

In the United States Court of Federal Claims

No. 18-1065V

(E-Filed: October 18, 2021)¹

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RAFAEL FRANCISCO OJEDA)	
COLON,)	
)	
Petitioner,)	Influenza Vaccine; National Vaccine
)	Injury Compensation Program, 42
v.)	U.S.C. §§ 300aa-10, <u>et seq.</u> ; Six-month
)	Severity Requirement; 42 U.S.C.
SECRETARY OF HEALTH AND)	§ 300aa-11(c)(1)(D); Review of
HUMAN SERVICES,)	Special Master’s Decision.
)	
Respondent.)	
)	

Roberto E. Ruiz-Comas, San Juan, PR, for petitioner.

Althea Walker Davis, Senior Trial Counsel, with whom were Brian M. Boynton, Acting Assistant Attorney General, C. Salvatore d’Alessio, Acting Director, Heather L. Pearlman, Deputy Director, Alexis B. Babcock, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

CAMPBELL-SMITH, Judge.

Petitioner filed the petition in this case on July 20, 2018. See ECF No. 1. The special master issued his initial entitlement decision on June 3, 2021, see ECF No. 60, and denied petitioner’s motion for reconsideration on June 30, 2021, see ECF No. 63. On July 1, 2021, petitioner filed a motion for review with this court, see ECF No. 64, and

¹ This opinion was filed under seal on September 22, 2021, in accordance with Rule 18(b) of the Vaccine Rules, Appendix B to the Rules of the United States Court of Federal Claims. See ECF No. 68. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before October 6, 2021. No proposed redactions were submitted to the court. Therefore, this public version of the opinion is identical to the sealed version with the exception of the date and content of this footnote.

respondent filed a response, on July 30, 2021, see ECF No. 67. Petitioner did not seek to file a reply.

The motion is now fully briefed and ripe for ruling. The court has considered all of the arguments presented by the parties and addresses the issues that are pertinent to the court's ruling in this opinion. For the following reasons, petitioner's motion for review is **DENIED**, and the special master's June 3, 2021 entitlement decision is **SUSTAINED**.

I. Background²

A. Medical Records

On October 17, 2013, petitioner received an influenza vaccination. See ECF No. 60 at 3. Petitioner was seventy years old at the time. See id. On or about October 23, 2013, petitioner developed numbness in his left leg, and began dragging his left foot. See id. On October 29, 2013, petitioner saw Dr. Edgardo Colon Zavala, and reported symptoms of difficulty walking and mild numbness and tingling in his left foot. See id. Petitioner also reported two days of diarrhea "after eating food in Columbia" on vacation. Id. Dr. Zavala's diagnosis was "acute infective polyneuritis," and he recommended that petitioner undergo "further evaluation for possible vaccine-induced [Guillain-Barré Syndrome (GBS)]." Id. at 3-4.

Petitioner was admitted to the hospital the same day for a "chief complaint of bilateral foot drop with numbness." Id. at 4. He reported difficulty walking, tingling in the soles of his feet, difficulty lifting his feet, and "no diarrhea prior to symptoms, only [two] days after symptoms." Id. (internal quotation marks and citation omitted). On October 31, 2013, petitioner was diagnosed with GBS and received intravenous immunoglobulin therapy to "prevent progression." Id.

On November 4, 2013, petitioner completed the intravenous treatment and a doctor's note indicated that petitioner had no "new def[icits]." Id. (internal quotation marks and citation omitted) (alteration in original). The next day, petitioner's medical records indicate that his condition had not further deteriorated, but that he was suffering from constipation. See id. On November 6, 2013, petitioner was discharged from the hospital "with diagnoses of GBS, polyradiculopathy, and diabetes mellitus." Id.

² In describing the background of petitioner's claim, the court refers primarily to the special master's findings of fact. See ECF No. 60 at 3-7. Petitioner's assignments of error do not contest the facts as stated by the special master, but rather challenge the legal conclusions drawn from those facts. See generally, ECF No. 64.

On November 7, 2013, petitioner saw Dr. Priscilla Mieses Llavat, who noted that he had a decreased range of motion, reduced strength, and decreased sensation in his distal lower extremities. See id. Dr. Llavat directed petitioner to attend physical therapy for GBS and left foot drop. See id.

