In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 24, 2020

To be published

MICHAEL BAILEY JR., *Administrator of the Estate of* MICHAEL BAILEY SR.,	*	No. 15-1417V
Petitioner,	*	
v.	*	Dismissal; Influenza Vaccine; Amyotrophic Lateral Sclerosis ("ALS"); Insufficient Proof of Causation.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Braden A. Blumenstiel, Blumenstiel Falvo, LLP, Dublin, OH, for Petitioner.
Colleen C. Hartley, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

Oler, Special Master:

On November 23, 2015, Michael Bailey Sr. ("Mr. Bailey")[2] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10,

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

[2] Mr. Michael Bailey Sr., the original petitioner in this case, passed away. His son, Mr. Michael Bailey, Jr. elected to continue the prosecution of the estate's claim. For ease of reference, I will refer to Mr. Michael Bailey Sr. as Mr. Bailey, and Mr. Michael Bailey, Jr. as Petitioner.

et seq.[3] (the "Vaccine Act" or "Program"). The petition alleges that Mr. Bailey's "doctors have diagnosed [him] with ALS" yet he "has every symptom associated with Guillain-Barre Syndrome" which was proximately caused by his flu vaccine, administered on December 12, 2012. *See* Petition (Pet.) at 2-3, ECF No. 1.

Upon review of the evidence submitted in this case, I find that Petitioner has failed to carry his burden showing that he is entitled to compensation under the Vaccine Act. In particular, Petitioner has failed to show that Mr. Bailey's injury and subsequent death were caused by the vaccination he received. The petition is accordingly dismissed.

I. Medical Records

Mr. Bailey was born in 1954. He was 58 years old on December 12, 2012, when he received the allegedly causal flu vaccination. Petitioner's Exhibit ("Ex.") 16 at 1-3.

A. Mr. Bailey's Medical History Prior to the Flu Vaccination

Mr. Bailey's medical history is significant for a diagnosis of right carpal tunnel syndrome in the months immediately prior to the vaccination. He reported numbness, tingling, and loss of grip strength in his right hand to his orthopedist, Dr. Matthew Kay, on October 30, 2012. Ex. 12 at 4. He told Dr. Kay that the symptoms had been present for years but had been slowing worsening over the last several months. *Id*. Bilateral wrist x-rays were normal and Dr. Kay's clinical impression was right carpel tunnel syndrome. *Id*. Dr. Kay performed a right carpal tunnel release on Mr. Bailey on November 12, 2012. Ex. 10 at 11. Dr. Kay examined Mr. Bailey on November 20, 2012 and noted a stable appearance with little or no pain reported and improved sensation in fingers. Ex. 12 at 8.

B. The Flu Vaccination and Mr. Bailey's Subsequent Medical History

After receiving his flu vaccination on December 12, 2012, Mr. Bailey did not seek medical care until January 8, 2013 when he presented to the Robinson Memorial Hospital emergency room for lacerations from a tripping incident. Ex. 10 at 12. He reported that he was walking and tripped over some wood, striking his right ear against the corner of a plastic piece. *Id.* According to the ER report, Mr. Bailey denied headache, dizziness, and neck pain. *Id.* He reported no numbness or tingling in his extremities. *Id.*

Mr. Bailey returned to the emergency room on April 16, 2013, almost four months after the flu vaccination. He described stroke-like symptoms including right upper extremity weakness, slurred speech, right facial drooping, and balance issues. Ex. 10 at 44. He reported the symptoms occurring since at least January 2013. *Id.* at 45. An MRI of the brain showed an old hemorrhage and his labs were mostly within normal limits. *Id*. The ER doctor attributed the symptoms to a

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

cerebrovascular accident and recommended follow up with a neurologist or his primary care provider ("PCP"). *Id.*

On April 29, 2013, Mr. Bailey presented to his PCP, William Raux, D.O., with complaints of weakness in his extremities and slow speech. Ex. 10 at 30. Dr. Raux ordered tests and arranged for Mr. Bailey to see a neurologist, Hugh Miller, M.D. *Id*. at 35. Dr. Miller examined Mr. Bailey on April 30, 2013 and noted that he had a flu vaccination in December and progressive right sided weakness since February. Ex. 17 at 2. Dr. Miller recommended a follow up appointment after further testing. *Id.* at 4.

Mr. Bailey tripped again on May 3, 2013, this time hitting his chin. He reported to the ER for treatment of a laceration to his left upper lip. Ex. 10 at 55. Mr. Bailey was scheduled for a cervical spine MRI and MRA of the head on the same day; the results were normal. *Id*. at 57-59.

On May 13, 2013, Mr. Bailey underwent a nerve conduction study ("NCS") that was suspicious for early motor neuron disease. Ex. 10 at 60-61. On May 15, 2013, Dr. Miller advised Mr. Bailey that the NCS, EMG, and physical examination all suggested amyotrophic lateral sclerosis ("ALS"). *Id*. at 8. Dr. Miller recommended Mr. Bailey get a second opinion and referred him to the Cleveland Clinic. *Id.*; Ex. 8 at 1.

Mr. Bailey presented to the Neuromuscular Center at the Cleveland Clinic Neurological Institute on August 29, 2013. Ex. 8 at 1. Melanie Taylor, M.D. took a history from Mr. Bailey who stated his symptoms started in November 2012 after a flu shot. *Id.* at 2. He said he "felt ill" for three weeks after the vaccination with heart palpitations, diarrhea, and headache. *Id.* Later he noticed progressive right extremity weakness and by February 2013, he was experiencing frequent falls. *Id.* Within the next few months, he had weakness in the left side with progressive muscle atrophy of both shoulders, chest, and back. *Id*. Since February, his family noticed "muscle twitches" in his arms and legs. *Id*. In March or April 2013, his speech worsened, becoming quieter and more slurred. *Id.* He described dysphagia that was worse with solids. *Id.* at 3. He also reported symptoms such as shortness of breath on exertion and while talking as well as minor memory loss, depressed mood with "surges of emotions," mild numbness/tingling in feet, and mild low back pain. *Id*. Dr. Taylor noted that he had a history of right carpal tunnel syndrome ("CTS") and that he stated that he developed right hand weakness two years ago and was told it was CTS. *Id*.

