In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-198V

BETTY A. DENNIS *Administratrix of the* ESTATE OF RICHARD P. DENNIS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 11, 2025

Lawrence R. Cohan, Saltz Mongeluzzi & Bendesky, Philadelphia, PA, for Petitioner.

Michael Bliley, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On February 25, 2020, Betty Dennis, as administratrix of the estate of Richard Dennis, filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of an influenza ("flu") vaccine administered on October 3, 2018, Mr. Dennis suffered from Guillain-Barré syndrome ("GBS") as defined by the Vaccine Injury Table (the "Table") which subsequently caused his death on November 17, 2018. Amended Petition (ECF

[1] Because this ruling and decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means this Ruling/Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

No. 39) at Preamble. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons set forth below, I find that Petitioner has carried her burden of proof in establishing that Mr. Dennis suffered a Table GBS injury, and therefore is entitled to compensation.

I. Relevant Procedural History

This claim was initiated on February 25, 2020, and activated from initial review on April 14, 2020. For approximately one year thereafter, Petitioner continued to file additional medical records. On September 17, 2021, Respondent filed his Rule 4(c) Report, contending that entitlement was not appropriate because the records reflected that Mr. Dennis' GBS symptoms began before he received the flu vaccine. Report at 17 (ECF No. 30). After filing more medical records, Petitioner filed the instant Motion for Ruling on the Record in December 2023 (ECF No. 38), along with an amended petition. (ECF No. 39). Respondent filed his Response brief on February 2, 2024 (ECF No. 40), and Petitioner filed her Reply on March 13, 2024. (ECF No. 44). This matter is now ripe for disposition.

II. Relevant Medical History

A. Medical Records

Prior to vaccination, Mr. Dennis had a complex pre-vaccination medical history significant for chronic interstitial lung disease ("ILS"), pulmonary fibrosis, chronic kidney disease, coronary artery disease, percutaneous coronary interventions, and multiple episodes of syncope. Ex. 2 at 6, 227-28, 227-28, 238, 352-58. From 2015 to 2018, Mr. Dennis showed a pattern of worsening lung disease, episodes of syncope, a progressively increasing need for supplemental oxygen, and a decline in his activity level. Ex. 2 at 26-27, 65-70, 105-110, 123-24, 135, 185-95, 319-23, 352-58, 365-66, 373-78, 383-86, 423, 430-31, 455, 460-62, 464-69; Ex. 9 at 6-9; Ex. 10 at 2, 10-15.

A few months prior to vaccination, on July 11, 2018, Mr. Dennis returned to his pulmonologist, Dr. Gregory Thompson. Ex. 2 at 474-75. Dr. Thompson felt that Mr. Dennis was clinically stable and noted that he was using oxygen for activity and sleep. *Id*. Mr. Dennis's physical examination showed "normal" extremities. *Id*. Mr. Dennis reported that he would be going to Texas for the winter and would return in March for reevaluation. *Id*.

Approximately three months later, on October 3, 2018, at 11:53 a.m., moments prior to receiving the flu vaccine at issue, Mr. Dennis was seen informally by his primary care physician Dr. John Udell. Ex. 1 at 3, Ex. 2 at 478. Dr. Udell stated:

> I saw Mr. Dennis informally a day after a visit for his wife. After finishing with her, she brought up a number of concerns about him. The patient's 2 daughters were present. They rolled him in the room in a wheelchair. He endorses vegetative symptoms and looks quite depressed. His first comment is to say, 'I have nothing to look forward to.' His [idiopathic pulmonary fibrosis] is O2 dependent. He apparently got a second opinion at Rochester. No new insights were gleaned. He understands this is a chronic progressive disease. Certainly is endorsing vegetative symptoms, and at this point, I am suggesting a trial of citalopram. I suggested 10 mg per day, though his daughter was concerned, so we agreed to start lowering just 5 mg per day. A prescription is provided, and hard copy for him to take to the pharmacy he chooses. He is instructed that it will take at least 3 weeks of therapeutic dose to know how much it may work. If he is not noticing much improvement within 2-3 weeks, I anticipate advising he increase to 10 mg per day. I trust he, and particularly his family, will keep me posted.

