

# In the United States Court of Federal Claims

No. 15-752V

(Filed: September 20, 2018)<sup>1</sup>

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PETER C. HARRINGTON,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Vaccine Act, 42 U.S.C. §§ 300aa-1 et  
seq.; Influenza Vaccine; Table  
Injury; Althen Test; Causation in  
Fact; Guillain-Barre Syndrome.

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Jeffrey C. Adams, 8491 121 Avenue North, Largo, FL, 33773, for Petitioner.

Chad A. Readler, C. Salvatore D'Alessio, Catherine E. Reeves, Gabrielle M. Fielding, and  
Amy P. Kokot, United States Department of Justice, Civil Division, Torts Branch, P.O. Box 146,  
Benjamin Franklin Station, Washington, D.C., 20044, for Respondent.

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## OPINION AND ORDER

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**WILLIAMS**, Judge.

This matter comes before the Court on Petitioner's motion for review of the Special Master's decision denying his claim that the influenza ("flu") vaccine caused him to develop Guillain-Barre Syndrome ("GBS") or symptoms similar to those experienced by individuals with GBS, including muscle weakness, tachycardia, speech difficulties, dizziness, and extreme fatigue. Petitioner lodges two challenges to the Special Master's decision denying his claim. First, Petitioner claims that the Special Master erred in finding that Petitioner was required to establish he had GBS to support a Table Vaccine claim. Second, Petitioner claims the Special Master erred in finding that Petitioner failed to establish causation in fact. For the reasons stated below, the Special Master's decision denying compensation is sustained.

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<sup>1</sup> Pursuant to Vaccine Rule 18 of the Rules of the United States Court of Federal Claims, the Court issued its Opinion under seal to provide the parties an opportunity to submit redactions. The parties did not propose any redactions. Accordingly, the Court publishes this Opinion.

## **Factual Background**<sup>2</sup>

On October 24, 2014, Mr. Harrington, a 40-year old male, received the flu vaccine at Graf Clinic in Pensacola, Florida. Pet'r's Ex. 3 at 20. Thirteen days after receiving this vaccine, on November 6, 2014, Petitioner went to the emergency room at West Florida Regional Medical Center complaining of "heaviness," shortness of breath, and muscle weakness in his arms and legs." Harrington v. Sec'y of Health & Human Servs., No. 15-752V, 2018 WL 1125831, at \*1 (Fed. Cl. Spec. Mstr. Jan. 19, 2018). A neurological examination and a chest x-ray were conducted, but neither revealed evidence of a physiological problem, and Petitioner was diagnosed with anxiety, dysrhythmia, dehydration, anemia, and an electrolyte imbalance. Id.

A few days later, on November 10, 2014, Petitioner returned to the hospital, and then returned again on November 18, 2014. Id. at \*2. Petitioner saw three different doctors and was subject to a battery of tests while in the hospital, including an evaluation for GBS, but none of these physicians diagnosed Petitioner as having GBS. Id. An MRI of Petitioner's brain evidenced no abnormalities, and an MRI of his spinal cord revealed "questionable stenosis," but was otherwise normal. Id. Later in November 2014, Petitioner saw a second neurologist, who also determined that "[Petitioner's] physical examinations [were] not consistent with Guillain-Barre." Id.

In December 2014, Petitioner saw a third neurologist, and in 2015, saw his primary care physician and one of the neurologists who had examined him in 2014. None of his treating physicians ever diagnosed Petitioner with GBS, or determined that the flu vaccine he received in October 2014, was connected with any of his symptoms. Id. at \*3. While some of Petitioner's physicians had initially explored whether GBS might explain his symptoms, ensuing medical examinations and testing did not corroborate that diagnosis.

Petitioner states that he continues to experience symptoms, including fatigue, jaw weakness, tingling in his legs, body aches, difficulty in concentration, and mood changes, but medical tests continue to yield normal results. Pet'r's Ex. 1 at 3.