On November 19, 2013, petitioner saw his primary care doctor, Dr. Gabriel Hernandez Denton, who noted both petitioner's GBS diagnosis and his constipation with an "episode of fecal compaction." Id.

Petitioner saw Dr. Llavat on a number of occasions throughout the next several months, including November 22, 2013, December 24, 2013, January 27, 2014, and February 11, 2014. See id. at 5. At the February 11, 2014 appointment, Dr. Llavat noted that petitioner had GBS and left foot drop, but stated that his condition was improved and that his numbness had "abated." Id. She recommended that he engage in exercises at home. See id.

Petitioner saw Dr. Denton on April 24, 2014, and May 1, 2014, due to "changes in his [b]owel habits." Id. (internal quotation marks and citation omitted) (alteration in original). On May 9, 2014, petitioner had a colonoscopy which revealed a colon polyp and hemorrhoids. See id. Petitioner saw Dr. Denton again on July 22, 2014, at which time Dr. Denton diagnosed petitioner with chikungunya, a mosquito-borne virus. See id.

On September 2, 2014, petitioner saw Dr. Llavat and reported bilateral hand pain "that started [seven] weeks ago with viral infection. No numbness." Id. (internal quotation marks and citation omitted) (alteration in original). Despite noting problems with range of motion and pain, "[t]here was no mention of sequelae of GBS at this visit." Id.

On October 20, 2014, petitioner saw Dr. Denton who noted that petitioner was "'S/P [status post]' GBS and chikungunya." Id. Petitioner saw Dr. Denton again on December 16, 2014, for routine lab work. See id. The only specific result noted was that his stool was negative for blood. See id.

One of petitioner's doctors noted, on January 12, 2015, that petitioner fell and hurt his right wrist and right knee, but did not mention any sequelae of GBS. See id.

On July 13, 2015, Dr. Denton visited petitioner at his home and noted that petitioner had "multiple pelvic fractures due to a fall." Id. at 6. On August 5, 2015, Dr. Llavat examined petitioner at his home and noted that petitioner had fallen from a horse in June 2015 and suffered multiple fractures to his pelvic and hip area. See id.

More than two years later, on December 18, 2017, Dr. Denton noted that petitioner had both type two diabetes and hypercholesterinemia, but mentioned no additional issues. See id.

In addition to the medical records previously noted, Dr. Llavat drafted a letter explaining that petitioner participated in physical therapy ten times from November 2013 through June 2017. See id. Dr. Llavat, however, did not provide any detailed notes about the visits or the reasons for the treatment. See id.

Finally, on October 1, 2019, petitioner saw Dr. Jose Carlo and requested his “opinion and recommendations regarding his sequelae of the GBS.”³ Id. (internal quotation marks and citation omitted). Dr. Carlo found: (1) “droop in the left nasolabial fold and mouth, which seems to date from GBS. [Petitioner] cannot whistle since his GBS;” (2) petitioner “[c]annot walk tandem;” and (3) reduced sensation to cold, vibration, and pin, “below the calves, bilaterally, but more pronounced in the left distal leg.” Id. (internal quotation marks and citation omitted) (alteration in original). According to Dr. Carlo, “the sequela of [p]etitioner’s GBS included ‘distal leg weakness, facial weakness . . . and distal, asymmetrical, sensory deficit . . . in the legs.’” Id. (citation omitted). He further assessed that the conditions were likely permanent. See id. at 7.

B. Affidavits

Petitioner submitted an affidavit in which he claims that he “spent almost a year recovering from a severe foot drop for which [he] initially had to use crutches and then later on move[d] to ambulating with a cane.” Id. at 6 (internal quotation marks and citation omitted). He also stated that he suffered from constipation “for about six months after the vaccination,” and that he “continued to suffer from poor balance and falls.” Id. (internal quotation marks and citations omitted).

Affidavits were also submitted by petitioner’s wife, Ms. Ada Diez de Ojeda, and two acquaintances, Mr. Vincente E. Rios and Mr. Eugenio Perez Matos. See id. at 5-6. Ms. Diez de Ojeda states that her husband suffered from occasional constipation beginning in November 2013 through February 29, 2020. See id. at 6. Both Mr. Rios and Mr. Perez Matos attested that they saw petitioner’s “‘left leg [give away] while walking’ on December 30, 2014.” Id. at 5 (citation omitted) (alteration in original).

