal, and no neurologic symptoms were reported or observed, but Petitioner conveyed the stress he was suffering from due to the existence of his lung mass, and Dr. Sylvester's exam revealed wheezing. *Id.* Dr. Sylvester's diagnosis included cough, COPD, hypercholesterolemia (excessive cholesterol in the blood) and coronary artery disease, and Petitioner was again prescribed steroid medication as well as an antibiotic. *Id.* At a follow-up with Dr. Sylvester a little over a week later, Petitioner's exam was negative for all problems but the pulmonary findings. *Id.* at 27-29. Accordingly, almost four months since receiving the vaccine, Mr. Strong was now reporting nothing similar, symptoms-wise, to what he purports to have experienced two to three weeks post-vaccination.

By February, however, the records reveal that Mr. Strong was experiencing symptoms relevant to the claim in this case. Thus, on February 5, 2013 (now four-and-a-half months after vaccination), Petitioner went to Dr. Sylvester's office complaining of leg pain (beginning three days before) severe enough to prevent sleep. Ex. 7 at 30-31. The pain was determined to be bilateral and migratory, and involved Petitioner's calves, thighs, and occasionally the joints, but

Petitioner did not report paresthesias or leg weakness. *Id.* at 30. Petitioner also reported that his tongue was sore, and the examination showed oral thrush, but no focal neurological deficits. *Id.* Petitioner was prescribed medicine for his leg pain. *Id.*

Four days later, on February 9, 2013, Mr. Strong went to the emergency room ("ER") at Martha Jefferson Hospital in Charlottesville, Virginia, complaining of persistent bilateral leg pain over several days, coupled with difficulty walking. Ex. 4 at 1-3. He reported having received multiple courses of antibiotics for bronchitis and also prednisone. *Id.* at 1. The neurological review of symptoms and neurological exam were negative. *Id.* The physical exam revealed tenderness of the right calf and hip, and the ER physician noted that Petitioner's "symptoms sound[ed] quite muscular in nature," but also could represent a neuropathy. *Id.* at 2. The ER physician prescribed pain medication but could not identify an etiology for Petitioner's condition. *Id.* Because Mr. Strong did not appear to be in acute distress, he was released. *Id.*

Mr. Strong returned to Dr. Sylvester on February 12, 2013, complaining of chronic pain, general weakness, and severe "myalgia/arthralgia" for the last couple weeks, which Dr. Sylvester observed was temporally related to Petitioner's cessation of steroids (thus, Petitioner argues, allowing for the inference that the steroid treatments suppressed these symptoms) as well as reduction in other medications. Ex. 7 at 33-35. The review of systems was now (and for the first time chronologically in the medical record) positive for paresthesia in a stocking glove distribution, as well as anxiety, depression, sleep disturbance, and concentration problems. *Id.* at 33. Petitioner also had difficulty getting onto the exam table, and appeared tired and anxious. *Id.* at 34. Dr. Sylvester discontinued Petitioner's statin medication due to possible statin-caused myalgia, and began a 12-day prednisone taper. *Id.* He also proposed (based on mildly elevated liver test results) that Mr. Strong's symptoms might have an infectious etiology, or reflect a medication side effect (while also allowing that Mr. Strong could still be suffering from anxiety relating to concern about the lung mass). *Id.* at 35. Petitioner was directed to follow up soon with Dr. Sylvester, in order to gauge whether he was suffering from a post-viral syndrome, or even possibly GBS. *Id.*

D. *GBS Raised as Explanation for Symptoms*

Petitioner's follow-up visit with Dr. Sylvester occurred on February 20, 2013. Ex. 7 at 36-38. The records from this visit note that Mr. Strong now reported a decrease in pain, and that his weakness had also largely resolved, but that he was still experiencing paresthesias of the feet and hands. The neurological and musculoskeletal exams were normal; gait and coordination were intact, and except for "slight" reflexes in the lower extremities, deep tendon reflexes were otherwise normal. *Id.* at 37. Dr. Sylvester noted difficulty in explaining the cause of Mr. Strong's symptoms. Although GBS had been a "major concern," Dr. Sylvester felt Petitioner's presentation was "not a perfect fit" for GBS since he had shown improvement, and therefore they together agreed "not [to] pursue this [diagnosis]." *Id.* at 38. Dr. Sylvester nevertheless prescribed

gabapentin for Petitioner's leg pain and paresthesia, and recommended daily walking. *Id.*

Mr. Strong visited Dr. Sylvester again on March 4, 2013, complaining of continued leg pain for three to four weeks, cough, and fatigue. Ex. 7 at 39-41. Petitioner's musculoskeletal and neurological exams were again normal, with "reflexes, gait and coordination . . . all intact." *Id.* at 40. Nevertheless, and noting that Petitioner's leg pain "continue[d] to behave like improving [GBS]," Dr. Sylvester now deemed GBS to be "probable." *Id.* at 39-40. Because it appeared to be working, Petitioner's gabapentin dosage was increased, and he was also prescribed an antibiotic. *Id.* at 41.

Petitioner saw Dr. Sylvester two more times that month – on March 15 and March 29, 2013. At the former visit, he complained of symptoms more like those he had been experiencing before the February ER visit (i.e., cough, shortness of breath), but reported less pain, and upon examination he displayed none of the neurologic/neuropathic symptoms that had more recently been the subject of his visits with Dr. Sylvester. Ex. 7 at 41-43. He was advised to continue with gabapentin. *Id.* at 44. At the second visit toward the end of March, Mr. Strong reported right flank pain for about a week and swelling on his left side, along with complaints of leg pain and weakness much like he had voiced before. *Id*. at 46. Again, however, Petitioner's neurologic and musculoskeletal exams were negative. *Id.* at 47. Dr. Sylvester's notes convey the concern that "there may be more going on with the amount of systemic symptoms he is experiencing," reiterating his speculation that Mr. Strong likely had experienced GBS but was otherwise improving. *Id.* at 48.

Petitioner had more doctor's visits with Dr. Sylvester that spring, at which time he complained of leg and rib-midsection pain, as well as shortness of breath. *See, e.g.*, Ex. 7 at 49-51. Dr. Sylvester continued to watch Mr. Strong's condition and maintained the gabapentin prescription. *Id.* Petitioner also saw Dr. Schult for his pulmonary problems, and told him of ongoing chest pain, numbness, and intermittent bilateral weakness and paresthesias in his feet (although they were attributed more to feet positioning than to a neurologic source). Ex. 8 at 53. He specifically informed Dr. Schult of the absence of nocturnal symptoms, as well as the fact that gabapentin seemed to relieve his chest pain and discomfort. *Id.*

On May 23, 2013, Mr. Strong saw Dr. Sylvester for an earache, but also complained of ongoing pain and feet paresthesias since the time GBS was first proposed as a potential diagnosis in February. Ex. 7 at 52-54. But Petitioner's neurological exam was again normal, and the musculoskeletal exam only revealed bilateral chest wall and epigastric tenderness. *Id.* Dr. Sylvester repeated his suspicion that many of Petitioner's symptoms were likely related to GBS, although he expressed concern about other, different presenting symptoms, such as weight loss. *Id.*

E. *Summer 2013 Treatment and HIV Infection Discovery*

The medical records reveal that for almost the next two months, Petitioner sought no additional medical care. On July 17, 2013, however, Mr. Strong went to the Martha Jefferson ER complaining of worsening extremity and body pain plus weakness. Ex. 6 at 7-14. He reported that he had been experiencing such symptoms since February, but that they had become "much worse" in the previous four days. *Id.* at 8. His exam revealed decreased upper and lower extremity strength and an inability to stand up without assistance. *Id.* The history from this visit noted that Petitioner had similar but milder symptoms of discomfort in the arms and legs in February, and although his usual treater (Dr. Sylvester) had thought it was "probably" GBS, he had improved with gabapentin, and for a couple of weeks "he actually felt back to his normal self." *Id.* at 7-10. It was also noted that he had not recently had any vaccinations or experienced any illnesses. *Id.* at 8.