Dr. Taylor examined Mr. Bailey and determined that the findings were consistent with a probable motor neuron disease ("MND"), including ALS. Ex. 8 at 6. Erik Pioro, M.D., Ph.D., FRCPC, is the ALS and Related Disorders Section Director and he agreed with Dr. Taylor's assessment and recommendation for further evaluation. *Id.* at 7.

After further testing to exclude other causes of motor neuron degeneration, Mr. Bailey returned to Dr. Taylor on September 23, 2013. Dr. Taylor confirmed a final clinical diagnosis of right upper extremity onset ALS. Ex. 8 at 38. Dr. Taylor wrote the following:

> Now that all the additional investigations have been completed, the final clinical diagnosis is right upper extremity-onset ALS. Because of the extent of upper motor

> neuron (UMN) and lower motor neuron (LMN) abnormalities at present, he meets the World Federation of Neurology El Escorial diagnostic criteria of probable ALS. There are combined upper motor neuron (UMN) and lower motor neuron (LMN) abnormalities at cervical and lumbosacral levels, with evidence of UMN signs in the bulbar region; by EMG here, LMN changes are not seen in thoracic myotomes. The clinical diagnosis of ALS is certain.

Id. Dr. Pioro agreed with the diagnosis and the proposed treatment plan, which included continuing Riluzole, the only FDA-approved prescription medication for the treatment of ALS. *Id*. at 38-39.

On August 23, 2013, Mr. Bailey started physical therapy and continued attending once or twice weekly until January 2014. Ex. 9 at 2. He discontinued physical therapy due to progressive physical limitations. *Id*. By March 2014, Mr. Bailey required the use of a power wheelchair for all mobility, positioning, and pressure relief needs. Ex. 8 at 50. He no longer had the ability to communicate except through an eye gaze communication device. *Id*. at 55.

Mr. Bailey had significantly worsened by July 23, 2014 when he returned to the ALS Clinic at Cleveland Clinic. Ex. 8 at 58. His swallowing was worse with choking, his upper extremity function was non-existent, and he was having breathing problems. *Id.* at 59. He required the placement of a PEG feeding tube on August 28, 2014 due to an inability to swallow. Ex. 10 at 66-67.

On December 17, 2014, Roswell Dorsett, D.O. examined Mr. Bailey and noted that his ALS had progressed to a quadriparesis. Ex. 14 at 3. He had a PEG tube in place and used a BiPAP at night. He was unable to speak. *Id.* Dr. Dorsett saw Mr. Bailey again on March 18, 2015 and noted his MRI showed no change from the prior study. *Id.* at 1.

Mr. Bailey continued to decline and passed away on July 28, 2017.

II. Affidavits

A. Affidavit of Michael Bailey

Mr. Bailey's wife signed his affidavit on his behalf on September 14, 2015. Ex. 1 at 8. Mr. Bailey stated that he enjoyed good health throughout his life. *Id.* at 1. For the last 20 years before the affidavit was drafted, Mr. Bailey worked as an operating room technician at Robinson Memorial Hospital in Ravenna, Ohio. *Id.* at 2. During this time, he received the nickname of "Forklift" because he could lift patients weighing up to 400 pounds. *Id.* Mr. Bailey did not believe in vaccinations, and as a result, did not receive any the entire time he worked at Robinson. *Id.* The year before his flu vaccination, Robinson changed their policy and required employees to receive a flu vaccination. *Id.* at 3.

Within two or three days of the vaccination, Mr. Bailey stated that he began to experience heart palpitations, headaches, and dizziness. Ex. 1 at 4. By early 2013, Mr. Bailey described that he began to fall and slur his speech. *Id.* at 5. After visiting various doctors, he went to the

Cleveland Clinic. *Id.* The doctors diagnosed him with ALS. *Id.* According to Mr. Bailey, one doctor told him, "I won't say this again, but I have had three patients of mine who got ALS after receiving the flu vaccination." *Id.*

Mr. Bailey described his continued deterioration. As of the date of the affidavit, he was unable to walk, talk, move his arms or legs, or swallow. Ex. 1 at 5. He was confined to a wheelchair and used a feeding tube to eat. *Id.*

Mr. Bailey stated that their attorney, Mr. James Blumenstiel came to the house and read a list of approximately 20 symptoms and asked Mr. Bailey to nod if he had experienced them. Ex. 1 at 7. Mr. Bailey indicated that he had experienced every symptom on the list. *Id.* Mr. Blumenstiel later informed them the list was from a Mayo Clinic article about Guillain-Barré syndrome ("GBS"). *Id.*

B. Affidavit of Petitioner

Petitioner (Michael Bailey, Jr.) is the son of Michael Bailey. He filed an affidavit on October 29, 2015. Ex. 3. Petitioner stated that his father's physical health before the December 12, 2012 flu vaccination was excellent. *Id.* at 2. Petitioner stated that within a few days of receiving the flu vaccination, his father began to complain of heart palpitations, dizziness, headaches, and not feeling like himself. *Id.* at 3. According to Petitioner, his father began to fall around that time. *Id.* Soon thereafter, his speech and facial features began to change and resembled someone who suffered a stroke. *Id.* As of the date of his affidavit, Mr. Bailey was wheelchair bound and incapable of caring for himself. *Id.*

Petitioner stated that their attorney, Mr. James Blumenstiel came to the house and read a list of approximately 20 symptoms to Mr. Bailey and asked Mr. Bailey to nod if he had experienced them. *Id.* Mr. Bailey indicated that he had experienced every symptom Mr. Blumenstiel read to him. *Id.* Mr. Blumenstiel later informed them the list was from a Mayo Clinic article about GBS. *Id.* at 4.

