

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 18-1602V
(Not to be published)

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ANDRES NIEVES,
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Petitioner,
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v.
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SECRETARY OF HEALTH AND
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HUMAN SERVICES,
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Respondent.
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Filed: January 11, 2021

Michael Adly Baseluos, Baseluos Law Firm, PLLC, San Antonio, TX, for Petitioner.

Mary Eileen Holmes, U.S. Dep’t of Justice, Washington, DC, for Respondent.

ORDER DISMISSING TABLE CLAIM (PARTIAL DISMISSAL OF CASE)¹

On October 17, 2018, Andres Nieves filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the “Vaccine Program”)² alleging that he suffered Guillain-Barré syndrome (“GBS”) caused by his receipt of the influenza (“flu”) vaccine on October 28, 2015. Petition (ECF No. 1) at 1. Respondent reacted by filing a Rule 4(c) Report on November 8, 2019, maintaining that this case is not appropriate for compensation. ECF No. 22. Because I find that (based both on the undisputed facts as well as admissions by Petitioner’s expert)

¹ Although, I have not designated this for publication, because this Order contains a reasoned explanation for my actions in this case, it 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). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Order’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Order will be available to the public. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) (“Vaccine Act” or “the Act”). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

the Table version of the claim cannot succeed, I hereby dismiss it—although this does not constitute the end of the case entirely.

I. Factual Background and Medical History

A. Petitioner's Pre-Vaccination Medical History

Before Mr. Nieves ever received the vaccination that is the basis for his claim, he had visited healthcare professionals complaining of symptoms similar to those he alleges resulted from the vaccination. Mr. Nieves has a past medical history significant for sinusitis, fibromyalgia rheumatica with myositis, obesity, status post-lap band surgery, anxiety, cervical spinal stenosis with related radiculopathy, and right carpal tunnel syndrome. Ex. 2 at 2–4; Ex. 3 at 3–121; Ex. 4 at 1–222 ; Ex. 7 at 1–22. He had been prescribed Gabapentin and Robaxin for his symptoms which provided little relief. Ex. 2 at 29. In 2013, Mr. Nieves saw a neurosurgeon with complaints of pain radiating to both shoulders and arms with sensations of heaviness, weakness, numbness, and tingling. *Id.* at 29–30. This was associated with some difficulty buttoning shirts, tying shoes, and accompanied by frequent falling. *Id.*

B. October 2015 Flu Vaccination and Subsequent Medical History

On October 28, 2015, Mr. Nieves received a seasonal flu vaccine in his right arm. Ex. 1 at 10. That same day, he reported feeling “feverish and a little achy.” Affidavit, filed as Ex. 18 (ECF No. 36-1) at 2. The next day (October 29, 2015), Mr. Nieves reported “waking up with general malaise and flu like symptoms with some aches and pains all over [] [his] body.” *Id.* Petitioner presented to his primary care physician with complaints of a mild allergic response four hours after receiving the flu shot. Ex. 5 at 20. He was advised to take ibuprofen and diazepam, with follow-up as needed. *Id.*

On October 31, 2015 (three days post-vaccination), Mr. Nieves reported experiencing a different kind of symptom. Now, he maintained that he had begun “feeling strange” and noticed that his “walking was a little different.” Affidavit at 2. He also reports that he began losing some sensation in his hands and feet later on that day. *Id.*

On November 2, 2015, Mr. Nieves reported to the emergency room with complaints of fatigue, leg pain and lower back pain with an onset five days prior (or on October 28th). Ex. 3 at 89–90. The next day (November 3, 2015), he was seen by neurologist Dr. Anna Marieta Moise, complaining of a “one-week history of paresthesia’s” in his distal extremities since he got his flu shot. *Id.* at 86–88. Dr. Moise’s exam showed normal strength and reflexes. *Id.* at 86. Dr. Moise’s assessment was paresthesias most likely due to nutritional deficiencies and planned treatment to supplement. *Id.* Another treater during this visit, Ethelyn D. Johnson, MD, noted “doubt guillan [sp] barre syndrome (GBS) PT [patient] has good strength on exam, gait minimally impaired, reflexes +1 bilat.” *Id.* at 89.