Ultimately, the ER treater characterized Petitioner's condition as "a fairly rapidly progressive lower greater than upper extremity weakness," as well as "dysesthesias of unclear etiology." Ex. 6 at 10. Mr. Strong was admitted to the hospital for further work-up, and specifically assigned for a consultation with a neurologist, Dr. Robert Adams. *Id.*

Dr. Adams saw Mr. Strong that same day. Ex. 6 at 76-80. His notes include a recitation (from Mr. Strong and his wife) of the relevant medical history. The Strongs informed Dr. Adams that onset of Petitioner's pain was "fairly abrupt" and had begun in February (contrary to their statements in this action about an earlier onset). *Id.* at 76. Petitioner had initially experienced pain in his legs, with tingling and paresthesias in the feet and "equivocal" symptoms of tingling and numbness in the hands as well. *Id.* These records further indicate that Petitioner himself reported that his symptoms had fluctuated in severity since February but had never dissipated entirely, becoming acutely worse over the next several days and beginning to feature progressive weakness. *Id.* Dr. Adams noted that the examination "reveal[ed] very little in the way of sensory impairment, but clear weakness, some clearly hypoactive reflexes." *Id.* at 76-77. He also noted that it was "[u]nclear what this process is, if it is a single process beginning in February, maintaining a fluctuating pattern for most of the time since, and then worsening substantially the last five days. It is possible there are two independent processes." *Id.* at 79. Dr. Adams did not, however, initially theorize that Petitioner's condition reflected GBS, CIDP, or some other neuropathic illness, proposing instead an "inflammatory process such as vasculitis, myelitis," or possibly Lyme disease. *Id.*

Dr. Adams proposed some testing in an effort to identify the possible cause of Mr. Strong's symptoms. He ordered bloodwork, which revealed that Mr. Strong suffered from a vitamin B6 deficiency. Ex. 6 at 1192. In addition, Petitioner's cerebrospinal fluid ("CSF") was drawn and analyzed, and it showed elevated proteins at 182 and 24 white blood cells, or "lymphocytic pleocytosis" - meaning abnormal numbers of white blood cells, thereby suggesting

infection or inflammation in the central nervous system. *Id.* at 1187; *Dorland's Illustrated Medical Dictionary* 1460 (32nd ed. 2012) (hereinafter *Dorland's*). More surprisingly, it was determined from the lab work that Mr. Strong suffered from an HIV infection. *Id.* at 1192. From the records and witness statements filed in this case, it appears Petitioner was not aware of this preexisting infection.

At this point, the records begin to reveal better-substantiated opinions as to a possible explanation for Mr. Strong's symptoms – and their connection to his preexisting HIV infection, rather than having a different cause. Thus, on July 18, 2013, Mr. Strong underwent an EMG/NCS, which "reveal[ed] evidence for an acquired, demyelinating radiculoneuropathy with lower extremities predominantly involved, and motor > sensory nerves." Ex. 9 at 63. Based upon these findings, Dr. Adams now speculated that Petitioner's condition "may represent 2nd episode (recurrence) GBS or GBS superimposed on other more chronic neuropathic process." Ex. 6 at 100. He recommended that Petitioner begin IVIG treatment[4] immediately. *Id.* By July 20, 2013, however, Dr. Adams was proposing that the GBS-like symptoms were a "likely provocation by HIV," and that his February symptoms were "possibly also HIV-related inflammatory neuropathy," which he noted explained "some [of the] atypical features in his clinical presentation," as well as Petitioner's lymphocytic pleocytosis. *Id.* at 105.

Other treaters echoed this conclusion. Thus, on July 22, 2013, infectious disease specialist Keri Hall, M.D., obtained a history from Mr. Strong's wife about his winter symptoms, and discussed with her what possible risk factors in Petitioner's past might have resulted in the positive HIV finding. Ex. 6 at 115-16. Dr. Hall proposed (much like Dr. Adams) that Petitioner's GBS was likely "[secondary] to HIV" and recommended starting antiretroviral therapy (after confirming his lung mass was not tuberculosis) "to treat most likely underlying cause (HIV)." *Id.* at 122. Although other treaters generally continued to maintain thereafter that Petitioner had experienced, and been recovering from, GBS, some in the summer of 2013 proposed an even different possible etiology for his symptoms. For example, neurologist Dr. Alexander Grunsfeld noted that in his view "GBS less likely CIDP," although he added that he favored "GBS with pre-existing B6 deficiency as an explanation for his acute or chronic decline versus CIDP." Ex. 6 at 149-50.

F. *Subsequent Treatment and Analysis of Petitioner's Condition*

By July 21, 2013, Mr. Strong's condition had worsened despite three courses of IVIG, and he was intubated secondary to respiratory failure. Ex. 6 at 107. Petitioner had a bronchoscopy (which was negative for malignancy and tuberculosis), a tracheotomy, and had a feeding tube

[4] Intravenous immunoglobulin ("IVIG") is a blood product used to treat patients with antibody deficiencies, including neurological disorders. *Clinical Uses of Intravenous Immunoglobulin*, NCBI (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (lasted visited on Aug. 28, 2017). It is commonly prescribed to treat diseases believed to be autoimmune in nature, increasing the effectiveness of an individual's immune response.

placed. *Id.* at 47-48, 70- 71, 89-91, 1216. He completed another IVIG treatment on July 24, 2013, but by that date Dr. Hall had proposed antiretroviral therapy. *Id.* at 122. A few days later, on July 29, 2013, Mr. Strong went into cardiac arrest secondary to hypoxia and was resuscitated with CPR. *Id.* at 63-66; 141. On August 10, 2013, Petitioner was discharged to University of Virginia HealthSouth Rehabilitation Hospital and noted to be "profoundly debilitated with his Guillain-Barre [sic] and remains quite weak." *Id.* at 80-84. At that point, he had been weaned off the ventilator and no longer required tube feeding. Ex. 5 at 1-5.

Throughout the remainder of 2013, and then on into 2014 and 2015, Mr. Strong continued to follow up regularly with Dr. Adams (neurology), Dr. Hall (infectious disease), Dr. Schult (pulmonary), and Dr. Sylvester (primary care). By September 19, 2013, Petitioner was ambulating with the support of a walking stick, and two days later he reported having used a chainsaw to cut down trees. Ex. 8 at 44-45; Ex. 10 at 19-21. In October 2013, Petitioner complained of leg swelling and pain, which Dr. Sylvester felt was likely medication-related. Ex. 8 at 42-43; Ex. 7 at 60-62. Throughout 2014 and 2015, Mr. Strong continued to complain of lower extremity paresthesias and pain. *See, e.g.*, Ex. 10 at 4-11, 13-14, 16-18; Ex. 7 at 67-72; Ex. 8 at 1-11, 13-28. Drs. Adams, Hall, and Sylvester all proposed that Petitioner's ongoing painful neuropathy could be related to GBS, but allowed as well that HIV neuropathy was an alternative explanation – along with the medication he took for his HIV infection (Truvada), which his doctors noted can cause neuropathic symptoms. Ex. 10 at 4-11; Ex. 7 at 70-72; Ex. 8 at 1-11, 13-23.

II. Expert Reports

A. *Dr. Marcel Kinsbourne*

Dr. Kinsbourne offered two expert reports opining that the flu vaccine caused Petitioner to develop CIDP. Expert Report, filed on June 5, 2016, as Ex. 12 (ECF No. 20-1) ("Kinsbourne First Rep."); Supplemental Expert Report, filed on November 21, 2016, as Ex. 13 (ECF No. 29-1) (Kinsbourne Second Rep.").