C. Affidavit of Mrs. Danette Bailey

Mrs. Danette Bailey stated that her husband had always been very healthy. Ex. 2 at 1. In their 36 years of marriage, she could only remember one time that he was sick. *Id.* She stated that he did not receive vaccinations because he was afraid of them, and specifically, was concerned that something bad could happen to him. *Id.* at 3. Mr. Bailey was told that if he did not receive the flu vaccination, he would be fired from his job at the hospital. *Id.*

Mrs. Bailey stated that immediately after he received the flu vaccination, Mr. Bailey began to have heart flutterings and headaches. Ex. 2 at 4. After that he began to fall, and in January, his face looked like he had suffered a stroke. *Id.* His hands also did not work well, and he could not grip things. *Id.* As of August 2013, Mr. Bailey was in a wheelchair, and Mrs. Bailey had to do everything for him. *Id.*

Mrs. Bailey stated that their attorney, Mr. James Blumenstiel came to the house and read a list of approximately 20 symptoms and asked Mr. Bailey to nod if he had experienced them. Ex. 2 at 7. Mr. Blumenstiel also asked Mrs. Bailey to indicate whether Mr. Bailey experienced these symptoms. *Id.* Mr. Bailey indicated that he had experienced every symptom on the list. *Id.* Mrs. Bailey also so indicated. *Id.* Mr. Blumenstiel later informed them the list was from a Mayo Clinic article about GBS. *Id.* at 8.

III. Procedural History

On November 23, 2015, Mr. Bailey filed a petition alleging that the flu vaccine he received on December 12, 2012 caused him to develop symptoms of GBS. Pet. at 3-4. He acknowledged in his petition that his doctors diagnosed him with ALS rather than GBS. *Id.* Mr. Bailey submitted treatment records from his medical providers over the following months. ECF Nos. 8, 9, 13, 17, 19.

Respondent filed a Rule 4(c) Report on April 5, 2016 requesting the petition be dismissed for failure to demonstrate entitlement to compensation. ECF No. 24. Respondent asserted that Petitioner failed to establish that Mr. Bailey suffered from GBS and, even if he did, Petitioner did not provide evidence that the flu vaccination caused the injury. Mr. Bailey was ordered to file an expert report by June 6, 2016. ECF No. 25.

On June 28, 2016, Mr. Bailey filed an expert report from Dr. Phillip DeMio. Ex. 20; ECF No. 31. Mr. Bailey filed a transcript of a deposition of Dr. Erik Pioro on September 12, 2016 as Exhibit 21. ECF No. 38. In response, Respondent filed the expert report of Dr. Vinay Chaudhry, on February 17, 2017. Ex. A. Respondent also filed supporting medical literature, (Exs. A-1 through A-4), Dr. Chaudhry's curriculum vitae ("CV") (Ex. B), and Dr. Chaudhry's updated CV (Ex. C).

On March 1, 2017, Mr. Bailey filed a motion for permission to obtain a rebuttal opinion which was granted on the same day. ECF Nos. 57, 58. Special Master Hastings ordered Petitioner to file his rebuttal expert report by May 1, 2017. ECF No. 58. On May 15, 2017, Petitioner was ordered to file his overdue report as soon as possible. Non-PDF Order dated May 15, 2017; ECF No. 63. Mr. Bailey died on July 28, 2017 and was eventually succeeded as Petitioner by the administrator of the estate, Michael Bailey, Jr. ("Petitioner"). ECF Nos. 71, 98. Petitioner's counsel changed from James Blumenstiel to Braden Blumenstiel on September 22, 2017. ECF No. 77. This case was reassigned to Special Master Brian Corcoran on October 4, 2017.

On October 18, 2017, Special Master Corcoran set Petitioner's expert report deadline for October 31, 2017. ECF No. 81. Petitioner requested and was granted an extension until December 15, 2017. In his Non-PDF Order, Special Master Corcoran stated, "In light of Petitioner's opportunity to file a rebuttal expert report since March of 2017, no further extensions of time shall be permitted." Non-PDF Order dated October 24, 2017.

This case was reassigned to my docket on December 1, 2017. ECF No. 86. On January 5, 2018, I ordered Petitioner to file his overdue supplemental expert report immediately. Non-PDF Order dated January 5, 2018. ECF No. 89. On January 15, 2018, Petitioner filed a request for an

extension of time. ECF No. 90. I granted that request. The rebuttal opinion, a report by Dr. James Lyons-Weiler, was filed on January 29, 2018. ECF No. 91.

On June 28, 2018, I held a Rule 5 status conference with counsel for Petitioner and Respondent. I reviewed and summarized the findings of the experts and articulated my belief that Mr. Bailey had ALS and not GBS. My assessment was based on the fact that no treating physician ever diagnosed Mr. Bailey with GBS or raised it as a differential diagnosis. Rule 5 Order, ECF No. 102. Rather, the treating physicians diagnosed Mr. Bailey with ALS. *Id.* I informed Petitioner of my belief that the medical records, medical literature, and medical opinions all supported and confirmed the diagnosis of the treating physicians in this case. *Id.* Petitioner requested the opportunity to address my concerns and I ordered him to file a status report by August 17, 2018 indicating how he would like to proceed. *Id*.

Petitioner twice requested additional time to respond, claiming he was searching for additional medical opinions, and then missed the third deadline. ECF Nos. 103, 104. On October 26, 2018, I issued an order to show cause why this case should not be dismissed pursuant to Vaccine Rule 21(b) for failure to prosecute and for failure to comply with prior orders in the action. ECF No. 105. Petitioner filed a response to the order to show cause on November 15, 2018 (ECF No. 107) and submitted two more reports from Dr. Lyons-Weiler on November 16, 2018. Exs. 26, 27; ECF Nos. 108, 109.