Ex. 2 at 478. Minutes later, at 12:05 p.m., shortly after his visit with Dr. Udell, Mr. Dennis received a flu vaccine in his left deltoid. Ex. 1 at 3.

On October 8, 2018 (now five days after vaccination), Mr. Dennis's daughter contacted Dr. Udell and reported that Mr. Dennis was having double vision. Ex. 2 at 484. She was concerned that he was not tolerating citalopram and it was causing the double vision. *Id*. Dr. Udell did not think the double vision was caused by the medication, but deemed it reasonable to try another medication instead. *Id*. He also prescribed physical therapy ("PT") at her request. *Id*.

Two days later, Mr. Dennis's wife contacted Dr. Udell's office and asked if there was anything more that could be done for Mr. Dennis. Ex. 2 at 484. She reported that his double vision persisted, he was getting weaker, and she felt that he was declining. *Id*. She had to cancel PT because she did not think she could get him in and out of the car. *Id*. Dr. Udell asked if they had considered Hospice. *Id*. She said that her children had mentioned it, but she was not ready for Hospice. *Id*. Dr. Udell noted that Mr. Dennis would need to be formally assessed at an office visit to appropriately evaluate his condition. *Id*. He also noted that "[a]ny more detailed history of his transition from doing well in June to his complaints now [would] help." *Id*.

Five days later, on October 15, 2018, Mr. Dennis's wife called Dr. Udell's office again. Ex. 2 at 486. Dr. Udell spoke with her and Mr. Dennis joined the call as well. *Id*. They reported that for the last two weeks (October 1, 2018) he was feeling much worse. *Id*. He started having numbness in his left hand, then numbness in the right hand, followed by pain, profound weakness, and difficulty walking. *Id*. Dr. Udell noted that his condition had clearly changed drastically, and he needed to be evaluated. *Id*. Mr. Dennis had an appointment with Dr. Udell in two days, but Dr. Udell advised that he should not hesitate to go to the emergency department at any time if needed. *Id*.

The next day, on October 16, 2018, Mr. Dennis presented to the emergency department of Gundersen Lutheran Hospital and was admitted. Ex. 2 at 606-10. He reported weakness that had worsened over the previous few days, difficulty walking and standing, pain and numbness in his hands bilaterally, weakness in his neck, double vision, and his wife stated that he had difficulty swallowing. *Id*. An attending physician noted no recent illness and no new medications. *Id*. at 493. MRIs of the head and cervical spine were without obvious causative findings. *Id*. A physical exam revealed left eye ptosis, 5/5 deltoid and elbow extension strength, 2/5 wrist strength, 4/5 hip flexor strength with the left greater than the right, 5/5 dorsiflexion and plantar flexion strength bilaterally, decreased sensation to light touch in the wrists, and absent reflexes throughout. *Id*. The attending physician thought that his presentation was most consistent with GBS, possibly the Miller Fisher variant. *Id*. Neurology also consulted on October 16, 2018, and stated:

> [Mr. Dennis] presents to the ER this day with progressive weakness to the point of not being able to walk. Symptoms may have begun on Tuesday of last week, at that time he noticed numbness in the digits 1-4 of his left arm, a couple days later as of Thursday this began in the right hand as well, same distribution. This is painful at times and radiating to his forearms. He does have chronic neck pain, has felt that [it] is hard to extend the head BACK in the past before his current symptoms. He does not think historically that he had trouble flexing the neck. He was having a lot of head drop on Thursday as well, again some of this may have been pre-existing position of comfort. He started having weakness in his hands [that was] most notable. The legs have also become involved in the last 3 days, starting Sunday and not prior, the legs have been having progressive weakness. For a short period, he was able to walk with a walker amidst this, now unable to walk at all. Prior to all of these symptoms, he denies walker use. In addition, he has had fluctuating diplopia, both vertical and horizontal, only binocular as monocular vision will resolve. New onset left ptosis also noted, one family member thought it might have been better in the morning but otherwise seems constant. His voice may be a little bit softer. He has not

> been hungry for some time and is unable to say if [he has] dysphagia but fluids [were] reported [as] ok. In terms of recent events, he had a Flu shot on Thursday,1 some but not all of the symptoms began before this as above. Shingles vaccination [o]n August 31. They deny any similar symptoms in the past ever. No recent URI or GI illness reported. Recent citalopram trial for depression just before symptoms, stopped amidst diplopia but … Dr. Udell felt [it was] likely unrelated to [the medication], [and noted] he was not endorsing other neurologic symptoms at that time.