As his curriculum vitae ("CV") indicates, Dr. Kinsbourne is board certified in pediatrics. *See* CV, dated Aug. 11, 2017 (ECF No. 40) ("Kinsbourne CV"). He received his medical degree in England, and he has been licensed to practice medicine in North Carolina since 1967. *Id*. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including professorships in pediatrics, neurology, and psychology. *Id*. at 2. His clinical experience includes serving as a senior staff physician in Ontario from 1974-1980, and a clinical associate in neurology at Massachusetts General Hospital from 1981-1991, although (as noted in other cases) many years have passed since he regularly saw patients. *Pope v. Sec'y of Health & Human Servs.*, No. 14-078V, 2017 WL 2460503, at *8 (Fed. Cl. Spec. Mstr. May 1, 2017). He has not personally studied the immunologic issues raised by theories claiming

vaccine causation, and lacks specialization in the field of peripheral neuropathies (although his general neurologic expertise rendered him competent to discuss such matters).

Dr. Kinsbourne's initial report included a detailed review of Mr. Strong's medical history and treatment. Kinsbourne First Rep. at 1-3. He acknowledged that Petitioner's treaters consistently settled on a diagnosis of GBS. However, Dr. Kinsbourne stressed as significant the lengthy, up-and-down course of Petitioner's symptoms, as well as the fact that steroid treatment (which is not used for GBS) was successful in ameliorating some of Mr. Strong's symptoms. *Id.* at 4. These factors – coupled with GBS's nature as an acute, monophasic illness – suggested to him that Mr. Strong likely suffered not from GBS but from CIDP, which is characterized by lengthy progression, relapses in symptom severity, and the responsiveness of his symptoms to treatments associated with CIDP rather than GBS. *Id.* at 4.

Based upon this proposed counter-diagnosis, Dr. Kinsbourne was able to propose a causation theory involving Mr. Strong's September 2012 flu vaccine. Borrowing from literature and accepted medical views about the association between GBS and the flu vaccine, Dr. Kinsbourne observed that "[s]ubstantial medical opinion holds that GBS and CIDP differ only with respect to their temporal profiles." Kinsbourne First Rep. at 5. Thus, the two share immunologic mechanisms. *Id.*; R. Loughlin, *et al.*, *Incidence and Prevalence of CIDP and the Association of Diabetes Mellitus*, Neurology 73: 39-45 (2009) ("Loughlin"), filed on Aug. 30, 2016 as Ex. 12-g (ECF No. 20-8); R. Hughes, et al., *Immunization and Risk of Relapse of Guillain-Barré Syndrome or Chronic Inflammatory Demyelinating Polyradiculoneuropathy*, 16 Muscle and Nerve:1230-1231 (1996), filed on Aug. 30, 2016 as Ex. 12-d (ECF No. 20-5).

Because of their close association, "evidence as to influenza vaccine causation of both GBS and CIDP" bears equally on Petitioner's claim. Kinsbourne First Rep. at 6. Thus, Dr. Kinsbourne invoked literature exploring the cross-reactive potential of components of the flu virus (via the mechanism of molecular mimicry – a well-accepted explanation for how the flu vaccine can result in GBS)[5] to support his explanation for how the same process could result in CIDP. *Id.* at 7.[6] He similarly referenced literature establishing CIDP's association with antecedent vaccination or infection, noting that the flu vaccine had been shown (in a classic

[5] I have previously found that molecular mimicry is "a reliable explanation for how the flu vaccine would induce an autoimmune reaction that would damage an individual's myelin or nerves." *See Auch v. Sec'y of Health & Human Servs.*, No. 12-673V, 2017 WL 1034396, at *20 (Fed. Cl. Spec. Mstr. Jan. 13, 2017); *see also Stewart v. Sec'y of Health & Human Servs.*, No. 06–777V, 2011 WL 3241585 (Fed. Cl. Spec. Mstr. July 8, 2011) (petitioner was entitled to compensation in a flu/GBS case); *Daily v. Sec'y of Health & Human Servs.*, No. 07–173V, 2011 WL 2174535 (Fed. Cl. Spec. Mstr. May 11, 2011) (entitlement proven on a claim that the flu vaccine more likely than not caused the petitioner to develop CIDP).

[6] Because I do not find it a contestable point to argue against the well-understood mechanisms for how the flu vaccine can cause GBS, and because this Decision does not turn on that point, I do not include herein reference to or recitation of the literature offered in Dr. Kinsbourne's expert report to support this assertion.

"challenge-rechallenge"[7] manner) to cause recurrence or spiking of neuropathic symptoms. *Id.* at 6; D. Vellozi, *et al.*, *Safety of Trivalent Activated Influenza Vaccine in Adults: Background for Pandemic Influenza Vaccine Safety Monitoring*, Vaccine 27: 2114-2120 (2009), filed on Aug. 30, 2016 as Ex. 12-n (ECF No. 21-6).

At the same time, Dr. Kinsbourne proposed an explanation for why the autoimmune pathogenic process involving an identical biologic mechanism would produce a somewhat different disease course and outcome. Kinsbourne First Rep. at 6, *citing* C. Comi, *Fas-Mediated T-Cell Apoptosis in Chronic Inflammatory Demyelinating Polyneuropathy*, J. of the Peripheral Nervous System 16 (supplement): 45-47 (2011) ("Comi"), filed on Aug. 30, 2016 as Ex. 12-b (ECF No. 20-3). Dr. Kinsbourne explained that GBS's more progressive and rapid disease course process was attributable to a "host variable," such as a genetic susceptibility, but did not occur with CIDP, resulting in the latter disease's "almost indefinite continuation." Kinsbourne First Rep. at 6.

With respect to the actual medical history at issue, Dr. Kinsbourne acknowledged that if Mr. Strong's allegations that he began to experience symptoms in October 2012 (or within two or three weeks of vaccination) were accurate, then his meandering course (with no treater diagnosis of GBS until months later, and no short, rapid progression) was "incompatible" with the conclusion that in fact he had GBS. Kinsbourne First Rep. at 4. However, since CIDP must in Dr. Kinsbourne's experience take at least two months to progress to nadir, the up-down, slow overall course of Mr. Strong's polyneuropathic symptoms better supported CIDP as the proper diagnosis. *Id.* at 4-5. Dr. Kinsbourne also gave some weight to the steroidal treatments Mr. Strong was receiving, since they proved effective, thereby reflecting CIDP as the appropriate diagnosis, since it is deemed appropriate for CIDP but not GBS; by contrast, whenever such treatments were abated, his symptoms resumed. *Id.* at 4.

In his first report, Dr. Kinsbourne also briefly mentioned Mr. Strong's HIV infection. He admitted that HIV could cause neuropathies, but asserted (without attribution) that it was "very rarely" associated with CIDP. Kinsbourne First Rep. at 7. He nevertheless acknowledged the existence of contemporaneous treater views connecting the HIV infection to Mr. Strong's polyneuropathy, allowing that it may have intensified his pain and injuries, but maintaining his position that the flu vaccine remained the more significant contributory factor. *Id.* at 7.