I held a status conference on December 17, 2018 with counsel on behalf of Petitioner and Respondent. I informed Petitioner that he had yet to provide evidence in support of a GBS diagnosis and Petitioner responded that he was still searching for expert medical opinions in support of the case. *See* Scheduling Order on 12/12/18, ECF No. 112. Respondent expressed concern that this case was "not progressing" given the numerous unfruitful attempts to obtain evidence. *Id.* I agreed with Respondent's concerns and directed Respondent to file a Motion to Dismiss if he believed that was appropriate, and informed Petitioner that he would have the opportunity to file a reply and include new evidence with the reply. *Id.*

On February 28, 2019, I issued a docket order instructing Respondent to file a Motion for Ruling on the Record rather than a motion to dismiss. On April 12, 2019, Respondent filed a motion for a ruling on the record, stating that Petitioner is not entitled to compensation because he failed to show that Mr. Bailey suffered from GBS and failed to show that the flu vaccine caused his injury. ECF No. 115. I ordered Petitioner to file a response and any new evidence he wished to submit by June 11, 2019. *See* Non-PDF Scheduling Order on 4/14/19. Petitioner filed four motions for extensions of time, stating that he was working with a neurologist; he then missed a deadline. ECF Nos. 116, 118, 119, 120. On October 16, 2019, I ordered Petitioner to file his overdue response immediately. Instead, Petitioner filed a motion for extension of time until December 16, 2019. ECF No. 121.

I held another status conference on November 5, 2019 and informed Petitioner that I would grant his request for more time but if he failed to file a responsive brief by December 16, 2019, I would consider the brief to be waived. During the status conference, Petitioner stated that he had retained a neurologist, Dr. Marcel Kinsbourne, and would file the brief after conferring with him.

ECF No. 124. Petitioner filed a response to the motion for ruling on the record on December 16, 2019. ECF No. 125. No new evidence was attached to the response.

On December 27, 2019, I held a status conference with the parties to address Petitioner's response. I confirmed with Petitioner that he is alleging that Mr. Bailey had GBS and the vaccine caused the GBS. Petitioner agreed that he is not asserting that Mr. Bailey developed ALS from the vaccine or that Mr. Bailey's pre-existing ALS was significantly aggravated by the vaccine.

I summarized this portion of the December 27, 2019 status conference as follows:

> Mr. Blumenstiel stated that Petitioner is not asserting that Mr. Bailey Sr. developed ALS from the vaccine or that Mr. Bailey Sr.'s pre-existing ALS was significantly aggravated by the vaccine.
>
> I made it clear to Mr. Blumenstiel that the only theory of causation I will be addressing in my Ruling on the Record is whether the vaccination caused Mr. Bailey Sr. to develop GBS. Mr. Blumenstiel indicated that he understood and agreed with this approach.[4]

ECF No. 126 (Order, Dec. 27, 2019).

Because all the evidence has been filed in this case, I will decide whether Mr. Bailey's December 12, 2012 flu vaccination caused him to develop GBS. ECF No. 126.

IV. Expert Opinions

A. Dr. Phillip DeMio

Petitioner submitted an expert report by Phillip C. DeMio, M.D. on June 28, 2016. Ex. 20 (hereinafter "DeMio Rep."). Dr. DeMio described his background as "a medical doctor who has cared for patients since 1984, and [his] current practice gives detailed ongoing care, including diagnosis and treatment, to patients with chronic sustained illnesses including those of neurologic and immunologic disorders." DeMio Rep. at 1. Petitioner did not submit Dr. DeMio's CV although he claimed it was attached to his response to Respondent's motion for ruling on the record. *See* ECF No. 125 at 6, fn 4. Dr. DeMio's credentials have been evaluated in other program cases.[5] Notably, Dr. DeMio is not a neurologist.

Dr. DeMio examined Mr. Bailey and reviewed his medical records and affidavits. He

[4] In accordance with this representation, I have not evaluated whether the flu vaccination Mr. Bailey received caused him to develop ALS, or whether the flu vaccination significantly aggravated his pre-existing ALS.

[5] *See Wyatt v. Sec'y of Health & Human Servs.*, 144 Fed. Cl. 531 (2019) "Dr. DeMio obtained his medical degree from Case Western Reserve University in 1984, and completed residencies in pathology and emergency medicine. Dr. DeMio treats patients with chronic tick-borne and other infections and Autism Spectrum Disorder as well as 'chronic pain and disease.'"

provided an overview of Mr. Bailey's medical history in his report and stated that Mr. Bailey "has severe advance [sic] neuromuscular degeneration" that "is quite consistent with GBS" and "was caused by his one [and] only influenza vaccine." DeMio Rep. at 2. Dr. DeMio wrote that "[m]any aspects of Mr. Bailey's case do not fit the more usual presentation of ALS" but Dr. DeMio did not elaborate on those aspects or explain the usual presentation of ALS. *Id.* Dr. DeMio concluded that Mr. Bailey's problems are permanent, but he is expected to live for many more years. *Id.*

B. Dr. Erik Pioro

Petitioner deposed Dr. Pioro, a neurologist at the Cleveland Clinic, on August 24, 2016 and filed the transcript on September 12, 2016. Ex. 21. Dr. Pioro testified that he arrived at the Cleveland Clinic in 1993 and took over as the director of the ALS clinic in 2000. *Id.* at 5. Dr. Pioro testified about ALS in general and about the evaluation and treatment that he and Dr. Taylor provided to Mr. Bailey at the Cleveland Clinic.

Dr. Piero described ALS as a progressive neuromuscular disease that gets worse with time with no typical or average progression of the disease. Ex. 21 at 10. He testified that he has seen close to 2000 patients over the last 15 years, and "no two patients are necessarily alike in terms of how the disease behaves in them." *Id.* Dr. Pioro explained that the median survival of his patients "is about two years" and the clock starts at the onset of symptoms. *Id.* at 10-12.

Dr. Pioro first saw Mr. Bailey on August 29, 2013 so he could not say whether the symptoms started before or after the influenza vaccination. Ex. 21 at 13. He testified that it is difficult to predict how long a patient might have ALS prior to the development of symptoms. *Id.* at 14. He illustrated the point by describing a situation where a patient might fall and strike their head and then develop symptoms of ALS. *See id.* at 15. He stated that,

> when you think of it superficially it suggests that head trauma was responsible for the development of ALS. But when you delve into it, you find the patient was having problems with their walking and balance and that's why they fell in the first place. So it's the chicken or egg phenomenon when it comes to things like that.

Id. at 15. Dr. Pioro agreed that Mr. Bailey's reported symptoms of heart palpitations, diarrhea, and headache are not manifestations of ALS. *Id.* at 16. He also agreed that other conditions can mimic ALS. *Id.* at 21.

Later in the deposition, Dr. Pioro noted that "the diagnosis of ALS is primarily based on the symptoms and signs the physician observes in the patient and a series of tests to rule out other diseases." Ex. 21 at 28. He distinguished GBS as a peripheral nervous system problem and ALS as a condition primarily in the central nervous system with peripheral components. *Id.* at 38. Although both conditions cause weakness in the extremities, GBS will often present with numbness and tingling that begins in the feet and ascends which is unusual in ALS patients. *Id.* at 50-51. He said he uses clinical exams combined with medical tests to distinguish between ALS and other diseases like GBS. As an example, he said the spinal fluid is going to be abnormal for GBS and the EMG is going to be different in a GBS case than in an ALS case. *Id.* at 51.

Upon questioning from Respondent, Dr. Pioro reviewed and explained Mr. Bailey's Cleveland Clinic treatment notes. According to Dr. Pioro, Mr. Bailey's symptoms and test results supported the diagnosis of ALS. Ex. 21 at 57-66. Dr. Pioro could not identify any medical evidence to suggest that the flu vaccine caused or worsened Mr. Bailey's condition. *Id*. at 55, 67-68. Dr. Pioro testified that he recommends ALS patients receive flu vaccines to prevent further chance of infection. *Id*. at 72.

C. Dr. James Lyons-Weiler

Petitioner submitted three reports from James Lyons-Weiler, Ph.D. Exs. 25-27. Dr. Lyons-Weiler is not a medical doctor. He holds a Ph.D. in ecology, evolution, and conservation biology from the University of Nevada, Reno. See Ex. 28 ("Lyons-Weiler CV").

In the first report, Dr. Lyons-Weiler prepared a table of symptoms that he said showed Mr. Bailey's symptomology favored a GBS diagnosis over ALS. Ex. 25 at 1. Then he explained that he had recommended a genetic test be performed but the report from the test was, in his opinion, incomplete. *Id.* Although Dr. Lyons-Weiler indicated this incomplete report seemed to favor an ALS diagnosis, he recommended that Mr. Bailey be considered to have a diagnosis of GBS and ALS. *Id.* at 3.

In the second report, Dr. Lyons-Weiler wrote that he had "re-reviewed his files and now present [sic] how clearly his symptoms cannot support ALS." Ex. 26 at 1. He stated that it is his "medical opinion" that Dr. DeMio's conclusion that Mr. Bailey had GBS is correct and that Dr. Pioro's diagnosis of ALS is incorrect. *Id*. at 6.

In the third report, Dr. Lyons-Weiler provided a list of medical studies that purported to show that flu vaccines can cause chronic inflammatory demyelinating polyneuropathy ("CIDP"). Dr. Lyons-Weiler claimed that ALS is similar enough to GBS and CIDP for the purpose of these studies. Ex. 27 at 1.

D. Dr. Vinay Chaudhry

On February 17, 2017, Respondent filed an expert report from Vinay Chaudhry, M.D. Ex. A (hereinafter "Chaudhry Rep."). Dr. Chaudhry is a professor of neurology at the Johns Hopkins University School of Medicine and Co-Director of the EMG Laboratory at Johns Hopkins Hospital. Exhibit C at 1 ("Chaudhry CV"). In this position, Dr. Chaudhry evaluates over 2000 patients per year with the majority related to neuromuscular diseases. Chaudhry Rep. at 1. Dr. Chaudhry has published more than 200 articles, book chapters and other relevant publications in his field. *See* Chaudhry CV at 3-17. He has received multiple grants related to ALS and neuropathy during the course of his career. *Id.* at 17-23. Dr. Chaudhry serves as a reviewer on a number of journals relating to neurology. *Id.* at 28. He is board certified in neurology with an added qualification in clinical neurology. *Id.* at 29.

Dr. Chaudhry summarized Mr. Bailey's medical records then concluded that his clinical

features are typical for the diagnosis of ALS. He applied the ALS diagnostic criteria[6] to Mr. Bailey's case in his report as follows:

1. Signs of lower motor neuron (LMN) degeneration.

   Mr. Bailey had fasciculations, atrophy, and EMG evidence (denervation potentials) of LMN degeneration.

2. Signs of upper motor neuron (UMN) degeneration

   Mr. Bailey had spasticity, and hyperreflexia all consistent with UMN signs.

3. Progressive spread of signs within a region or to other regions.

   Mr. Bailey had progression from the right side to the left side, from arm to face to breathing and leg muscles.

4. Absence of other disease processes by electrophysiology and neuroimaging studies.

   Mr. Bailey had no evidence of sensory involvement of demyelination and no features on neuroimaging to raise the possibilities of other disease processes in the peripheral nerve or brain/spinal cord to explain his progressive symptoms and signs.

Chaudhry Rep. at 4.

Next, Dr. Chaudhry applied the criteria for GBS[7] and demonstrated that Mr. Bailey did not show signs or symptoms of GBS:

1. Presence of progressive ascending weakness starting in the legs in a relatively symmetrical fashion.

   Mr. Bailey did not display an ascending pattern of weakness and his weakness was not symmetrical.

2. Areflexia or absent reflexes.

   Mr. Bailey rather than having absent reflexes, had brisk reflexes.

[6] Dr. Chaudhry referenced a website for the El Escorial World Federation for Neurology criteria for diagnosing ALS: http://www.alsa.org/als-care/resources/publications-videos/factsheets/criteria-for-diagnosis.html. Ex. A-1.

[7] Dr. Chaudhry cited to the following article for GBS's diagnostic criteria: Willison et al., *Guillain-Barré syndrome*, LANCET 2016; Vol. 388, pp. 717-27. (Hereinafter "Willison"). Filed as Ex. A-3 at 5.

3. Progressive phase that lasts days to 4 weeks (often 2 weeks).

   Mr. Bailey has continued to show progressive disease for over 4 years. GBS is a monophasic illness that evolves rapidly reaching its zenith at < 4 weeks. There is improvement over several months. Mr. Bailey's illness didn't peak at < 4 weeks and didn't show stabilization or improvement. On the contrary, he has continued to progress for four years. This rules out any possibility of the diagnosis of GBS or any other immune mediated neuropathy.

4. Sensory symptoms or signs including pain.

   Mr. Bailey did not show pain or sensory involvement (beyond carpal tunnel syndrome).

5. Nerve conduction studies show features of demyelination in the form of decreased conduction velocities, prolonged distal motor latencies, increased F-wave latencies, conduction block and temporal dispersion.

   Mr. Bailey didn't have any of the above noted features in his nerve conduction studies.

6. GBS is treated with IVIG or plasma exchange. None of these treatments were even considered since none of the physicians entertained this diagnosis.

Chaudhry Rep. at 5.

Dr. Chaudhry addressed and disputed Dr. DeMio's various claims individually. For example, Dr. DeMio claimed that "we physicians only rarely see bulbar variant of ALS and many physicians will never see a case in their entire career," but Dr. Chaudhry stated that he sees approximately 50 patients per year with this diagnosis and with similar presentation to Mr. Bailey. Chaudhry Rep. at 6-7. Contrary to Dr. DeMio's claim, Dr. Chaudhry stated that all aspects of Mr. Bailey's presentation fit the usual presentation of ALS. *Id.* at 7. Finally, Dr. Chaudhry stated that he agreed with the majority of Dr. Pioro's deposition including when Dr. Pioro testified that Mr. Bailey had ALS and not GBS. *Id.*

V. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 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 [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *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 (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 v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

With respect to *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). Proof that a vaccine likely caused an injury or that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex 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).

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 ("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 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 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." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. 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 413, 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 determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present 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 proposition 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), *mot. for review den'd* (Fed. Cl. Feb. 11, 2019), *appeal docketed*, No. 19-1753 (Fed. Cir. 2019); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

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, contemporaneous 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 per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), (citing *United States v. U.S. 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*, 23 Cl. Ct. at 733)). 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).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Opinion Evidence

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her 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. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *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 persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. 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 his 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. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. 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. *Id.* 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").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Petitioner alleges that Mr. Bailey's flu vaccination caused him to develop GBS. The first step in analyzing a claim is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Human Servs*., 656 F.3d 1341,1353 (Fed. Cir. 2011). The question of whether the vaccination caused Mr. Bailey's injury turns on Mr. Bailey's correct diagnosis. *Broekelschen v. Health & Human Servs*., 618 F.3d at 1346. Therefore, I must first determine which injury is best supported by the evidence presented in the record before determining whether the vaccination caused the injury. After a careful review of the record, I find the evidence supports that Mr. Bailey had ALS and not GBS.

A. GBS Generally

GBS is an acute paralytic neuropathy that affects approximately 100,000 people annually. *See* Willison at 1. AIDP is the most common GBS variant seen within the United States. It is characterized by focal demyelination of motor and sensory nerves. *Id.* at 3. Other recognized GBS variants do not involve damage to the myelin coating the nerve fibers, but instead involve damage to the axons themselves (the nerve fibers). *Id.* at 5. GBS generally follows some form of stimulation to the immune system and is a rapidly progressing, monophasic illness characterized by progressive weakness in the legs and arms along with decreased tendon reflexes. *Id.* at 2, 5. Weakness is the key presenting symptom, and is typically described as ascending, beginning in

the distal lower extremities. *Id.* at 5. The progressive phase of GBS, depicted in the below chart, generally lasts up to four weeks.

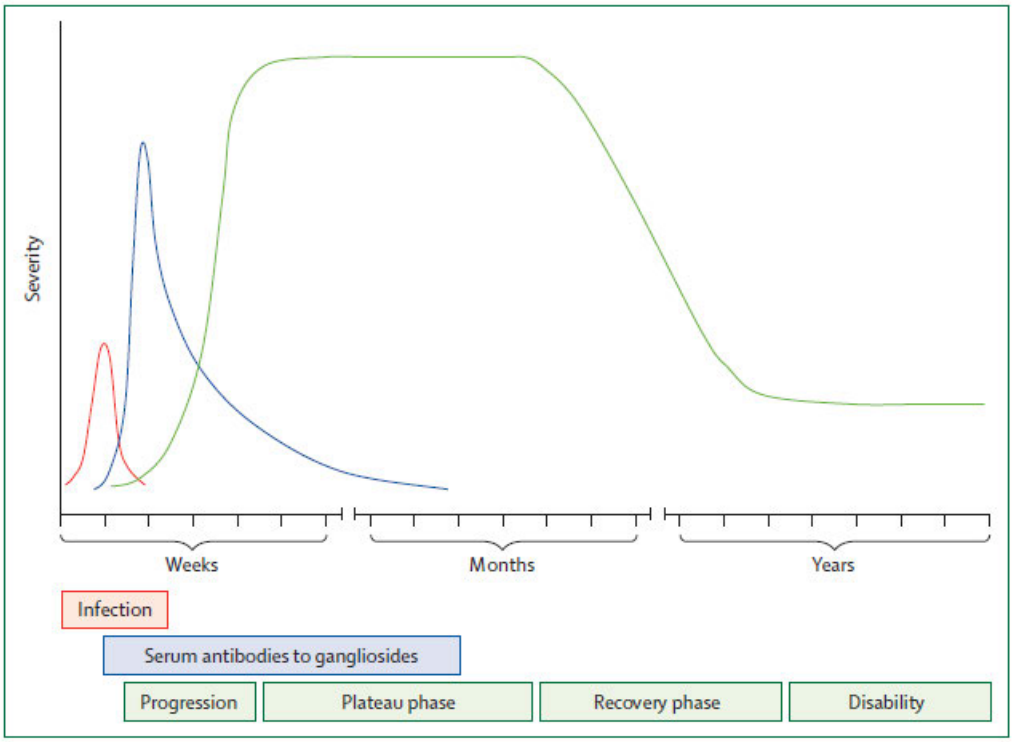

Figure 1: **Guillain-Barré syndrome time course**

Id. at 2. During the progressive phase of GBS, 20-30% of patients develop respiratory failure and need the support of a ventilator. *Id.* at 5. GBS is effectively treated with IVIg or plasma exchange. *Id.* at 7.