Ex. 2 at 522-23 (emphasis added).

Following an examination, neurology's differential diagnosis included possible superimposed root level pathology such as some degree of radicular pain in the arms and noted "symptoms may be most likely caused by bulbar onset acute demyelinating polyradiculopathy such as AIDP (acute inflammatory demyelination polyradiculoneuropathy)." Ex. 2 at 531. Neurology further noted that "[n]euromuscular junctional process [wa]s not clinically favored but not excluded," and the tiny infarct on MRI was likely incidental and not clinically significant to his presentation of weakness. *Id*. at 531. The plan was for a lumbar puncture and to start IVIG treatment. *Id*.

The next day, on October 17, 2018, neurology reviewed the lumbar puncture results and stated "though unable to completely exclude for superimposed root level pathology such as some degree of radicular pain in the arms," Mr. Dennis's symptoms were most consistent with bulbar onset acute demyelinating polyradiculopathy such as GBS, likely Miller-Fisher variant. Ex. 2 at 521. Testing for anti-GQ1b antibodies was negative. *Id*. at 741.

A progress note from neurology on October 20, 2018, stated that Mr. Dennis was stable. Ex. 2 at 560-61. His diplopia had resolved; he was eating a modified diet without problems; and his shortness of breath was unchanged. *Id*. He continued to have limited use of his upper extremities and minimal strength in the legs, but the overall impression was that his strength had shown definite improvement with now normal neck strength and improved extremity strength. *Id*. He completed five days of IVIG treatment. *Id*. at 558. A progress note from October 22, 2018, recorded the fact that Mr. Dennis had made some small improvements after five doses of IVIG, but remained quite debilitated and would need to go to a skilled nursing facility for ongoing therapy. Ex. 2 at 552.

On October 24, 2018, Mr. Dennis was discharged to a swing bed at Winona Health in Winona, MN. Ex. 2 at 492-93. On November 1, 2018, a progress note sated that Mr. Dennis was up in his chair and reported that he was doing well. Ex. 10 at 33. He

completed breakfast with speech therapy and was able to use adaptive tools/silverware. *Id*. He continued to have moderate to severe weakness but was making improvement with some exercises and mobility and his hand grasp and finger movements had noticeably improved. *Id*. He continued to have upper extremity lymphedema, right greater than left, and compression fabric was recommended for the upper extremities; he was already using compression fabric for lower extremity edema. *Id*.

Three days later, on November 4, 2018, a progress note stated that the previous evening Mr. Dennis was complaining of shortness of breath, his oxygen saturations dropped to the 80s, and he required additional oxygen. Ex. 3 at 3-6. He denied any chest pain or significant cough. *Id*. A chest CT was performed and the impression was no pulmonary embolism or aortic dissection; "chronic airways disease with pulmonary fibrosis, cannot exclude an atypical interstitial type pneumonia;" and moderate-sized bilateral pleural effusions. *Id*. The physician's assessment included fluid overload with "[s]trong suspicion for congestive heart failure (BNP elevated at 1646 and he ha[d] a history of [coronary artery disease]," but the physician did not think he had a recent heart attack. *Id*. The plan included around-the-clock diuresis with Lasix as well as a repeat echocardiogram. *Id*. A chin wound was infected and he was placed on topical antibiotics, and he appeared to have protein calorie malnutrition. *Id*. His resuscitation status was noted to be DNR/DNI. *Id*.

A transthoracic echocardiogram was performed on November 6, 2018, revealed findings suggestive of right ventricle pressure overload; the right atrial size was moderately dilated; right atrial pressure was moderately elevated; and there was mild aortic valve regurgitation and moderate to severe pulmonary hypertension. Ex. 2 at 724-30.

A progress note on November 7, 2018, reported that Mr. Dennis had been having progressive issues with fatigue and inability to participate in PT and occupational therapy. Ex. 3 at 7. He was alert and minimally interactive and reported feeling tired but was cheerful and denied pain. *Id*. The impression included "AIDP with slow progression," cor pulmonale likely secondary to chronic pulmonary disease, and dermatitis secondary to Methicillin-resistant Staphylococcus aureus (MRSA), Klebsiella, and herpes simplex virus. *Id*.

Two days later, on November 9, 2018, a provider note stated that Mr. Dennis had difficulty overnight with increasing shortness of breath. Ex. 3 at 10-11. He was not hypoxic during these episodes, and he felt that they resolved with increasing his oxygen. *Id*. Further assessment in the morning revealed nasal obstruction with dried mucus that was removed by nursing and a very good response to nebulizer treatment, but had coughed

up a quarter-sized amount of bloody sputum. *Id*. He continued to progress very slowly with PT and required a mechanical lift from the bed to the chair. *Id*. A neurology consult regarding his slow progression in PT noted that he would need three to six months of rehabilitation, his progress was likely complicated by his significant lung disease and cor pulmonale, but additional IVIG would be considered. *Id*.

A head MRI without contrast was performed on November 9, 2018, revealed extensive periventricular deep white matter lesions, which could be seen with demyelinating disease or small vessel ischemic change; cerebral atrophy; inflammatory changes in the paranasal sinuses; and fluid signal left mastoid, which appeared slightly more prominent than on October 16, 2018. Ex. 10 at 19. It was noted that an infectious inflammatory process "must be considered." *Id*.

A medical record note on November 15, 2018, stated that Mr. Dennis was making slow progress and was getting better at feeding himself. Ex. 3 at 11. The next day, on November 16, 2018, Mr. Dennis followed up with neurologist Michael Leone, M.D., at Gundersen Health. Ex. 2 at 667-68. Dr. Leone noted that he was able to move very little and could not see out of his left eye except for some very hazy vision. *Id*. He was able to talk, but had a fairly hypophonic voice and was extremely short of breath. *Id*. Dr. Leone's impression was:

> On examination in the clinic today, I believe he has a central visual loss and not visual loss due to his [GBS]. Visual loss in [GBS] is exceedingly rare and not thought to be an actual part of the Miller-Fisher variant. Additionally, his MRI shows evidence, on the 16th, of restricted diffusion in the right parieto-occipital region, this [is] likely producing left-sided visual loss and also would go along with Mr. Dennis' assertion that the visual loss came on suddenly and after the other symptoms. Nonetheless, he is still exceedingly weak, and I believe we should perform an EMG. We could consider further treatment for his [GBS]. He is on aspirin and simvastatin, and I do not think I would change that therapy at this time. He is quite fatigued now, so at this time, he will go back to the nursing home. We will try to get him in for his EMG in the morning.

Ex. 2 at 667. Also on November 16, 2018, Mr. Dennis saw Dr. Edwards for a "walk-in" eye appointment. *Id.* at 673. He reported loss of vision in the left eye that began eight days prior. *Id*. His medical history noted that he had been diagnosed with GBS and his first symptoms began in September with neck weakness followed by ptosis of the left upper lid, and diplopia. *Id*. Dr. Edwards noted that Mr. Dennis's examination was difficult

because he needed to be in a reclining position in a wheelchair, however, following examination the impression was probable optic neuritis/neuropathy of the left eye. *Id*.

The following day, on November 17, 2018, Mr. Dennis passed away. Ex. 4. On November 19, 2018, Dr. Udell spoke with Mr. Dennis's wife and daughter. Ex. 2 at 676. He noted that Mr. Dennis "certainly was struggling with [GBS], though his rapid decline and clinical scenario raises the question of whether some other intervening event accelerated his death. At this point, it is an academic point. I do not believe an autopsy was requested." *Id*.

The death certificate lists "Acute Inflammatory Demyelinating Polyneuropathy" as Mr. Dennis's immediate cause of death, and "Interstitial Lung Disease" as a contributing condition. Ex. 4.

B. Witness Evidence

Petitioner has submitted one affidavit in support of her claim, executed on March 16, 2020. Ex. 6. It simply indicates that prior to the vaccination, Mr. Dennis had no history of neurological problems; that he received the vaccination on October 3, 2018; that he suffered the residual effects of his alleged injury until he passed away on November 17, 2018; and that no civil action has been filed nor has she received or collected an award or settlement of a civil action for damages for Mr. Dennis' alleged injury and death.