Dr. Kinsbourne's second expert report was filed in response to questions I had raised with the parties in light of Respondent's expert reports. The first issue raised was why the contemporaneous medical records did not reflect the proposed CIDP diagnosis. Dr. Kinsbourne responded by speculating that Petitioner's treaters may not have been aware of his more

[7] Re-challenge refers to the concept of an adverse event following vaccination, here the flu vaccine, which reoccurs after a subsequent dose, "suggesting, but not confirming, a causal association" with the vaccine. Vellozi, *et al.*, *Safety of trivalent activated influenza vaccine in adults: Background for pandemic influenza vaccine safety monitoring*, Vaccine 27: 2114-2120, at 2115 (2009).

immediate, post-vaccination symptoms, and therefore failed to take into account the true course of his illness. Kinsbourne Second Rep. at 1. He also stressed the fact that the effectiveness of the steroid treatments Petitioner received further bulwarked the conclusion that a CIDP diagnosis was more accurate. *Id.* However, Dr. Kinsbourne acknowledged that if Mr. Strong's symptoms were found to have begun no sooner than the winter of 2013 (and hence approximately four months post-vaccination) rather than when Petitioner alleges, his opinion that CIDP was the proper diagnosis in this case would be vitiated. *Id.*

Dr. Kinsbourne's second report also addressed the issue of the discovered HIV infection and its possible causal role in Petitioner's neuropathy – another question I raised in light of Respondent's expert opinions. Dr. Kinsbourne again acknowledged that both GBS and CIDP are associated with HIV. Kinsbourne Second Rep. at 2, *citing* Verma, A., *Epidemiology and Clinical Features of HIV-1 Associated Neuropathies*, J. of the Peripheral Nervous System 6: 8-13 (2001), filed on Nov. 17, 2016 as Ex. 13-c (ECF No. 28-3). But he otherwise referred back to his original opinion on this topic, declining to elaborate on why the HIV infection should be given less weight than the flu vaccine as a possible explanation for Mr. Strong's symptoms. He also made no mention of the two expert reports Respondent had filed, both of which (as discussed in greater detail below) included extensive discussion in favor of this alternative explanation. Kinsbourne Second Rep. at 2.

B. *Dr. Peter Donofrio*

Dr. Donofrio, one of Respondent's two expert witnesses, prepared two expert reports in this case. *See* Report, dated September 10, 2016, filed as Ex. A (ECF No. 22-1) ("First Donofrio Rep."); Report, dated February 24, 2017, filed as Ex. E (ECF No. 32-1) ("Second Donofrio Rep."). As his first report and CV (filed as Ex. B (ECF No. 23) ("Donofrio CV")) establish, Dr. Donofrio is a professor of neurology at the Vanderbilt University Medical Center. First Donofrio Rep. at 1. He received his B.S. at the University of Notre Dame, and then attended the Ohio State University School of Medicine for his M.D. He is board certified in neurology, internal medicine, electro-diagnostic medicine, and neuromuscular disorders. Donofrio CV at 2. He is experienced in treating peripheral neuropathies like GBS and CIDP, and is a member of organizations focusing on these kinds of neuropathic conditions. First Donofrio Rep. at 1. Among his publications is a textbook on the specific topic of peripheral neuropathy. Donofrio CV at 21.

Both of Dr. Donofrio's reports contained detailed review of Petitioner's medical history, for the purpose of substantiating his opinion that Mr. Strong's neuropathy (whether it was GBS or CIDP)[8] could not have begun before the summer of 2013 (or about ten months from the date

[8] Dr. Donofrio's opinion did not turn appreciably on the accuracy of the GBS diagnosis Petitioner received (especially given his overall conclusion that the preexisting HIV infection was more likely the cause of his neuropathy). Donofrio First Rep. at 9. He also agreed that, for present purposes, CIDP and GBS were analogous, although (as discussed

of vaccination). He saw no persuasive evidence of any neuropathy in December 2012 or January 2013, given the overall normal neurologic evaluations that Petitioner received at these times. First Donofrio Rep. at 9; Second Donofrio Rep. at 2. While GBS was included in Petitioner's differential diagnosis, treaters did not settle on that explanation until more persuasive results confirmed it. Petitioner also displayed no measurable weakness in his February 2013 doctor's visits. By contrast, Dr. Donofrio did not see until much later in the temporal record test results he would strongly associate with GBS or CIDP, such as areflexia or nerve conduction study results confirming the existence of demyelination.[9] First Donofrio Rep. at 8. And he found significant the fact that Petitioner received no medical care at all between May 23, 2013, and July 13, 2013 – a time gap he deemed inconsistent with CIDP, which (even though chronic and relapsing) would likely feature some occasions of discomfort or other symptoms in such a long timeframe. *Id.* at 10.

Dr. Donofrio discounted many of the items from the medical record cited by Dr. Kinsbourne in support of his proposed CIDP diagnosis. For example, Dr. Donofrio characterized record evidence from the winter of 2013 of complaints of weakness, or instances in which Petitioner expressed pain or displayed problems consistent with weakness (for example, his difficulty getting onto the examination table), as anecdotal or nonspecific. Second Donofrio Rep. at 1.[10] He took particular issue with Dr. Kinsbourne's emphasis of Petitioner's favorable response to steroid treatment as circumstantially corroborating a CIDP diagnosis. He noted that corticosteroids were prescribed for a variety of inflammatory but non-neurologic illnesses and conditions, and therefore their alleged effectiveness in this case did not necessarily corroborate the proposed CIDP diagnosis. *Id*. at 3. Indeed, in Dr. Donofrio's view, if Mr. Strong had actually suffered from CIDP, he would have expected a more muted response, rather than the dramatic improvement alleged. First Donofrio Rep. at 8.

Dr. Donofrio deemed vastly more significant the finding of Mr. Strong's treaters in July 2013 that he carried an HIV infection. As Dr. Donofrio explained, it is well understood in the medical community that neuropathies like GBS and CIDP are associated with HIV infections. First Donofrio Rep. at 7. In support of this opinion, Dr. Donofrio offered several items of medical or scientific literature. *See, e.g.,* A. Gabbai, et al., *HIV Peripheral Neuropathy,* 115 Handbook of Clinical Neurology 515-29 (3rd. Ser. 2013), filed as Ex. A-Tab 14 (ECF No. 23-4) ("Gabbai"); G. Schleicher, et al., *Effect of Human Immunodeficiency Virus on Intensive Care*

herein) he disputed some of the evidence cited by Dr. Kinsbourne (in particular, the alleged effectiveness of steroid treatments) to substantiate the conclusion that CIDP was the correct diagnosis.

[9] Nerve conduction studies (electroneurography) measure the functionality of peripheral nerves, which can identify damage in the nerves. *Dorland's* at 602.

[10] Dr. Donofrio also rejected evidence concerning a rash or skin problem Mr. Strong displayed in February as having no relevance to the neuropathic injuries at issue in this case. Second Donofrio Rep. at 2.

Unit Outcome of Patients with Guillain-Barré Syndrome, 31 Critical Care Medicine, 6:1848-50 (2003), filed as Ex. A-Tab 3 (ECF No. 22-4) ("Schleicher"); T. Brannagan, et al., *HIV-Associated Guillain-Barré Syndrome*, 208 J. Neurological Sciences, 39-42 (2003), filed as Ex. A-Tab 4 (ECF No. 22-5) ("Brannagan"). Gabbai in particular (a textbook chapter providing a review of the different types of peripheral neuropathies seen in connection with HIV infection) provided a thorough consideration of what is known about the connection, and observed that "AIDP[11] and CIDP occurring in HIV-positive patients are clinically and electrophysiologically indistinguishable from those occurring in HIV-negative individuals." Gabbai at 521.

Based upon Petitioner's overall course as revealed in the medical records, Dr. Donofrio proposed that Mr. Strong more likely than not was suffering from "HIV associated polyradiculopathy." First Donofrio Rep. at 8. Dr. Donofrio noted two things in particular from the record (besides the very fact of the infection itself) that he maintained corroborated his opinion. First, he observed that when Petitioner's CSF was tested in July 2013 (at the time the most medically-defensible GBS diagnosis was made, based upon the record) he displayed pleocytosis, a significant finding that is highly consistent with an HIV-derived neuropathy. *Id.* at 9; Brannagan at 1; Schleicher at 1850. Second, looking at Mr. Strong's pre-vaccination history, his recurring URIs and other infections were consistent with HIV immunosuppression (since it is highly likely that Petitioner's HIV infection predated his vaccination by some time). First Donofrio Rep. at 9-10.[12]

C. *Dr. Kathleen Collins*

Dr. Collins, like Dr. Donofrio, submitted two expert reports. *See* Report, dated July 21, 2016, filed as Ex. C (ECF No. 24-1) ("First Collins Rep."); Report, dated February 24, 2016, filed as Ex. F (ECF No. 33-1) ("Second Collins Rep."). Her opinion largely mirrored Dr. Donofrio's, although she added some additional details and viewpoints arising from her expertise in different medical topics.

Dr. Collins received her medical degree and doctorate from Johns Hopkins University School of Medicine (after receiving an undergraduate degree from Wellesley College) in 1993. Ex. D (ECF No. 25-10) ("Collins CV") at 1. She then completed her residency in internal medicine at Brigham and Women's Hospital before serving as a clinical fellow of infectious disease at Beth Israel Hospital and served as a research fellow at Harvard University. *Id*. Dr. Collins was also a post-doctoral fellow at MIT researching the immune response to viral

[11] AIDP is an acute inflammatory demyelinating polyradiculoneuropathy, and is a GBS variant. *Dorland's* at 1493.

[12] Dr. Donofrio also allowed in passing that these URI and other infections could themselves have been the source of Mr. Strong's neuropathy (First Donofrio Rep. at 10), although this suggestion is not favored over the HIV infection under Dr. Donofrio's interpretation of the record, and the record does not permit me to find this to be more likely than not.

infections. *Id*. Dr. Collins is board certified in infectious disease, and currently works as a professor of internal medicine and microbiology and immunology at the University of Michigan. *Id.* Her opinion in this case was based on review of the medical records, along with personal review of various medical or scientific literature. First Collins Rep. at 1.

Dr. Collins's first report included a review of Petitioner's medical history consistent with what is set forth above, along with a brief summary explanation for the diseases at issue. First Collins Rep. at 1-7. In particular, she observed that HIV is associated closely with GBS as well as other forms of peripheral neuropathy like CIDP, albeit usually in the earliest stages of the infection, before an individual has become immunocompromised. *Id.* at 7-8; Vriesendorp, *Pathogenesis of Guillain-Barré Syndrome,* UpToDate, Wolters Kluwer Health (2015), filed as Ex. C-2 (ECF No. 24-9). Nevertheless, she maintained, HIV-associated neuropathies can also occur on the discontinuation of antiretroviral medication (although Dr. Collins relied on case study reports for this assertion). First Collins Rep. at 7, *citing* G. de Castro, *et al.*, *Episodes of Guillain-Barré Syndrome Associated with the Acute Phase of HIV-1 Infection and with Recurrence of Viremia,* Arquivos De Neuro-psiquiatr, 64(3A), 606-8 (2006) filed as Ex. C-8 (ECF No. 24-3). She also proposed that the medical record evidence (which in her view most strongly supports Petitioner's neuropathy as having begun in July 2013) supported the timeframe in which his neuropathy manifested due to the HIV infection as medically appropriate. First Collins Rep. at 8-9.

Dr. Collins emphasized several factual points that she maintained corroborated Respondent's position that Mr. Strong's neuropathy was far more likely attributable to his HIV infection than to the flu vaccine. She agreed with Dr. Donofrio as to the significance of pleocytosis as corroborating the causal association in this case between the HIV infection and Mr. Strong's neuropathy. First Collins Rep. at 9. She also maintained that Petitioner's symptoms (transient decreased reflexes, bilateral lower extremity pain, and the gradual onset) were more consistent with what is known about HIV neuropathies, while not appearing to fit the classic clinical definition of GBS. First Collins Rep. at 9; *see also* Second Collins Rep. at 2. She similarly found significant Petitioner's responsiveness to gabapentin, which she maintained is more effective for HIV-caused neuropathies than GBS. First Collins Rep. at 9; Hahn, K., *et al.*, *A Placebo-Controlled Trial of Gabapentin for Painful HIV-Associated Sensory Neuropathies,* J. Neurology 251(10), 260-6 (2004), filed as Ex. F.3 (ECF No. 33-4).

In addition, when Petitioner's treaters first began to evaluate his symptoms in the winter of 2013 (at which time his underlying HIV infection was unknown), they resisted embracing a GBS diagnosis, acknowledging the lack of fit between his presentation and what is commonly understood to be the proper clinical indicia for GBS. First Collins Rep. at 8. Dr. Collins found this particularly significant. To establish the accepted GBS criteria, she cited Loughlin. First Collins Rep. at 9; Second Collins Rep. at 2. Comparing those criteria to the facts, Dr. Collins observed that at the time Mr. Strong first purportedly began to experience neuropathic symptoms

in the winter of 2013, he lacked "preferential defects in motor over pain" symptomology (the second Loughlin criterion), and displayed no areflexia or hyporeflexia (the third criterion). Loughlin at 2. He also displayed worse symptoms at night. Dr. Collins opined that these differences were evident consistently in the medical record between November 2012 and May 2013, bulwarking the conclusion that his neuropathy was not GBS but an HIV-associated neuropathy. Second Collins Rep. at 2.

The remainder of Dr. Collins's reports were devoted to attacking assertions made by Dr. Kinsbourne.[13] For example, she opined that the relationship between an HIV infection and neuropathy was far stronger than Dr. Kinsbourne allowed. First Collins Rep. at 9. By contrast, she disputed Dr. Kinsbourne's proposal (carried forward by Petitioner more generally) that an HIV infection would merely exacerbate a neuropathy with a different etiology, rather than be the actual source of it, noting the lack of literature supporting that proposal. First Collins Rep. at 9. She also questioned Dr. Kinsbourne's assumption that Mr. Strong's responsiveness to steroids corroborated his proposed CIDP diagnosis, arguing that this treatment's effectiveness under the circumstances equally supported her counter-proposal that Petitioner's symptoms were derived from his HIV infection. *Id*. And she stressed that gabapentin (known to be effective in treating an HIV neuropathy) was in fact successfully administered in this case. *Id*.

III. Procedural History

As noted above, this case was initiated in October 2015. Petitioner thereafter began filing medical records, completing the process to the satisfaction of both sides by the end of March 2016. Respondent subsequently filed a Rule 4(c) Report on May 21, 2016, contesting the appropriateness of an entitlement award (*see* ECF No. 14). Before a status conference could be held, Petitioner filed Dr. Kinsbourne's first expert report,[14] and I in turn ordered Respondent to file reports of his own in reaction. Drs. Collins's and Donofrio's reports, plus medical literature, were thereupon filed on September 14, 2016 (ECF Nos. 22-25).

Not long after, I held a status conference with the parties on September 26, 2016, at which

[13] In a few instances, Dr. Collins makes erroneous factual assertions, or presents arguments that are not well-accepted in the Vaccine Program (even if they possess scientific validity). For example, she mistakenly says "no" physician ever proposed CIDP as a possible diagnosis, despite the fact that Dr. Grunsfeld did in fact include it in his differential diagnosis. First Collins Rep. at 8. She also devotes some time attempting to rebut the concept that the flu vaccine is reasonably associated with peripheral neuropathies like GBS or CIDP, as well as the proposed mechanisms by which it is theorized the vaccine could produce an autoimmune response (*Id.* at 9-11), despite an abundance of Program case law going the other way on this issue. These aspects of Dr. Collins's reports did not, however, color my overall reading of her opinion, especially since the case turned more on the significance of the preexisting HIV infection – a topic such statements did not bear upon–as well as the record facts of Mr. Strong's medical history.

[14] As the docket reveals, Petitioner initially filed Dr. Kinsbourne's first report on June 5, 2016 (ECF No. 15), but at the request of Petitioner it was stricken and refiled in August in order to be in compliance with the Vaccine Program filing guidelines. *See* ECF Nos. 18 (Order granting Motion to Strike, dated Aug. 19, 2016), and 20 (refiled First Kinsbourne Rep.).

time I expressed my concerns about the strength of Petitioner's claim in light of Respondent's expert reports, along with the medical record. I ordered him to file a supplemental expert report from Dr. Kinsbourne, and he did so on November 21, 2016 (ECF No. 28). This generated a second round of supplemental expert reports from Respondent's two experts, filed on March 7, 2017 (ECF Nos. 32-33). I thereafter proposed, by Order dated March 15, 2017 (ECF No. 34), that the parties consider allowing me to resolve this case on the papers in light of the nature of the questions raised rather than by hearing, and they accepted my proposal. *See* March 31, 2017 Joint Status Report (ECF No. 35). I set a briefing schedule that (after one request to extend the relevant deadlines) was completed by mid-August of this year. The matter is now fully ripe for resolution.

IV. Parties' Respective Arguments

Petitioner filed his brief in support of a ruling on the record on June 5, 2017. Memorandum in Support of Motion for Ruling on the Record (ECF No. 38) ("Mot."). In it, he argues that Dr. Kinsbourne's opinion, bulwarked by the various supporting pieces of literature filed as well as his reading of the medical record, established all of the three prongs required of claimants by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioner's motion first provides his own reading of the medical records. He emphasizes his allegations of onset of neuropathic symptoms in one to two weeks after vaccination. Mot. at 1-2, 6-7. He acknowledges that the first medical record of any problems that could be arguably attributed to a neuropathy are from February 2013 (when leg pain is reported), but notes that the absence of other symptoms that would render a GBS or CIDP diagnosis more conclusive should not be given great weight, given that tests specific to these conditions were not performed at that time. *Id.* at 2-3. He also purports (as per Dr. Kinsbourne's opinion) that the steroid treatments he was then receiving may well have suppressed his symptoms. *Id.* at 2. But the July 2013 records do contain a reference to CIDP (contrary to Dr. Collins's assertion) in addition to GBS. *Id.* at 3. To the extent treaters did not take into account Mr. Strong's overall course (and in particular whether the timeframe from alleged onset to acuity was reasonable), it was because they did not have the benefit of the review of the entire record. *Id.*

Petitioner also endeavors to diminish the significance of his inadvertently-discovered preexisting HIV infection. He argues that (based on records from July 2013) it is likely that the HIV infection merely exacerbated his vaccine-caused GBS, rather than was the cause of it. Mot. at 4, *citing* Ex. 6 at 75. He stresses the importance of Dr. Adams's initial view that GBS alone was the source of Petitioner's symptoms. *Id.* at 4. And he observes that treaters (aware of his HIV diagnosis) nevertheless recommended that he not receive vaccinations in the future, thus suggesting they placed greater weight on the vaccine's causality than the HIV infection. *Id.* at 4-5, *citing* Ex. 8 at 51.

Relying on the foregoing, Petitioner maintains that he has carried his *Althen* burden. He proposes that the association between the flu vaccine and peripheral neuropathies like GBS or CIDP is well-supported by both medical literature and the decisions of the Vaccine Program. Mot. at 5. He argues that Petitioner's course, as Dr. Kinsbourne opined, is consistent with a CIDP diagnosis, and that the medical record establishes that treaters considered this a valid explanation. *Id.* at 5-6. The HIV infection, by contrast, is at best a co-factor that exacerbated Petitioner's neuropathy but did not primarily cause it. *Id.* at 5, 7, and 9. And the timing of his onset, considered in the context of his overall disease progression, is consistent with Dr. Kinsbourne's opinion regarding CIDP. *Id.* at 8-9.

Respondent's opposition brief requests dismissal of the case entirely. Response, dated August 4, 2017 (ECF No. 39) ("Opp."). Respondent primarily[15] bases his position on the contention that Petitioner suffered not from CIPD but instead from an HIV-caused neuropathy. Opp. at 21. Respondent disputes the validity of Petitioner's assertion that he first experienced symptoms in the fall of 2012 (something Dr. Kinsbourne's opinion is admittedly reliant upon). *Id.* at 18-19, 25-26. In Respondent's view, however, the medical records do not support a CIDP diagnosis, but instead are consistent with a more general HIV neuropathy. *Id.* at 21, 24. Petitioner has otherwise failed to establish that the flu vaccine played a more contributory role in causing his neuropathy, whatever it was, than his preexisting HIV infection. *Id.* at 24-25. And the timing of his symptoms (assuming they did not begin in the fall of 2012 as alleged) is not sufficiently medically acceptable to be linked to his flu vaccination. *Id.* at 25-26.

Petitioner filed a succinct reply on August 11, 2017. Reply (ECF No. 40). In it, he largely summarizes his prior arguments, but gives particular emphasis to the "overlap" between the HIV infection and allegedly causal role of the flu vaccine for his neuropathic symptoms. Reply at 2. He questions whether the HIV infection could be deemed primarily causal, since it predated the flu vaccine and therefore should have caused similar symptoms long before. *Id.* at 2-3. Characterizing the infection and the vaccine as "two snakes" that had bitten him, Petitioner maintains that the interplay between the two and their effects on his heath cannot be easily separated, but that the standards of the Vaccine Program require that he receive the evidentiary "benefit of the doubt" in favor of a causation determination. *Id.* at 3.

V. Relevant Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table –

[15] Respondent also argues that Petitioner has not met her *Althen* prong burdens, and reviews each individually. Opp. at 21-26. As noted below, however, not all of these prongs are integral to my resolution of this case, regardless of whether they were satisfied.

corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that her illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[16] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "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*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature,

[16] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

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*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *appeal docketed*, No. 2015-5097 (Fed. Cir. June 19, 2015). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[17]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). 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 1367; *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 v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views 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. 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

[17] There is ample contrary authority for the more straightforward proposition that the first *Althen* prong, like the overall test itself, simply applies a preponderance standard when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). For purposes of the present analysis, I am stressing those cases focusing on the *plausibility* of the causal theory proposed, as opposed to whether preponderant evidence supports it, in order to avoid imposing on Petitioners a greater evidentiary burden than the law requires. This does not, however, change the fact that *any* theory's plausibility, for purposes of satisfying the *Althen* test, is properly analyzed by subjecting its components to the *Daubert* tests for scientific reliability. *Terran v. Sec'y of Health & Human Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999).

be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* 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." *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.*, 2013 WL 1896173 (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).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are

presumed to be accurate and "complete" (*i.e.*, presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must

subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act"). It is in the exercise of my duties as a special master to weigh competing expert testimony. *Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 6947389, at *5 (Fed. Cl. Oct. 20, 2016) ("Special Masters may use their discretion in weighing expert testimony, and case law supports that discretion").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert offers an opinion that exceeds his training or competence. *Walton v. Sec'y of Health & Human Servs.*, No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I heard and have considered all of the testimony of the experts offered at the entitlement hearing, I may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g., King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, including some articles (such as those discussing molecular mimicry and protein sequences in vaccines) that do not factor into the outcome of this decision. I have reviewed all of the medical literature submitted in this case, but I only discuss those articles that are most relevant to my determination and/or are central to Petitioners' case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs.*, 527 F. App;x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to — and likely undermines — the conclusion that it was not considered").