³ The special master refers to Dr. Carlo as Dr. Carlos throughout his entitlement decision. See generally, ECF No. 60. It appears from the record that Dr. Carlo is correct. See ECF No. 61-2 (letter written by Dr. Jose R. Carlo, attaching his curriculum vitae).

C. Special Master’s Decisions

In the entitlement decision, the special master explained that petitioner was required to “demonstrate that his injuries continued through at least mid-to-late April 2014.” *Id.* at 7. To support this conclusion, the special master cited to 42 U.S.C. § 300aa-11 of the National Vaccine Compensation Act, which states, in relevant part, that a petition must include documentation “demonstrating that the person who suffered such injury . . . suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” 42 U.S.C. § 300aa-11(c)(1)(D)(i).

After reviewing the evidence submitted by petitioner, the special master concluded that petitioner had not met this burden. *See* ECF No. 60 at 7. He explained that “the medical records reflect that [p]etitioner was last assessed with GBS sequelae on February 11, 2014—approximately four months from onset. And there are no records thereafter that document specific treatment or care associated with the GBS that [p]etitioner unquestionably experienced in the fall of 2013.” *Id.* On this basis, the special master dismissed the petition. *See id.* at 10.

Petitioner moved for reconsideration of the special master’s decision. *See* ECF No. 62. Petitioner attached new medical documentation to the motion, and also argued that an intervening change in controlling law militated in favor of reconsideration, citing Kirby v. Secretary of Health and Human Services, 997 F.3d 1378 (Fed. Cir. 2021). *See id.* at 2. The special master denied the motion, explaining that the medical documentation was unpersuasive, *see* ECF No. 63 at 5, and that the entitlement decision “follows the contours of Kirby even if it does not explicitly invoke it,” *id.* at 4.

Petitioner now seeks review of the special master’s determination that petitioner has not satisfied the six-month severity requirement. *See* ECF No. 64.

II. Legal Standards

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. *See* 42 U.S.C. § 300aa-12(e)(2). “Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]’” de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing Althen v. Sec’y of Health & Hum. Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)).

This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master’s judgment is under scrutiny.

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the “not in accordance with law” standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec’y of Dep’t of Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

As the United States Court of Appeals for the Federal Circuit has held, when reviewing a special master’s decision, this court does not “reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder.” Porter v. Sec’y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011). “Rather, as long as a special master’s finding of fact is ‘based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.’” Id. (quoting Cedillo v. Sec’y of Health & Hum. Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Under this standard “reversible error is ‘extremely difficult to demonstrate’ if the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” Lampe v. Sec’y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting Hines v. Sec’y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Petitioner bears the burden of proving his case by a preponderance of the evidence, including that he “suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” 42 U.S.C. § 300aa-11(c)(1)(D)(i); see Song v. Sec’y of Dep’t of Health & Human Servs., 31 Fed. Cl. 61, 65-66 (1994), aff’d, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence).

III. Analysis

Petitioner assigns three errors to the special master’s entitlement decision. First, he argues that the special master “engaged in arbitrary and capricious fact-finding in evaluating whether the evidence showed that petitioner satisfied the Vaccine Act’s severity requirement for a Table Injury.” ECF No. 64 at 2. Second, he argues that the special master applied an “erroneous legal standard for silent medical records together with non-conflicting affidavits.” Id. And finally, he argues that the special master “applied an impermissibly high burden of proof for the ‘preponderance of the evidence’” standard that governs whether the six-month severity requirement is met. Id. The court will address each of petitioner’s concerns in turn.

A. The Special Master’s Fact-Finding Was Not Arbitrary or Capricious

According to petitioner, his medical records “together with the new medical opinion letter . . . by Dr. Priscilla Mieses Llavat [submitted with his motion for reconsideration], fulfilled his burden of proof that it is medically reasonable and more probable than not that [p]etitioner’s GBS sequelae could not ha[ve] been resolved by the beginning of May 2014 at a minimum, fulfilling the six-month severity requirement.”⁴ Id. at 5. Petitioner also argues that the special master failed to take into consideration that he had not been released from physical therapy at the time of his February 11, 2014 appointment. See id. at 6. The special master’s failure to do so, petitioner contends, was arbitrary and capricious. See id.