On November 4, 2015, Mr. Nieves returned to the emergency room with worsening back pain and generalized weakness. Ex. 3 at 76–77. Mr. Nieves also indicated he previously had difficulty walking. *Id.* He was given pain medications. *Id.* On November 9, 2015, Mr. Nieves again returned to the emergency room, reporting worsening low back pain radiating up to his neck and shoulders and down to his lower extremities. Ex. 3 at 67–69. He was assessed with chronic back pain, and it was again proposed that his condition was unlikely a primary neurological problem like GBS or cord compression. *Id.*

On November 10, 2015, Mr. Nieves returned to his primary care physician complaining of weakness, fatigue, and generalized muscle pain after getting the flu vaccine. Ex. 5 at 1. He was referred to the emergency department for further evaluation and neurology care. *Id.* at 7. Later that day, Mr. Nieves was admitted to the hospital for weakness and concerns for GBS. Ex. 3 at 65. A lumbar puncture showed mildly elevated protein after which Mr. Nieves was diagnosed with GBS and treated with IVIG. *Id.* He improved and was discharged 10 days later, on November 20, 2015 with a treatment plan to continue physical therapy (“PT”) and occupational therapy (“OT”) *Id.* Diagnosis at discharge was GBS. Ex. 6 at 107–117; 122–125; 150–154.

C. Petitioner’s Ongoing Symptoms and Change in Diagnosis

Two months later, on January 8, 2016, Mr. Nieves was seen by a neurologist. Dr. Adetoun Musa. Ex. 3 at 44–48. Mr. Nieves indicated he was now having worsening paresthesias, balance issues, and that his weakness had not improved with PT/OT, or since his prior IVIG treatment in November the prior year. *Id.* at 45. Dr. Musa expressed concern for underlying chronic inflammatory demyelinating polyneuropathy (“CIDP”) given the prolonged duration of symptoms. *Id.* at 47.

On February 8, 2016, Mr. Nieves underwent an EMG which showed generalized sensorimotor polyneuropathy, which was predominately demyelinating in type and mild in degree. Ex. 3 at 43. These findings were deemed to be consistent with an acquired segmental demyelinating polyneuropathy, like that seen in CIDP and related disorders. *Id.* On February 11, 2016, Mr. Nieves returned to Dr. Musa who noted the EMG had shown findings consistent with CIDP.

Petitioner continued to receive treatment for CIDP for the remainder of 2016. *See, e.g.,* Ex. 3 at 15–18, and Ex. 8 at 6–80. However, follow-up EMG tests performed in the fall of 2016 did not confirm the condition, or any demyelinating neuropathy for that matter. Ex. 11 at 63–65. The most recent EMG performed on Petitioner showed no CIDP, and treaters instead attributed Mr. Nieves’s pain and cramps to fibromyalgia. *Id.*

II. Procedural History

As noted above, the case was initiated in October 2018, and it was originally assigned to Special Master Roth. After Respondent indicated his intent to contest entitlement, Petitioner filed

an expert report and supporting medical literature. Report, dated Feb. 6, 2020, filed as Ex. 17 (ECF No. 23-2) (“Kinsbourne First Rep.”). The parties were subsequently ordered to file briefs regarding the disputed issue of onset of Petitioner’s symptoms. *See* Order, May 1, 2020 (ECF No. 30). While such filings were pending, this case was reassigned to me. *See* Docket Entry, July 20, 2020 (ECF No. 32).