E. *Ruling on the Record*

The parties accepted my proposal to determine entitlement based on written submissions and evidentiary filings, including both side's expert reports, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide

petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns,* 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

F. *Law on "Substantial Factor" Analysis*

In this case, the parties disagree as to the relative effects of two indisputable factors – the preexisting HIV infection and Petitioner's flu vaccination – in causing his neuropathic symptoms. The Court of Federal Claims has recognized that "when two forces act in concert," it is appropriate to apply the "substantial factor" test first set forth in the Federal Circuit's *Shyface* decision, and evaluate *not* what cause predominates, but whether the vaccine can be deemed a "substantial" cause. *Heinzelman v. Sec'y of Health & Human Servs.,* No. 07-01V, 2008 WL 5479123, at *4 (Fed. Cl. Dec. 11, 2008); *see also Walther v. Sec'y of Health & Human Servs.,* 485 F.3d 1146, 1151 n.41 (Fed. Cir. 2007). *Shyface* predates the Federal Circuit's enunciation of the *Althen* test in 2005, and it has been noted that *Althen* largely subsumes it within its three-prong test (and therefore the two tests are not inconsistent). *Deribeaux v.Sec'y of Health & Human Servs.*, 105 Fed. Cl. 583, 590 (2012), *aff'd,* 717 F.3d 1363 (Fed. Cir. 2013).

Nevertheless, in cases such as the present, in which joint causes may plausibly explain the same disease or condition, the *Shyface* version of the Vaccine Program standard provides a more exact standard for measuring a claimant's success. *Heinzelman,* 2008 WL 5479123, at *2-4 (applying *Shyface* to demonstrate a lack of joint factors). "Substantial" has been defined as a factor "that falls somewhere between causing the injury to a non-negligible degree and being the 'sole or predominant cause.'" *Deribeaux,* 105 Fed. Cl. at 595. I will utilize this standard in evaluating whether the flu vaccine can in this case be deemed a "substantial factor" in injuring Petitioner.

ANALYSIS

I. *Petitioner's HIV Infection was a More Likely Cause of his Injuries than the Flu Vaccine*

In resolving Vaccine Program cases, it is not within the special master's domain to propose a correct diagnosis for a given injury or disease. *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249–50 (Fed. Cir. 2011); *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1351 (Fed. Cir. 2011); *Broekelschen,* 618 F.3d at 1345; *Andreu,* 569 F.3d at

1382; *Althen*, 418 F.3d at 1277 n. 4, 1280–81. Rather, special masters should evaluate what determination the *evidence* best supports – and if that same evidence does not allow for the conclusion that the injury is vaccine-related, then the petitioner cannot prevail, even if the actual cause of a claimant's injuries remains unknown. *Andreu*, 569 F.3d 1367, 1380.

Here, the record evidence better supports the conclusion that Mr. Strong's neuropathic symptoms, regardless of how they are classified, were more likely related to his HIV infection rather than vaccination. The fact of the preexisting infection, discovered around the time of Petitioner's most acute symptoms in July 2013, is indisputable,[18] and it is highly likely as well that it long predated his September 2012 flu vaccination. Moreover, Respondent's experts persuasively demonstrated a high association between HIV and neuropathic symptoms much like Petitioner experienced. Gabbai at 521. Dr. Kinsbourne was hardly able to deny this showing, and did not endeavor to do so, acknowledging the known association between HIV and CIDP yet disavowing a connection in conclusory fashion, without reference to his own experience, or medical or scientific evidence, that would bulwark his view. *See* Second Kinsbourne Rep. at 2.

Certain facts in the medical history are favorable to Petitioner's position, but an overall, comprehensive consideration of the record better supports the conclusion that his neuropathy was connected with his HIV infection. As Respondent's experts underscored, a number of test results or clinical symptoms experienced by Petitioner are more consistent with an HIV-caused neuropathy than GBS or CIDP linked to the flu vaccine. They persuasively established that pleocytosis would not be viewed as a finding associated with GBS normally, while at the same time Petitioner (at least when his symptoms first manifested in February) lacked the classic presenting indicia of GBS, like areflexia or weakness and parasthesias (as opposed to the pain he complained of at that time). First Donofrio Rep. at 8-9. In addition, and relying on the same factors, Petitioner's treaters leaned to an interpretation of the medical history that embraced the HIV infection as the source of his symptoms; no treater, by contrast, identified the flu vaccine as causal.

Petitioner was unable to rebut the above by arguing that his injuries may have been initially caused by the vaccine but were exacerbated by the underlying, preexisting infection. This assertion is not supported by any persuasive evidence – in the form of reliable scientific or medical literature, or testimony from Dr. Kinsbourne arising from his own expertise with peripheral neuropathies – that an undiscovered, likely subclinical HIV infection could lay

[18] I note that the same literature also suggests that an HIV-associated neuropathy would usually begin before an infection's immunosuppressive stage – meaning several weeks after the infection, when the antibodies are first produced and rising to detectable levels, and also before the patient is prescribed anti-retroviral treatments. Gabbai at 521. Thus, it is possible that if Mr. Strong's infection long predated his vaccination, the likelihood that the infection was still associated with the neuropathic symptoms would be diminished. However, the record does not allow me to conclude *when* that infection began, thereby preventing a determination that too long a time passed to deem the HIV infection a more likely cause. And as discussed below, Petitioner did not otherwise establish that the vaccine was a substantial factor in causing his injuries regardless of the HIV infection's role.

dormant and then interact later with a vaccine-caused neuropathic injury, and/or that any HIV-caused neuropathy was aggravated by the flu vaccine.[19] And Petitioner did not demonstrate instances from the medical record to corroborate that this was in fact what he experienced.

My analysis does not change if I apply the "substantial factor" analysis set forth in *Shyface*, and consider whether the vaccine was significant to Petitioner's injuries even if the HIV infection is conceded to also have played a role. Petitioner has not demonstrated that the vaccine played *any* role in his injuries, given (as discussed below) the long temporal period between vaccination and first corroborated onset of symptoms, and the inconsistencies between his own allegations of onset and what the record establishes, and I therefore cannot even reach the point of concluding that both acted "in concert." The strong correlation between HIV infection and neuropathies, coupled with the record evidence suggesting the nature of Petitioner's presentation (along with certain lab results more associated with an HIV-caused neuropathy than a typical case of GBS) further diminish any role the flu vaccine might have played in Petitioner's injuries. I therefore need not disentangle the impact of the vaccine from the more likely impact of the HIV infection.

II. *Althen Prongs Analysis*

In order to explain in the clearest manner possible how my findings impact Petitioner's success in establishing causation, I shall briefly review how the evidence applies to each of the three *Althen* prongs.

A. *Althen* Prong One

Petitioner in this case successfully established what is often referred to as the "can cause" prong. There are many persuasive decisions discussing the association between GBS and the flu vaccine. *See, e.g., Stitt v. Sec'y of Health & Human Servs.,* No. 09-653V, 2013 WL 3356791 (Fed. Cl. Spec. Mstr. May 31, 2013); *Stewart v. Sec'y of Health & Human Servs.*, No. 06–777V,

[19] Although Petitioner has not so alleged, Program claimants can obtain an entitlement award based upon the claim that a vaccine significantly aggravated a preexisting condition. To do so, and in addition to proving the three *Althen* prongs, petitioners must also show "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), [and] (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination." *See Loving v. Sec'y of Health & Human Servs.,*No. 02-469V, 2009 WL 3094883, at *2 (Fed. Cl. Spec. Mstr. July 30, 2009), *recons. granted in part on other grounds*, 2010 WL 1076124 (Fed. Cl. Spec. Mstr. Mar. 2, 2010). At its simplest, the question is "but for" the vaccine, would the petitioner's condition have been as severe as it was with the vaccine. *Id*. at *11.