The court is unconvinced by petitioner’s argument for two reasons. First, in his decision denying petitioner’s motion for reconsideration, the special master cogently explained why he found Dr. Llavat’s new opinion letter to be unpersuasive. See ECF No. 63 at 5. He noted that Dr. Llavat’s letter lacked precision, and that petitioner offered no explanation as to why the letter and accompanying chart now offered to clarify earlier-submitted records “could not have been added to the record long prior to” the entitlement decision. Id.

In addition, the special master’s decision documented petitioner’s medical records in detail, see ECF No. 60 at 3-7, including the February 11, 2014 note in which Dr. Llavat “assessed [petitioner] with GBS and left foot drop,” and recommended that petitioner do exercises at home, id. at 5. The special master observed that “the medical records reflect that [p]etitioner was last assessed with GBS sequelae on February 11, 2014—approximately four months from onset. And there are no records thereafter that document specific treatment or care associated with the GBS that [p]etitioner unquestionably experienced in the fall of 2013.” Id. at 7 (citation omitted).

The special master reviewed the evidence submitted by petitioner “in toto,” and concluded that the medical “record establishes (a) no specific GBS treatment after February 2014, (b) no mention of GBS sequelae thereafter either, but (c) ample evidence for the three to four-year period after substantiating treatment for many other conditions and illnesses, some of which might better explain [p]etitioner’s [gastro-intestinal] distress.” Id. at 8. He further found that it was reasonable to conclude “that [p]etitioner

⁴ In this section of his motion for review, petitioner also quotes from the expert opinion letter written by Dr. Jose Carlo that petitioner submitted with his motion for reconsideration. See ECF No. 64 at 4. Petitioner’s substantive argument, however, omits any discussion of how that letter should have been considered, instead addressing only Dr. Llavat’s letter. See id. at 5-6. The court cannot construct petitioner’s argument on his behalf, and thus, does not address Dr. Carlo’s letter in detail in this opinion.

would have sought treatment or intervention if he had continued to suffer sequelae for his GBS, and/or that his treaters would have mentioned it—and the fact that the records are silent on these matters has more evidentiary significance than [p]etitioner’s after-the-fact assertions of ongoing symptoms.” Id.

Petitioner has not demonstrated, or even argued, that the special master overlooked or discounted medical records that reference his continued physical therapy to treat GBS sequelae. To the contrary, petitioner seems to suggest that the absence of a record releasing him from treatment should be understood as evidence that such treatment continued. See ECF No. 64 at 5. The court disagrees. Plaintiff bears the burden of demonstrating by a preponderance of the evidence that he meets the six-month severity requirement, see Song, 31 Fed. Cl. at 65-66, and the special master reasonably considered the evidence timely submitted by petitioner in determining that he failed to do so.

B. The Special Master Did Not Apply an Erroneous Legal Standard

Petitioner argues that “a motion for review is also warranted as there has been an intervening change in controlling law,” in reference to Kirby v. Secretary of Health and Human Services, 997 F.3d 1378 (Fed. Cir. 2021).⁵ Id. at 6. According to petitioner, the special master should have, but did not, apply the holding from Kirby with regard to circumstances in which medical records are silent as to a material issue. See id. at 7. Specifically, in Kirby, the Federal Circuit made clear that no presumption exists “that medical records are accurate and complete as to all the patient’s physical conditions.” Kirby, 997 F.3d at 1382. Petitioner contends that the special master improperly credited such a presumption in this case. See ECF No. 64 at 7.