On September 9, 2020, Petitioner filed a status report confirming his view that he had a viable Table claim for GBS caused by the flu vaccine, and therefore sought Respondent’s input on whether the claim could be settled as such. *See* Status Report, filed Sept. 9, 2020 (ECF No. 37). On September 28, 2020 Respondent reacted to this contention, disputing that Petitioner’s Table claim was proper, and requesting a finding of onset no later than one day post-vaccination. *See* Resp.’s Onset Brief (ECF No. 39). Respondent also noted inconsistencies in Petitioner’s brief and expert report as well as the contemporaneous medical record. *Id.* at 1. Petitioner responded with a rebuttal memorandum on November 16, 2020 and filed additional supporting documents including a supplemental expert report. *See* Pet.’s Response Brief (ECF No. 41-1); Report, dated Nov. 16, 2020, filed as Ex. 20 (ECF No. 41-3) (“Kinsbourne Supp. Rep.”).

ANALYSIS

To receive compensation under the Vaccine Program, a petitioner must prove either: (1) that she suffered a “Table Injury”—i.e. an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question, or (2) that her illnesses were actually caused by a vaccine (a “non-Table injury”). *See* §§ 300aa-13(a)(1)(A), 11(c)(1); § 300aa-14(a), as amended by 42 C.F.R. § 100.3; 300aa-11(c)(1)(C)(ii)(I); *see also* *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 592 F.3d 1317, 1320 (Fed. Cir. 2006).³

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also* *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.”

³ Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d*, 104 F. App’x 712 (Fed. Cir. 2004); *see also* *Spoonerv. Sec. of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Moberly, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

Here, it is not completely clear whether Petitioner seeks to establish a Table claim. However, the Petition clearly alleges that that he suffered from “Guillan-Barre [sic] Syndrome (GBS) secondary to symptoms of ataxia (i.e. difficulties with balance), ascending paralysis of the lower extremities proximally up above the waist and to a lesser degree in the upper extremities resulting in IVIG; severe constipation; and disabling fatigue, which was ‘caused-in-fact’ by [the flu] vaccination” he received on October 28, 2015, and that he continues to suffer sequelae from the injury. Petition at 1. Moreover, in addressing the onset issues raised in the matter, Petitioner confirmed his view that he had a viable Table claim, based on his contentions about onset. ECF No. 37. It is accordingly appropriate for me to evaluate the factual support for that claim.

To establish any Table claim, a petitioner must make a precise factual showing sufficient to meet the claim’s relevant definitions, as set forth in the Table’s “Qualifications and aids to interpretation” (“QAIs”). Section 14(b). If successful, the petitioner need not also demonstrate vaccine causation, as it is presumed if the Table requirements for a particular claim are met. Section 14(a). To establish a GBS Table Injury, a petitioner must prove that the onset of symptoms was no less than three days and no more than forty-two days after vaccine administration. 42 C.F.R. § 100.3(a)(XIV)(D). Moreover, a petitioner must also demonstrate that there is no more likely diagnosis for his symptoms. *See* C.F.R. § 100.3(c)(15)(v). An ultimate diagnosis of CIDP is considered an exclusionary criterion for a flu-GBS claim. Section 14(b).

In this case, onset is not a basis for dismissal, given the medical record and filings. Respondent correctly observes that contemporaneous medical records establish that Petitioner began experiencing *some* kind of initial symptoms either the day of or the day following vaccination. Resp.’s Onset Brief at 6. Had these symptoms been deemed an initial presentation of GBS, a Table claim would not be tenable, since onset cannot be sooner than three days post-vaccination.

But Petitioner has convincingly demonstrated reason to distinguish his immediate, same-day symptoms from those that later could be deemed to be neuropathic in nature, with the former more evidence of a transient, non-specific vaccine reaction. Pet.’s Response Brief at 2. In support, Petitioner points to a medical record dated November 2, 2015 (five days post-vaccination) in which he expressed to treaters that he was (as of that date) experiencing leg and lower back pain. Ex. 3 at 89–90. By contrast, he has alleged feeling feverish and achy as of the day he received the vaccine—and indeed he sought treatment not long after for a mild allergic response to the vaccination. Ex. 5 at 20. As Dr. Kinsbourne observed, moreover, there are a number of symptoms that medicine recognizes can follow receipt of the flu vaccine, including soreness, redness and

swelling, fever, muscle aches, and headaches. Kinsbourne Supp. Rep. at 1-2 (citing Center for Disease Control (2019)). Mr. Nieves otherwise did not present with symptoms of progressive tingling, numbness, and frequent falls until November 9, 2015. *Id.* at 5 (citing Ex. 3 at 70). Accordingly, it is not more likely than not that Petitioner's onset of neuropathic symptoms began outside the Table's 3–42 day post-vaccination timeframe.