B. ALS Generally

ALS is a "rapidly progressive neurodegenerative disorder." Morgan & Orrell, *Pathogenesis of amyotrophic lateral sclerosis*, BRITISH MEDICAL BULLETIN, Vol. 119, pp. 87-97. (Hereinafter "Morgan"). Filed as Ex. A-2 at 1. The rapid degeneration of motor neurons results in weakness and muscle wasting. *Id.* at 2. The clinical symptoms of ALS include the loss of arm and hand function, loss of the ability to walk, shortness of breath, and difficulty with speech and swallowing. *Id.* Typical time from symptom onset to death is three to five years. *Id.* The pathogenesis of ALS is largely unknown, although there are an increasing number of recognized genetic factors. *Id.*

C. Mr. Bailey Was Correctly Diagnosed with ALS by his Treating Physicians

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom

they are diagnosing. *See McCulloch v. Sec'y of Health & Human Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). During the course of his illness, Mr. Bailey was evaluated and treated by three neurologists, Dr. Hugh Miller, Dr. Melanie Taylor, and Dr. Erik Pioro. All three doctors agreed that Mr. Bailey's correct diagnosis was ALS, and all documented their examinations and conclusions in the contemporaneous medical records. Ex. 10 at 8, Ex. 8 at 38-39.

Dr. Miller performed initial testing including an NCS and EMG and noted on May 15, 2013 that the results suggested ALS. Ex. 10 at 8. Dr. Miller referred Mr. Bailey to the Cleveland Clinic for a second opinion. *Id.*

Dr. Taylor examined Mr. Bailey on August 29, 2013 and determined that the findings were consistent with a probable motor neuron disease including ALS. Ex. 8 at 6. Dr. Taylor noted the following in Mr. Bailey's medical records:

> Now that all the additional investigations have been completed, the final clinical diagnosis is right upper extremity-onset ALS. Because of the extent of upper motor neuron (UMN) and lower motor neuron (LMN) abnormalities at present, he meets the World Federation of Neurology El Escorial diagnostic criteria of probable ALS. There are combined upper motor neuron (UMN) and lower motor neuron (LMN) abnormalities at cervical and lumbosacral levels, with evidence of UMN signs in the bulbar region; by EMG here, LMN changes are not seen in thoracic myotomes. **The clinical diagnosis of ALS is certain.**

Id. (emphasis added). Dr. Pioro supervised Dr. Taylor and agreed with her assessment. Dr. Pioro also agreed with the proposed treatment plan, which included continuing with Riluzole, the only FDA-approved prescription medication for the treatment of ALS. *Id*. at 38-39.

Dr. Pioro testified in a deposition on August 24, 2016 wherein he described the nature of ALS and how ALS is diagnosed. Ex. 21. He explained that Mr. Bailey's symptoms and test results supported the diagnosis of ALS rather than GBS. Dr. Pioro has been the director of the ALS Clinic at the Cleveland Clinic for over 15 years and has seen close to 2000 patients during that time. I find his opinion to be persuasive and fully supported by the contemporaneous treatment records.

Ultimately, all of Mr. Bailey's treating neurologists concluded that he suffered from ALS. None of them considered GBS as a diagnosis or a differential diagnosis, or even noted it as a possibility in the medical records.

D. Respondent's Expert Agrees with Mr. Bailey's Treating Physicians and is Persuasive

Respondent's expert, Dr. Vinay Chaudhry, is a professor of neurology at Johns Hopkins University School of Medicine. Chaudhry CV at 1. He agreed with the treating physicians' assessment that Mr. Bailey suffered from ALS rather than GBS. Dr. Chaudhry included in his report the criteria for the diagnosis of ALS and described how Mr. Bailey met the criteria.

Chaudhry Rep. at 4. He summarized by stating that "all aspects of Mr. Bailey's presentation fit the usual presentation of ALS." *Id.* at 7.

Dr. Chaudhry also listed the criteria for GBS and explained how Mr. Bailey did not display those signs or symptoms. Chaudhry Rep. at 5. In particular, Dr. Chaudhry noted that 1) Mr. Bailey did not display an ascending pattern of weakness, and that his weakness was not symmetrical; 2) Mr. Bailey had brisk as opposed to absent reflexes; 3) instead of a progressive phase that typically lasts up to four weeks, Mr. Bailey continued to show deterioration for four years, until the time of his death; 4) Mr. Bailey did not exhibit pain or sensory involvement; 5) Mr. Bailey's nerve conduction studies did not show features of demyelination in the form of "decreased conduction velocities, prolonged distal motor latencies, increased F-wave latencies, conduction block and temporal dispersion"; and 6) Mr. Bailey's treating physicians did not consider treating with IVIg or plasma exchange, standard therapies for GBS. *Id.* Dr. Chaudhry summarized his assessment by stating, "nothing about [Mr. Bailey's] presentation is consistent with GBS." *Id.* at 6.

Importantly, Dr. Chaudhry is a neurologist who is qualified to opine on the question of diagnosis. I find Dr. Chaudhry's opinion to be persuasive and well supported by the medical records.

E. Petitioner's Experts Are Not Qualified to Opine of the Issue of Diagnosis and Are Not Persuasive in Contending that Mr. Bailey Suffered from GBS

Petitioner presented two experts in support of the allegation that Mr. Bailey had GBS. Neither expert treated Mr. Bailey, neither expert is a neurologist, and neither expert claims to have specialized knowledge or experience in diagnosing or treating patients with ALS or GBS.

1. Dr. DeMio

Dr. DeMio is a medical doctor who treats patients with autism spectrum disorder, chronic pain and disease. He is not a neurologist. Dr. DeMio concluded that Mr. Bailey suffered from GBS rather than ALS but provided no basis, factual or medical, for this conclusion. *See* Ex. 20 ("DeMio Rep.). He did not discuss the diagnostic criteria for GBS or compare those criteria with Mr. Bailey's medical history. *Id.* While I considered Dr. DeMio's report, I did not find it persuasive.

Dr. DeMio's expert opinion has been discredited by other special masters in the Vaccine Program. In *Wyatt*, the special master stated "[o]nce again, Dr. DeMio has rendered an opinion in a case in which he lacks the underlying requisite medical expertise. Dr. DeMio has neither specialized training in either autoimmune or neurological disorders nor has he ever conducted research or written papers in either of these fields", *mot. for review den'd*, slip op. No. 14-706V (Fed. Cl. June 5, 2019); *See Wyatt v. Sec'y of Health & Human Servs.*, 144 Fed. Cl. 531 (2019) (finding that the Special Master properly determined Dr. DeMio lacked the requisite medical expertise to render an opinion on Petitioner's injury, due to his lack of specialized training in the fields of autoimmune or neurological disorders); *McKown v. Sec'y of Health & Human Servs.*, No. 15-1451V, 2019 WL 4072113 (Fed. Cl. Spec. Mstr. July 15, 2019) (noting Dr. DeMio's "questionable medical credentials to offer a reliable opinion on this subject"); *Wolf v. Sec'y of*

Health & Human Servs., No. 14-342V, 2015 WL 6518581, at *16 (Fed. Cl. Spec. Mstr. Sept. 15, 2016) (finding Dr. DeMio provided a conclusory opinion supported by scant scientific support). In a different case, Dr. DeMio testified regarding the cause and treatment of autism in 2013 despite having no formal specialized training in the area. *Holt v. Sec'y of Dept. of Health and Human Servs.*, No. 05-136V, 2015 WL 4381588 at *16 (Fed. Cl. Spec. Mstr. June 24, 2015). The former Chief Special Master described his testimony in that case as "involving broad, general statements" and stated that he "used medical terminology vaguely and indiscriminately." *Id.* at 17. She did not find his testimony reliable in general or useful in resolving the issues and gave little weight to his opinion. *Id.* In another vaccine case, a special master took issue with the decision to retain Dr. DeMio. *Dia v. Sec'y of Health & Human Servs*. No. 14-954V, 2017 WL 2644695 at *3 (Fed. Cl. Spec. Mstr. May 25, 2017) (finding the "conclusory nature of Dr. DeMio's report made it practically valueless and forced the petitioner to seek the report from a second expert.") *Id.*

In this case, I similarly find Dr. DeMio's opinion to be unpersuasive. He is not a neurologist and is inherently less qualified to render an opinion on Mr. Bailey's correct diagnosis than Dr. Chaudhry or Mr. Bailey's treating neurologists.

2. Dr. Lyons-Weiler

Petitioner's other expert, Dr. Lyons-Weiler, is not a medical doctor. Of the three documents submitted by Dr. Lyons-Weiler, the first indicated that Mr. Bailey had ALS but should be considered to have both GBS and ALS, the second included his "medical opinion" that Mr. Bailey had GBS, and the third simply claimed that ALS was similar enough to GBS and CIDP for purposes of claiming the flu vaccine can cause ALS. Dr. Lyon-Weiler's background in biology and genetic sequencing does not qualify him to opine, as an expert or otherwise, on the topic of medical diagnoses. I considered the documents submitted by Dr. Lyons-Weiler but I did not find them relevant or useful. I have reviewed Dr. Lyons-Weiler's work in a prior case and determined that his report did not advance any theory as to how the flu vaccine caused petitioner to develop GBS 15 weeks and five days after the vaccination. *Kamppi v. Sec'y of Health & Human Servs.*, No. 15-1013V, 2019 WL 5483161 (Fed. Cl. Spec. Mstr. July 24, 2019).

Dr. Lyons-Weiler, a Ph.D. in ecology, evolution, and conservation biology, and Dr. DeMio, an emergency room doctor, are inherently less qualified to opine on Mr. Bailey's correct neurologic diagnosis than a neurologist. I consider the opinions of the four neurologists (three treating physicians and Dr. Chaudhry) to be significantly more persuasive than the opinions of Dr. DeMio and Dr. Lyons-Weiler. *See Contreras v. Sec'y of Health & Human Servs.*, No. 05–626V, 2013 WL 6698382, at *33-34 (Fed. Cl. Spec. Mstr. Nov. 19, 2013) (discussing that a treating neurologist's opinion is more credible in determining the cause of a neurological illness than the opinions of a treating emergency medicine specialist and a treating pediatric specialist), *vacated and remanded on other grounds,* 116 Fed. Cl. 472 (Fed.Cl.2014), *on remand,* 2014 WL 8098606 (Fed. Cl. Spec. Mstr. Oct. 24, 2014), *aff'd,* slip op. (Fed. Cl. Apr. 17, 2015).

Based on my review of all the evidence in this case, particularly the medical records and the expert reports, the evidence overwhelming supports that Mr. Bailey's correct diagnosis is ALS rather than GBS.

F. Causation of Injury

I have determined that the preponderance of the evidence establishes that Mr. Bailey's injury is ALS rather than GBS. Therefore, in order to prevail, Petitioner must establish by a preponderance of the evidence that the flu vaccination caused Mr. Bailey's ALS "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. Petitioner has not provided evidence that a flu vaccine can cause ALS or that it did so in Mr. Bailey's case. In fact, he has confirmed that he is not asserting Mr. Bailey developed ALS from the vaccine or that his pre-existing ALS was significantly aggravated by the vaccine. *See* ECF No. 126. Accordingly, Petitioner cannot meet his burden of proof under any of the *Althen* prongs.

VII. Conclusion

I express my deep personal condolences to Mr. Bailey's family for their loss. It is clear that Mr. Bailey's life was cut short by a terrible illness. However, the evidence in this case prevents me from awarding compensation. Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits, the experts' opinions, and medical literature, I conclude that Petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. Petitioner has failed to offer preponderant evidence showing that Mr. Bailey had GBS. Further, he has not offered evidence (or pursued a theory) that Mr. Bailey's ALS was either caused or significantly aggravated by vaccination. **His petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[8]

IT IS SO ORDERED.

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

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