Petitioner also raised this issue in his motion for reconsideration, see ECF No. 62 at 2, which gave the special master the opportunity to explain why the entitlement decision is consistent with Kirby. He stated as follows:

My Decision was consistent with Kirby. In it, I noted that there were no records after February 11, 2014, that documented specific treatment or care associated with [p]etitioner’s previous GBS diagnosis. But I did not end my analysis there. Rather, I also considered and weighed witness statements and testimony, as well as other subsequent records offered to support ongoing sequelae. In effect, my overall balancing of all evidence offered in the record

⁵ The court notes that Kirby v. Secretary of Health and Human Services, 997 F.3d 1378 (Fed. Cir. 2021), was decided on May 20, 2021, two weeks before the special master issued his entitlement decision on June 3, 2021, see ECF No. 60. As such, the decision is not properly considered to be an intervening one; rather, Kirby was binding precedent at the time the special master rendered the entitlement decision.

resulted in my severity determination—it did not flow from my unexamined preference for what the medical records say in the face of contrary allegations. As such, Kirby cannot be said to compel a different outcome, such that reconsideration in light of it is required.

ECF No. 63 at 4 (citations omitted). In the court’s view, this is a fair assessment of the special master’s analysis.

The special master engaged in a detailed analysis of both the medical records and the affidavits submitted by petitioner. See ECF No. 60 at 7-10. There is no indication that the special master applied a presumption that because petitioner’s medical records did not mention GBS after February 11, 2014, he could not meet the severity requirement. Instead, the special master noted the important facts that, although petitioner saw doctors following various falls that occurred after February 11, 2014, the records from those visits did not mention GBS sequelae. See id. at 8 (noting medical record indicating difficult walking following a fall from a horse); 9 (noting affidavits and medical record indicating injuries to his right wrist and right knee from a fall).

Furthermore, the special master concluded his analysis by noting as follows:

I am aware that a variety of evidence can be used to satisfy issues like severity, and I am reluctant to dismiss a case simply on this basis, especially given the [Vaccine] Program’s emphasis on generosity in reaching entitlement decisions. However, severity is a claim requirement, and cases may legitimately be dismissed if the record does not preponderantly reveal sufficient evidentiary support for this claim element. Here, I have conducted a thorough record review in reaching my determination, and even giving [p]etitioner’s witness statements some weight, I cannot find that severity is met.

Id. at 10 (citations omitted).

Regardless of whether the court would have reached the same conclusion, it is clear that the special master’s decision complies with the Federal Circuit’s decision in Kirby because he considered the record as a whole, rather than presuming petitioner could not meet the severity requirement based only on the medical records. See Porter, 663 F.3d at 1249 (stating that in reviewing a special master’s decision, this court does not “reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder”).

C. The Special Master Properly Applied the Preponderance of the Evidence Standard

Of petitioner's three arguments, his argument that the special master applied an "erroneous[ly] high burden of proof," is the least persuasive. ECF No. 64 at 10. After reciting the preponderance of the evidence standard and other required elements of a successful claim, petitioner contends that the special master inappropriately applied a heightened standard of proof in petitioner's case. See id. at 9-10. Petitioner does not, however, define what that higher burden was, or explain how it departed from the preponderance standard. See id. at 9-11. Petitioner simply argues, without specifically identifying the evidence to which he refers, that the special master was "arbitrarily and capriciously unfair to [p]etitioner when weighing all the evidence by disregarding medical opinion evidence on GBS musculoskeletal sequelae." Id. at 11.

The court has thoroughly reviewed the special master's entitlement decision, and sees no indication that the special master employed an improperly heightened standard of proof. The special master acknowledged the proper standard, see ECF No. 60 at 2-3, recited the relevant facts at length, see id. at 3-7, carefully considered the record, see id. at 7-10, and noted his hesitance to dismiss a case for failure to meet the severity requirement, see id. at 10, but ultimately found that "[b]ased on the record as a whole, [p]etitioner has failed to prove by preponderant evidence that his GBS or its residual effects lasted for more than six months," id.

Absent a more specific and meritorious argument from petitioner or an obvious error in the special master's application of the preponderance standard, the court will sustain the decision.

IV. Conclusion

Accordingly, for the foregoing reasons:

- (1) Petitioners' motion for review, ECF No. 64, is **DENIED**;
- (2) The decision of the special master, filed on June 3, 2021, ECF No. 60, is **SUSTAINED**;
- (3) The clerk's office is directed to **ENTER** final judgment in accordance with the special master's June 3, 2021 decision; and
- (4) On or before **October 6, 2021**, the parties shall separately **FILE** any proposed redactions to this opinion, with the text to be redacted blacked out.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge