In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

WILLIAM SMITH,	*	
	*	No. 15-1194V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	
	*	Filed: October 31, 2018
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Diagnosis; statement of treating doctors.
	*	
Respondent.	*	

PUBLISHED RULING ON PETITIONER'S MOTION FOR FINDING OF FACT REGARDING DIAGNOSIS[1]

On January 26, 2018, petitioner moved for a finding of fact that "petitioner was diagnosed with a Guillain-Barre syndrome (GBS) variant" following the administration of a flu vaccination on March 14, 2014. Pet'r's Mot. at 5. The respondent opposes petitioner's motion, noting that petitioner's claim that he was diagnosed with GBS is not consistent with the medical records filed in this case. Resp't's Resp., filed March 16, 2018, at 9. Based on a review of the medical records, expert reports, and the statements from the petitioner's treating physicians, the undersigned finds that preponderant evidence does not exist to support petitioner's claim that he was diagnosed with GBS in the spring of 2014.

I. Factual Summary

Prior the vaccination in question, Mr. Smith had a complex medical history that included type 2 diabetes. Mr. Smith was not compliant with the treatments prescribed for his diabetes and

[1] Because this ruling contains a reasoned explanation for the action in this case, the undersigned is 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 the ruling will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), petitioners have 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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material before posting the ruling.

his disease was considered "uncontrolled." Exhibit 4 at 12. He suffered from various symptoms that were secondary to his diabetes, including ulcers and osteomyelitis in his toe, diabetic neuropathy, and diabetic retinopathy. Exhibit 1 at 4, 6; exhibit 2 at 4; exhibit 3 at 3.

Two days before the vaccination in question, on March 12, 2014, Mr. Smith experienced shortness of breath, signs of heart failure, swollen ankles, anemia, hypokalemia, and acute renal failure. Exhibit 4 at 29-30. He was admitted to the hospital for these issues on March 13, 2014. Id. at 31. On March 14, 2014, he was administered the flu vaccine into his right arm during the course of his hospitalization. Exhibit 7 at 209.

On March 25, 2014, after being discharged from the previous hospitalization, Mr. Smith was admitted to the Medina Hospital for sudden weakness in his legs that began that morning. Exhibit 5 at 175-76. On admission, although it was noted that the etiology of the leg weakness was uncertain, the physician remarked that Mr. Smith had recently been administered the flu vaccine, which is "[one] of the risk factors for something such as GBS." Id. at 176. During the course of Mr. Smith's admission to the Medina Hospital, his treating neurologist, Dr. Eric Baron, noted that the possibility of GBS was part of Mr. Smith's differential diagnosis and several tests were run at Medina Hospital to try to determine whether GBS was the cause of Mr. Smith's symptoms. See exhibit 5 at 178. Based on the results from these tests, notably a test on Mr. Smith's cerebrospinal fluid (CSF), as well as Mr. Smith's "mixed clinical picture," Dr. Baron decided to not move forward with treatment for GBS due to his "lower suspicion for GBS" following examination and testing. Id. at 201.

On March 27, 2014, Mr. Smith was transferred from Medina Hospital to the main campus of the Cleveland Clinic Hospital System because Medina did not have the necessary diagnostic tools or care for Mr. Smith. Id. At the main campus, he was seen by Dr. Tina Waters, Dr. Donika Patel, and Dr. Jessica Rundo, among others. On his initial evaluation by Dr. Waters, she noted that the tests had been inconclusive in determining if Mr. Smith's pathology was central or peripheral in nature. Exhibit 9 at 19-20. She recommended additional testing, including nerve conduction studies. Id.

On March 30, 2014, while still admitted to the hospital, Mr. Smith woke up with worsened weakness in his right leg and new weakness in his right arm. Exhibit 9 at 52. An MRI revealed that Mr. Smith had suffered a stroke, which caused the additional weakness. Id. However, the cause of Mr. Smith's initial symptoms remained unidentified. Id. at 58.

Additional medical testing was performed during the course of Mr. Smith's stay at the Cleveland Clinic main campus. These tests appeared to rule out GBS as the cause of Mr. Smith's symptoms. For instance, during a neuromuscular consultation with Dr. Patel on April 2, 2014, Dr. Patel noted that there was not strong evidence of an acute peripheral nerve injury causing his symptoms. Exhibit 9 at 35. Instead, Dr. Patel concluded that Mr. Smith had "severe generalized polyneuropathy" that she associated with Mr. Smith's diabetes. Id. She concluded that GBS was a "less likely" diagnosis. Id.

Dr. Rundo also concluded, based on a second examination of Mr. Smith's CSF as well as the nerve conduction studies and a physical exam, that Mr. Smith was not suffering from an acute peripheral nerve disease. Id. at 72.

Mr. Smith was discharged from the hospital on April 4, 2014, with a diagnosis of lower extremity weakness and acute stroke. Exhibit 9 at 7. The discharge papers state that the treating physicians did not have a definitive conclusion about the etiology of Mr. Smith's condition, but the record does state that "neuromuscular specialists were consulted, and they attribute the symptoms to possibly diabetic neuropathy." Id. at 9. Following his discharge, Mr. Smith was transferred to an inpatient rehabilitation facility at Lodi Community Hospital (LCH).

On intake at LCH, the records show that Mr. Smith's chief complaint was that he had suffered from GBS and a stroke. Exhibit 8 at 32. The records even state that Mr. Smith was "diagnosed with Guillain-Barre syndrome" and should no longer be administered the flu vaccine. Id. at 32, 44. However, the source of this information and other references to GBS from the LCH records is not obvious. It is also notable that subsequent medical records from Dr. Cullen, Mr. Smith's primary care physician, incorporated GBS into Mr. Smith's past medical history. See, e.g., exhibit 11 at 6, 7.

II. Expert Reports

Dr. Thomas Morgan, the petitioner's expert, opined that based on his examination of the medical records, Mr. Smith suffered from post-vaccination immune-related acute motor-sensory axonal polyneuropathy (AMSAN). Exhibit 16 at 3. Dr. Morgan stated that this is a variant of GBS. Id. Dr. Morgan came to this conclusion on the basis that Mr. Smith had an abrupt onset of paralysis in his lower extremities. Id. at 4. In support of his conclusion, Dr. Morgan stated that Mr. Smith's diabetic neuropathy had not presented in that manner previously and thus it was not likely that the symptoms experienced following the flu shot were consistent with being secondary to the diabetes. Id. He further stated that the EMG findings were consistent with AMSAN / GBS. Id.

In a rebuttal report, the government's expert, Dr. Daniel Feinberg, stated that it was "clear from the medical records, that Mr. Smith did not have transverse myelitis or Guillain Barre syndrome." Exhibit A at 3. He stated that the constellation of his poorly controlled diabetes, acute congestive heart failure, and acute renal failure superimposed upon severe diabetic neuropathy resulted in the acute leg weakness that Mr. Smith experienced. Id. Dr. Feinberg further evaluated the objective tests that were performed on Mr. Smith (EMG, NCS, CSF, and MRI) and concluded that these tests were not consistent with GBS. Id.

Addressing Dr. Morgan's report specifically, Dr. Feinberg stated that "Mr. Smith's course was not consistent with AMSAN at all." Id. at 4. Dr. Feinberg contrasted Mr. Smith's mild proximal weakness with the severe paralysis expected in AMSAN. Id. Dr. Feinberg concluded by saying that he agreed with the treating physicians insomuch as AMSAN was not a possible diagnosis. Id.

In a rebuttal report, Dr. Morgan addressed both Dr. Feinberg's report as well as the undersigned's request for diagnostic criteria for AMSAN / GBS. More specifically, Dr. Morgan stated that Mr. Smith met the "general criteria" for GBS, including subacute classic paralysis that was symmetric in both legs, a loss of reflexes in the lower extremities, and an abnormal EMG / NCS. Exhibit 23 at 1. Regarding Dr. Feinberg's report, Dr. Morgan stated that he disagreed with Dr. Feinberg's conclusions, but did not elucidate why beyond noting that he thought that the medical testing was consistent with chronic kidney disease, but not end stage kidney disease. Id. at 2. Again, Dr. Morgan noted that he interpreted the findings from the EMG and NCS as being consistent with AMSAN / GBS. Id. Dr. Morgan ended his report by saying that his opinion is "consistent with the opinions of [Mr. Smith's] treating neurologist, Dr. Baron" as well as the opinion of Dr. Tina Waters. Id.

In a supplemental report, Dr. Feinberg addressed the undersigned's question regarding how Mr. Smith's pre-existing medical conditions may have resulted in leg weakness. In this supplemental report, Dr. Feinberg stated that nerve injury occurs in 60-100% of patients with end-stage renal disease. Exhibit C at 1. He also noted that diabetes causes polyneuropathy in 45% of patients, though he noted that glycemic control may prevent peripheral neuropathy in patients with diabetes. Id. Relating back to Mr. Smith, Dr. Feinberg noted that Mr. Smith's diabetes was labelled as uncontrolled as early as 2009 and that he had symptoms consistent with uncontrolled diabetes (toe ulceration and osteomyelitis). Id. (citing exhibits 1, 4). Dr. Feinberg also notes that Mr. Smith had already experienced documented diabetic neuropathy and retinopathy. Exhibit C at 1 (citing exhibits 2, 3). Based on the fact that Mr. Smith already had two significant disorders that have a strong association with neuropathy and that his course was not consistent with AMSAN / GBS, Dr. Feinberg concluded that Mr. Smith suffered from peripheral neuropathy secondary to uremia and poorly controlled diabetes. Exhibit C at 1.

III. Opinions of Mr. Smith's Treating Physicians

An evaluation of the parties' briefs and the expert reports submitted in Mr. Smith's case emphasized the fact that the parties held different interpretations of how Mr. Smith's treating physicians characterized his disease. Compare Pet'r's Mot. at 4 (noting that Dr. Morgan's opinion that Mr. Smith suffered from AMSAN / GBS was consistent with the opinion of Mr. Smith's treating neurologists) with Resp't's Resp. at 4-6 (noting that Mr. Smith's treating physicians *did not* diagnose Mr. Smith with GBS). Because of the importance of the opinion of treating physicians, especially as it pertains to questions of diagnosis, the undersigned ordered the parties to jointly draft letters to Mr. Smith's treating physicians, seeking information that may prove helpful for the question at bar. See order, issued Apr. 27, 2018 (citing 42 U.S.C. § 300aa-12(d)(3)(B) (authorizing special masters to seek information)).

During a status conference held on May 17, 2018, the parties reported that they had sent letters to Drs. Baron, Waters, Patel, and Rundo. Ultimately, the parties were able to obtain information from only Dr. Baron and Dr. Rundo.

In his letter, Dr. Baron reported evaluating Mr. Smith at Medina Hospital, the small community hospital, on March 25, 2014, and March 27, 2014. Exhibit 25. He stated that only preliminary testing was performed at Medina Hospital and that Mr. Smith was transferred to the main campus of the Cleveland Clinic on March 27, 2014 because Medina was not set up for advanced testing and potential treatment that Mr. Smith might need. Id. However, Dr. Baron stated that while GBS was a diagnostic possibility at that time, "there were no test results which suggested GBS" prior to Mr. Smith's transfer to the main campus. Id. Dr. Baron did state that he evaluated the notes from the treating physicians at the main campus and concluded that:

> there were no test results that suggested GBS as the cause of his symptoms (negative spinal fluid and EMG / NCV results), and they felt his comorbid medical issues / decompensation combined with diabetic neuropathy were the most likely culprits of his symptoms, not GBS, in addition to a small stroke found on subsequent testing.

Id. Dr. Baron concluded by qualifying his opinion as being based on his interpretation of the records from the main campus and that additional information would need to come from a member of the neurology team that treated Mr. Smith at the main campus of the Cleveland Clinic. Id.

Fortunately, a member of that team, Dr. Rundo, also provided helpful information in response to the parties' request. Dr. Rundo reported that "Mr. Smith was not, in fact, diagnosed with Guillain-Barre syndrome during his hospital stay." Exhibit 26. She noted that Mr. Smith's CSF testing was normal on two different tests, which effectively ruled out GBS as a diagnosis. Id. She further stated that Mr. Smith's leg weakness was attributable to his diabetic neuropathy and stroke, though she noted that myelitis could not be completely ruled out. Id. Dr. Rundo concluded her letter by stating that she could not comment on whether the flu vaccine caused or contributed to Mr. Smith's GBS since Mr. Smith was not diagnosed with GBS. Id.

In a status conference held following the filing of the letters from Dr. Rundo and Dr. Baron, petitioner stated a desire to file a rebuttal from Dr. Morgan, his expert. See order, issued Sep. 5, 2018. The undersigned granted the petitioner 30 days to do so. Id.

In his rebuttal, Dr. Morgan stated that he disagreed with the opinions of Dr. Baron and Dr. Rundo. Exhibit 27 at 1. Dr. Morgan implicitly questioned the qualifications of both doctors by highlighting that their specialties were related to headaches and sleep disorders, respectively. Id. He continued by noting that both physicians did not address the fact that some of Mr. Smith's symptoms were consistent with AMSAN / GBS. Id. Dr. Morgan concluded his rebuttal by criticizing Mr. Smith's two neurologists for not rendering medical opinions to a reasonable degree of medical probability. Id. at 2.

IV. Analysis

Mr. Smith claims that the flu vaccination he received caused him to suffer from GBS or a variant of GBS. As a result, Mr. Smith has an affirmative burden to show that he has the injury he claims he has. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011); see also Hibbard v. Sec'y of Health and Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) ("[i]f a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by 'reputable medical or scientific explanation,' by which a vaccine can cause the kind of injury that the petitioner claims to have suffered.")

The Federal Circuit has advised special masters to afford the opinions of treating physicians a level of deference. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). This guidance appears especially apt when considering questions of diagnosis as opposed to causation. In the undersigned's estimation, no person is better qualified to opine on Mr. Smith's condition in 2014 than the physicians that treated him at that time. It is worth noting that Mr. Smith has, himself, advocated for the importance of the treating physicians' opinions regarding his diagnosis. See Pet'r's Mot., filed Jan 26, 2018, at 4 ("the treating physicians' opinions deserve significant weight in finding petitioner's diagnosis of Guillain Barre syndrome").

Based on the medical records and the reports of Dr. Morgan and Dr. Feinberg alone, the undersigned was inclined towards finding that Mr. Smith did not meet his burden to establish that he suffered from his alleged injury. The notes from the medical records failed to indicate that any of Mr. Smith's physicians concluded, based on their observations and testing, that Mr. Smith had GBS / AMSAN instead of neuropathy associated with his diabetes or his stroke. In fact, numerous records explicitly stated that his treating physicians interpreted the objective findings as being inconsistent with GBS.

While there are records that indicate that Mr. Smith was diagnosed with GBS, these records do not indicate that those conclusions were made by the physicians that actually treated him. In fact, the records are unclear as to who exactly made the GBS conclusion at all and, based on the records, it appears that they simply could have been incorporating the patient's own account of his medical history. Accordingly, the records must be weighed appropriately in comparison to those records that convey first-hand accounts of the opinions of his treating physicians. See Castaldi v. Sec'y of Health & Human Servs., No. 09-300V, 2014 WL 3749749, at *11 (Fed. Cl. Spec. Mstr. June 25, 2014) ("the records of treating physicians can be questioned and the weight afforded to them depends on whether the physician is noting her own observations or merely recording statements made by the patient"), mot. for rev. denied, 119 Fed. Cl. 407 (2014). Cf. Dobrydnev v. Sec'y of Health & Human Servs., 566 F. App'x 976, 983 (Fed. Cir. 2014) (a special master may refrain from crediting the finding of a doctor who obtained an inaccurate history).

The addition of direct statements from Drs. Rundo and Baron put to rest any ambiguity in the records and, accordingly, any uncertainty about the undersigned's ruling on petitioner's motion. The petitioner has moved for the undersigned to find, as a matter of fact, that Mr. Smith was "diagnosed with a Guillain Barre syndrome variant." Pet'r's Mot., filed Jan. 26, 2018, at 5. The statements from Drs. Rundo and Baron make this finding of fact untenable. While Dr. Morgan attempted to rebut the statements from the treating physicians, his last report did little to undermine their conclusions. In fact, the report undermined his own opinion insomuch as Dr. Morgan, who had previously asked the undersigned to credit the opinions of Mr. Smith's treating physicians, now sought to discredit those same physicians and their medical opinions.

V. Conclusion

For the aforementioned reasons, Mr. Smith's motion for a finding of fact that he was diagnosed with GBS is DENIED. The undersigned tentatively finds that Mr. Smith did not suffer the injury he alleged, but instead manifested a disease course that was consistent with his pre-existing chronic conditions as well as with the stroke he experienced during the course of his hospitalization.

Accordingly, Mr. Smith is ORDERED to file a status report on his next steps in this case on or before **Friday, November 30, 2018.**

IT IS SO ORDERED.

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