III. Parties' Respective Arguments

Petitioner argues that the medical records and affidavits support her claim of a *prima facie* case for entitlement for an on-table GBS claim, because she has satisfied all of the criteria under the QAI for establishing GBS.

Respondent argues that Petitioner has failed to make a showing of Table GBS because his medical records do not preponderantly establish that the onset of Mr. Dennis's GBS was within the Table timeframe of 3-42 days. Response at 11. Rather, Respondent argues that the medical records provide evidence that his GBS started on October 1, 2018 - two days before receiving the flu vaccine - because there are reports of GBS symptoms such as numbness, weakness, and difficulty walking placed on or around that date. *Id.*

IV. Applicable Law

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act

Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined 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. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

V. Analysis

I. Fact Findings – Onset and Entitlement

To establish a GBS Table injury following a flu vaccination, a petitioner must demonstrate by preponderant evidence that the onset of his GBS occurred at least three days but no more than forty-two days post vaccination. 42 C.F.R. § 100.3(a). The Table's Qualifications and Aids to Interpretation ("QAIs") define GBS as:

> [A]n acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes .... For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death my occur without a clinical plateau.

42 C.F.R. § 100.3(c)(15)(i).

The Table identifies the four subtypes of GBS as acute inflammatory demyelinating polyneuropathy ("AIDP"), acute motor axonal neuropathy ("AMAN"), acute motor and sensory neuropathy ("AMSAN"), and Fisher Syndrome ("FS"). 42 C.F.R. § 100.3(c)(15)(ii)–(iii). It provides requirements for the diagnosis of the different subtypes of GBS – The diagnosis of AIDP, AMAN, and AMSAN requires:

(A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
(B) A monophasic illness pattern;
(C) An interval between onset and nadir of weakness between 12 hours and 28 days;
(D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
(E) The absence of an identified more likely alternative diagnosis.

Id. at § 100.3(c)(15)(ii). Evidence of "electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter[ ]" is not required to establish a diagnosis of GBS consistent with the Table, but it is "supportive" evidence. 42 C.F.R. § 100.3(c)(15)(iv). The QAIs also specify that "[t]o qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness." 42 C.F.R. § 100.3(c)(15)(v). The QAIs state that "[e]xclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of" a list of conditions, which include hyperkalemia and hypokalemia. 42 C.F.R. § 100.3(c)(15)(vi).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

A. Factual Findings Regarding a Table GBS

After a review of the entire record, I find that a preponderance of the evidence supports the conclusion that Petitioner has satisfied the QAI requirements for Table GBS.

1. Onset

Respondent's sole objection to entitlement is that Petitioner has failed to demonstrate by preponderant evidence that Mr. Dennis's GBS started between 3-42 days following his October 3, 2018, flu vaccination. Based on the record as it stands, I find that Petitioner has met this timing/onset element.

In support of his argument, Respondent points to a call made by Mr. Dennis's wife to Dr. Udell from October 15, 2018, in which she indicated that "for the last two weeks he was feeling much worse." Response at 11; Ex. 2 at 486. Respondent interprets this literally to mean that Mr. Dennis' condition started to *deteriorate* on October 1, 2018, which was two days before his flu vaccination. Response at 11. Respondent further notes that on October 16, 2018, when Mr. Dennis reported to the emergency department, "he reported weakness that had *worsened*, not weakness that began, over the previous few days, difficulty walking and standing, pain and numbness in his hands bilaterally, weakness in his neck, double vision, and his wife stated that he had difficulty swallowing." *Id.* (emphasis in original); Ex. 2 at 606-610. Finally, Respondent argues that the record establishes that Mr. Dennis began displaying GBS symptoms prior to his October 3, 2018, vaccination, because on that date he arrived at his appointment in a wheelchair and was noted to be in a vegetative state of unclear origin. Response at 12. It is further added that notes from his neurological consultation note that "some but not all of the symptoms" began before vaccination. *Id.*; Ex. 2 at 522-523.

Although Mr. Dennis' extensive medical history certainly complicates the overall evidentiary picture, the record as it now stands suggests it is more likely than not that Petitioner's GBS began *after* his October 3, 2018, flu vaccination, and within the 3-42 day post-vaccination timeframe. Although Mr. Dennis presented for his vaccination in a wheelchair, this fact did not seem unusual to Dr. Udell, as he notes it without further comment. However, given Mr. Dennis' medical history, including ILS, pulmonary fibrosis, multiple episodes of syncope, and overall use of oxygen to manage these conditions, it would not be unusual to expect him to minimize his overall physical exertion whenever possible, and the records reflect that Mr. Dennis was accompanied by his wife and two daughters on that day, and was feeling symptoms of depression to the point where he endorsed vegetative symptoms, and Dr. Udell prescribed citalopram, an antidepressant medication. Ex 2 at 478. Thus, Petitioner's presentation as of the date of vaccination was more likely reflective of his overall poor health and condition.

In addition, even though he had the opportunity at this October 3rd visit, Mr. Dennis did to complain of any particular new symptoms that were troubling him, either due to his existing conditions or any potentially new conditions which would be neurological in nature. Indeed, Dr. Udell notes at that visit "[a]fter finishing with [Petitioner], she brought up a number of concerns about [Mr. Dennis." Ex 2 at 478. However, it does not appear that any of the stated concerns were of a neurologic nature, or that could reasonably be linked to what transpired later.

By one week later, on October 10, 2018, Mr. Dennis had deteriorated to a point where his wife was concerned that he was getting weaker. Five days after that, Mr. Dennis and his wife called Dr. Udell complaining of a new onset of numbness first in his left and then in his right hand, followed by pain, profound weakness, and an inability to walk. Ex. 2 at 486. One day later, Mr. Dennis was admitted to the emergency room and a neurologist diagnosed him with GBS. *Id.* at 531. At this time, the neurologist noted that his symptoms (specifically numbness in his left hand) may have begun on "Tuesday of last week," or October 9, 2018 - six days after vaccination. *Id.* at 522. At that time Mr. Dennis also indicated that two days later, on October 11, 2018, hand numbness had begun in his right hand as well. *Id.* He also placed the onset of weakness in his legs at approximately October 13, 2018. *Id.* at 523. These records all permit the conclusion that the start of Mr. Dennis's GBS was no later than **October 15, 2018**, if not on October 9, 2018. Either date satisfies the onset requirement.

Respondent's arguments against onset rely on a far too literal interpretation of the medical records. For example, Respondent argues that because Petitioner indicated that Mr. Dennis had been feeling worse for the past two weeks, she literally meant 14 days, placing onset on October 1, 2018, two days before vaccination. But it is unlikely that Petitioner intended her statement to be read with that level of precision, and more likely an approximation of time. Given Mr. Dennis's endorsement of new vegetative symptoms prior to receiving his flu vaccination, if he had been also experiencing neurological symptoms related to GBS, he (or a member of his family) likely would have mentioned them.

Additionally, five days after vaccination, when Mr. Dennis's daughter spoke with Dr. Udell, she was concerned about his intermittent double vision, but did not endorse any other neurological concerns of the kind that Mr. Dennis would report several days later. Ex. 2 at 481. And Mr. Dennis's treating neurologist indicated later that he believed Mr. Dennis had a central visual loss - not visual loss due to his GBS, although a formal diagnosis ultimately could not be made due to his death. *Id.* at 667. Similarly unavailing is Respondent's argument that because Mr. Dennis indicated that his neurological symptoms had worsened over the previous days instead of started, it is a sign that Mr. Dennis experienced neurologic symptoms prior to October 6, 2018 (three days after vaccination). Response at 11.

Respondent's interpretation of Mr. Dennis' October 16, 2018 neurology consultation notes is inconsistent. Respondent asks that some statements be deemed erroneous, but others considered to be proof of an earlier onset. The actual record does not reflect a specific date as to when Mr. Dennis received the vaccination, however, noting only that "he had a Flu shot on Thursday", which Respondent interprets to refer to the

prior Thursday (October 11, 2018). *Id.* at 523. But there is no doubt that the reference to a flu shot on Thursday is incorrect, as the record definitely establishes that Mr. Dennis received his vaccination on October 3, 2018, a Wednesday. Ex. 1.