Here, although Mr. Strong has not formally alleged a significant aggravation claim, some of his arguments could be interpreted to propose a similar theory—that Petitioner's HIV infection would not have resulted in the neuropathy that he now experiences had he never received the flu vaccine. But neither the evidence nor Petitioner's expert reports support this theory of recovery. The overall record would not allow the conclusion that Mr. Strong's neuropathy would not have been as severe but for the vaccine, given the weak relationship between that vaccination and his subsequent health problems, plus the lack of treater support identifying the vaccine as causal in any way.

2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011); *see also Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557 (Fed. Cl. Spec. Mstr. Nov. 12, 2014). Although I do not embrace Dr. Kinsbourne's suggestion that CIDP is little more than GBS with a longer course,[20] there is no doubt that both are related peripheral neuropathies characterized by a number of common symptoms – as well as a common pathogenesis, with one having a more chronic course. Accordingly, the large and persuasive body of evidence (and well-reasoned decisions of special masters past and present) noting the reliable connection between the flu vaccine and GBS has applicability herein even if CIDP were the correct diagnosis.

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

B. *Althen* Prong Two

A threshold question presented by the "did cause" analysis in this case is whether Petitioner had CIDP (Dr. Kinsbourne's favored diagnosis). Petitioner's overall course was characterized by some purported initial symptoms; a several-month dormancy period; and then a relapse in February, later progressing to his July hospitalization. Dr. Kinsbourne agrees that this course was too long and halting to meet the clinical criteria for GBS, a disease characterized by acute symptoms that resolve quickly. Second Kinsbourne Rep. at 1 ("[i]f the Court affirms Mr. Strong's account, then the diagnosis of GBS is ruled out"). He instead proposes CIDP was the correct diagnosis, relying on (a) the immediate symptoms, (b) the longer, stop-start course, (d) Petitioner's seemingly favorable response to steroidal treatments, and (d) some limited treater support for the alternative diagnosis from the summer of 2013, when Petitioner's symptoms were obvious enough to cause treaters to embrace GBS as a credible diagnosis for the first time. *Id*.

Dr. Kinsbourne's proposed alternative diagnosis is a reasonable interpretation of the record (putting aside whether I accept Petitioner's early onset allegations), and also accords with what is known about the relapsing/remitting character of CIDP. *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *21-23 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). Yet, even if there is record support for Dr. Kinsbourne's position, it is difficult to discern in the record *what* final diagnosis for Mr. Strong's symptoms is best supported by the evidence. Most of the treater

[20] I have previously discussed in detail the differences between GBS and CIDP. *See, e.g., Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *21-23 (Fed. Cl. Spec. Mstr. Jan. 9, 2015) ("CIDP and GBS represent two separate (if related) conditions rather than opposing points on the same disease spectrum—and that as such it would be incorrect to view CIDP simply as a chronic form of GBS").

notes from the winter of 2013 characterized his condition as GBS or at least like it. *See, e.g.*, Ex. 10 at 4-11; Ex. 7 at 38-40, 70-72; Ex. 8 at 1-11, 13-23. But those views did not take into account Mr. Strong's current assertions of an earlier onset closer in time to the vaccine administration (and the fact that these alleged symptoms appear not to have been mentioned to treaters cuts against accepting them as accurate). Also, as Respondent's experts observed, Petitioner's presentation was in many ways *inconsistent* with GBS (for example, the lack of areflexia), while being more consistent with an HIV-derived neuropathy. First Donofrio Rep. at 8. And as noted above, various testing results were also more consistent with an HIV-caused neuropathy than a vaccine-induced GBS.

Later, some references to CIDP can be found in the record from around the time that Petitioner sought urgent care for his symptoms in July 2013. *See,* Ex. 6 at 79, 149-150. Ordinarily, such treater opinions would be important in evaluating if preponderant evidence supported one diagnosis over an alternative. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326. But at best, this record reveals that treaters merely included CIDP as part of a differential diagnosis – they never fully embraced it later, even as the record of Petitioner's treatment and responses continued to unfold. There is better evidence supporting the conclusion that treaters ultimately associated Petitioner's symptoms with his HIV infection. *See, e.g.*, Ex. 6 at 105, 115-16. And there is *nothing* in the record in which a treater proposes that the flu vaccine had anything to do with Mr. Strong's illness.

This highlights a more fatal problem with Petitioner's claim when his theory is evaluated in light of the record. Dr. Kinsbourne forthrightly acknowledged that his proposed CIDP diagnosis hinges upon the acceptance of Petitioner's after-the-fact assertions about onset of symptoms beginning in the fall of 2012. Second Kinsbourne Rep. at 2 ("[i]f the Court issues a finding to the effect that Mr. Strong's symptoms began no earlier than January 2013, then my diagnosis of CIDP would be inapplicable *and so would my opinion as to vaccine causation*") (emphasis added). But I do not find that those assertions, uncorroborated as they are by circumstantial evidence, should be credited.[21] Rather, I determine herein that Mr. Strong's neuropathic symptoms in fact began no sooner than February 2, 2013, based upon his assertions to Dr. Sylvester at a February 5th visit that his leg pain had begun around three days before (but over four months from the date of vaccination). Ex. 7 at 30-31. Mr. Strong repeated such onset claims to Dr. Adams in July 2013. Ex. 6 at 76. Medical records, as noted above, are entitled to presumptions of truthfulness in the Program, and Petitioner has not established a basis for finding otherwise in this case. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326.[22]

[21] Mr. Strong's preexisting health problems – CODP plus a lung mass that appears to have caused him considerable anxiety – may better explain any physical symptoms he experienced closer in time to the vaccination, although I do not herein determine any explanation for these alleged symptoms.

[22] Dr. Kinsbourne's written admission on the scope of his opinion is not the only reason for me to reject his proposed diagnosis. I note as well that literature submitted by the parties regarding CIDP also suggests that the condition would

Accordingly, I do not find sufficient preponderant evidence exists in this case to support Petitioner's contention that the flu vaccine "did cause" him to experience CIDP. Petitioner has not established a "logical sequence of cause and effect," because the time period that passed from vaccination to initial neuropathic symptoms reflected by the record is too attenuated. Vaccine-caused GBS is also ruled out for much the same reason. Rather, as noted above, Petitioner's preexisting HIV infection was a more likely causal factor than a vaccine received more than four months before initial symptoms began, and various testing results are more corroborative of HIV as the source of Mr. Strong's symptoms than a vaccine-induced injury. And there is no treater support at all for the conclusion that the vaccine was connected to Mr. Strong's various neuropathic symptoms, while there is ample support for the conclusion that his symptoms stemmed from his HIV infection.

C. *Althen* Prong Three

Matters discussed above are relevant to why I do not find herein that Petitioner has established sufficient preponderant evidence supporting the conclusion that the timing of his post-vaccination illness was medically acceptable. As noted, I find that onset of his neuropathic symptoms began no sooner than February 2013 – too long, by Dr. Kinsbourne's admission, after vaccination to be reliably associated with a flu vaccine-caused GBS or CIDP. The preexisting HIV infection compounds this analysis, and Petitioner has failed to persuasively explain why it should be given less causal weight than the later-in-time vaccination. And literature filed in the case otherwise was consistent with Dr. Kinsbourne's admission about the most medically acceptable onset for CIDP after vaccination. P. Kelkar, *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) with Rapid Progression after Influenza Vaccine*, J. of Clinical Neuromuscular Diseases 8:20-25 (2006), filed as Ex. 12-f (ECF No. 20-7).

CONCLUSION

A Program entitlement award must be supported by a preponderant evidentiary showing. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation under the Vaccine Program.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

initially present within at least four weeks of initial insult, whether by vaccine or infection. P. Kelkar, *Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) with Rapid Progression after Influenza Vaccine*, J. of Clinical Neuromuscular Diseases 8:20-25 (2006), filed as Ex. 12-f (ECF No. 20-7). The onset of symptoms herein (more than 16 weeks) vastly exceeds that period.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master