However, Petitioner cannot meet the QAI diagnostic requirement for a flu-GBS Table claim—because the record preponderantly establishes that Petitioner's ultimate diagnosis was CIDP. At most, the record reveals that treaters initially believed that GBS was the proper diagnosis at the time of Petitioner's initial presentation. But the same record *also* reveals that by January 2016 (approximately two months post-onset), Petitioner was continuing to experience neurologic/neuropathic symptoms—and treaters began to propose (based on a longer history) that CIDP rather than GBS best explained his symptoms. This is consistent with the fact that GBS is known to be acute and monophasic—not chronic and meandering like CIDP. Under such circumstances, it is proper to conclude that CIDP best explains a claimant's injury, even if treaters (based on far less data) initially understood the presenting symptoms to be GBS. *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935 (Fed. Cl. Spec. Mstr. Jan. 9, 2015).

My conclusion is also supported by Petitioner's expert in this case. Dr. Kinsbourne has opined that “Mr. Nieves had a polyneuropathy, *which was first diagnosed as Guillain-Barre syndrome but as it evolved turned out to be CIDP.*” Kinsbourne Rep. at 5 (emphasis added). He bases his opinion on the fact that the treating neurologists thus diagnosed him, both on clinical grounds and based on electrodiagnostic and cerebrospinal fluid findings” with CIDP. *Id.* Further, the electrodiagnostic test results in February 2016 removed any doubt that Petitioner was suffering from CIDP. *Id.* at 6. And Dr. Kinsbourne otherwise distinguished GBS, a far more common polyneuropathy, from CIDP, whose progression from onset to maximal deficit takes two months at least. Kinsbourne First Rep. at 6.

As a result, any Table claim, to whatever extent it may have been alleged, that the flu vaccine caused Petitioner's GBS, fails in this case and is dismissed. However, the case *in its entirety* is not properly dismissed at this time—because the question of whether the flu vaccine can and did cause Petitioner's alleged CIDP in a medically acceptable timeframe raises a reasonable, non-Table/causation-in-fact claim.⁴ Such a claim will require Petitioner to establish the three prongs of the test set by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed.Cir.2005) as well as the propriety of the CIDP diagnosis, which Respondent disputes.⁵ At this point, Petitioner has already offered expert support for such a non-Table claim.

⁴ There is no CIDP/flu vaccine table claim.

⁵ Respondent argues that the EMG studies undermine the reliability of the initial GBS/CIDP diagnosis. Rule 4(c) Report at 8. Thus, although the first EMG showed evidence of CIDP, the second and third tests showed no evidence of demyelinating condition. *Id.* And treaters eventually concluded that Petitioner's symptoms were due to

See Kinsbourne Rep. at 13. Respondent will therefore be offered the opportunity to provide a rebutting expert report.

CONCLUSION

Petitioner's flu-GBS Table claim fails because the record preponderantly establishes that Petitioner's ultimate diagnosis was CIDP. Accordingly, **Petitioner's Table claim is hereby dismissed.** Respondent shall file a status report **on or before January 22, 2021**, proposing a deadline for the filing of an expert report of his own if he wishes to contest the expert opinions already offered by Dr. Kinsbourne in support of a non-Table claim that the flu vaccine caused Petitioner to experience CIDP.

IT IS SO ORDERED

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

fibromyalgia, which had been present since at least 2013. *Id.* at 2. Respondent cites as additional support two records from Petitioner's treating neurologists who noted that Petitioner's symptoms did not respond to high dose IVIG or steroid treatment. *Id.* at 2 (citing Ex. 11).