Respondent argues that because of this error, the reference that Ms. Dennis's symptoms "may have begun on Tuesday of last week "(October 9, 2019) is not reliable. Response at 11. But Respondent then goes on to state that "[t]he neurology consultation provides a detailed description of the progression of Mr. Dennis's symptoms that clearly place onset at least one week prior to Tuesday (October 9, 2018) of the previous week, as indicated. For example, the neurology consultation notes that Mr. Dennis had progressive weakness in his legs and was able to ambulate with a walker for a short period of time prior to being unable to walk at all." *Id.* at 12. Yet the consult states that "[t]he legs have also become involved in the last 3 days, starting Sunday and not prior, the legs have been having progressive weakness. For a short period of time he was able to walk with a walker amidst this, now unable to walk at all." Ex. 2 at 523. The last three days, including October 16, 2018, places onset of leg weakness on October 14, 2018, which is a Sunday as correctly reflected in the notes. It is unclear then how Respondent could interpret this to mean his GBS symptoms began "at least one week prior to Tuesday (October 9, 2018) of the previous week." Response at 12.

Finally, Respondent notes that at the neurology consultation, it was noted that "[i]n terms of recent events, he had a Flu shot on Thursday, some but not all of the symptoms began before this as above," and argues that this supports his contention that Mr. Dennis's GBS symptoms began prior to vaccination. Ex. 2 at 523. However, this statement appears predicated on the aforementioned incorrect date of Petitioner's vaccination. The "detailed description of the progression of Mr. Dennis's symptoms," Response at 12, places the onset of hand numbness on Tuesday, October 9, 2018. Based on that, the incorrect belief that the flu vaccine was administered on October 11, 2018, would lead the neurologist to make the statement that some, but not all of the symptoms began before the vaccination. Accounting for this error supports the conclusion that his bilateral limb weakness did not start before October 9, 2018, six days after vaccination – still within the Table timeframe.

Based on all of the above, I find it more likely than not that the first manifestation of Mr. Dennis' GBS symptoms began between 3-42 days following his October 3, 2018, flu vaccination. Therefore, Petitioner has established onset.

2. Other QAI Requirements

Although Respondent has not offered any argument that Petitioner has failed to meet the other QAI requirements for Table GBS, they will be discussed briefly herein. A claimant alleging a Table GBS must show they suffered bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs. There is no doubt that Mr. Dennis suffered weakness in both of his hands as well as his legs. Ex. 2 at 522-523. Therefore, this requirement is satisfied.

A GBS diagnosis must also be consistent with a monophasic illness pattern – and there is no question that Petitioner's GBS has had a monophasic course. Petitioner first reported neurologic symptoms approximately six days after vaccination, when it was noted that he started feeling numbness and weakness in his left hand. By October 16, thirteen days after vaccination, Mr. Dennis had presented to the emergency room and was hospitalized due to his GBS. By October 20, 2018, the records note, Mr. Dennis's condition was "stable." Ex. 2 at 560. By October 22, 2018, it notes that Mr. Dennis had made small improvements after five doses of IVIG but was still debilitated and would need to be transferred to a skilled nursing facility for ongoing therapy. *Id.* at 552. By November 1, 2018, it was noted that his hand grasp and finger movements had noticeably improved. Ex. 10 at 33. Indeed, as recently as two days before his death, it was noted that Mr. Dennis was making slow progress and was improving with his ability to feed himself. Ex. 3 at 11.

Another QAI consideration is evidence of an interval between onset and nadir of weakness that runs between 12 hours to 28 days. As previously noted, the onset of symptoms was likely on or about October 9, 2018, when Mr. Dennis first complained of weakness in his left hand and arm. Within 28 days, on November 16, 2018, his symptoms were severe enough to require hospitalization – reflecting his nadir.

Finally, there is the absence of an identified more likely alternative diagnosis. There is nothing in the record to suggest that Petitioner's treating physicians diagnosed him with anything other than GBS for these symptoms (and despite his documented preexisting health concerns).

Therefore, based upon my review of the record as a whole, I find that Petitioner has carried her burden in proving the requirements for Table GBS.

B. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). The overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Mr. Dennis received a flu vaccine intramuscularly on October 3, 2018. Ex. 1; *see* Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for his injury. Petition at 4; Section 11(c)(1)(E) (lack of prior civil award).

Conclusion

In view of the evidence of record, I find Petitioner is entitled to compensation. A damages order will be entered following the issuance of this ruling to direct the parties of the next steps in resolving damages.

IT IS SO ORDERED.

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