## **Petitioner's Expert Reports**

Petitioner submitted two expert reports to the Special Master, both prepared by Dr. William Shackelford, a physician.<sup>3</sup> Harrington, 2018 WL 1125831, at \*4. Dr. Shackelford opined that Petitioner suffered GBS symptoms following receipt of the flu vaccine. Id. Dr. Shackelford maintained that Petitioner experienced a "typical Guillain-Barré reaction" and noted that Petitioner was generally healthy prior to receiving the flu vaccine (apart from his past diagnoses of

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<sup>2</sup> The factual background is derived from the Special Master's Decision and medical records filed by Petitioner. Harrington v. Sec'y of Health & Human Servs., No. 15-752V, 2018 WL 1125831 (Fed. Cl. Spec. Mstr. Jan. 19, 2018).

<sup>3</sup> Petitioner did not submit a curriculum vitae for Dr. Shackelford to the Special Master. The only reference to Dr. Shackelford's credentials in the record are statements in Dr. Shackelford's report that he graduated from the University of Illinois Medical School in 1955, entered practice in 1956, in Cerro Cordo, Illinois, was still in that practice as of the date of his report, and had administered several thousand flu vaccinations and treated "many" patients with GBS. Dec. 5.

hypertension, allergic rhinitis, and ear infections). Id. Dr. Shackelford opined that all of Petitioner's symptoms were consistent with GBS and concluded that the flu vaccine caused Petitioner to suffer GBS symptoms "within days" following receipt of the vaccine, primarily because physicians could find "no other cause" for his symptoms. Id. Petitioner submitted no scientific literature in support of Dr. Shackelford's opinions.

### **Respondent's Expert Report**

Respondent's expert, Dr. Jeffrey Cohen, a professor of neurology at Dartmouth Hitchcock Medical Center and the Geisel School of Medicine, is board certified in neurology with added qualifications in clinical neurophysiology and neuromuscular disease, and his primary area of practice involves neuromuscular diseases, including GBS and Chronic Inflammatory Demyelinating Polyradiculoneuropathy. Id. at \*5.

Dr. Cohen concluded that Petitioner's symptoms following his flu vaccine were inconsistent with GBS based on his review of the established criteria for a GBS diagnosis in the accepted medical literature. Id. Dr. Cohen opined that Petitioner's clinical course, medical evaluations, and test results did not suggest that he suffered from GBS for the following reasons:

- Petitioner never displayed bilateral flaccid paralysis in his limbs;
- even though Petitioner complained of weakness, numerous evaluations documented Petitioner's normal strength;
- Petitioner's treating neurologists never noted any decreased or absent tendon reflexes in the weakened limbs; and
- Petitioner's symptoms tended to get better over time and then worsen, rather than to spiral downward in the progressive, acute manner consistent with the expected GBS nadir.

Id. Dr. Cohen opined that Petitioner's symptoms—"a racing heart, difficulty breathing, jaw symptoms, and twitching"—could credibly be attributed to "anxiety with hyperventilation." Id.

### **Discussion**

#### **Jurisdiction and Standard of Review**

In Vaccine Act cases, the Court of Federal Claims has "jurisdiction to undertake a review of the record of the proceedings" and may: (1) uphold the findings of fact and conclusions of law and sustain the special master's decision; (2) set aside any of the findings of fact or conclusions of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law" or (3) "remand the petition to the special master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2)(A)-(C) (2012); Doe 93 v. Sec'y of Health & Human Servs., 98 Fed. Cl. 553, 564-65 (2011).

"Findings of fact of the special master are reviewed under the arbitrary and capricious standard, conclusions of law are reviewed under the not in accordance with law standard, and discretionary rulings are reviewed under the abuse of discretion standard." Broekelschen v. Sec'y

of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), aff'd, 618 F.3d 1339 (Fed. Cir. 2010) (internal citation and quotation marks omitted). The Court's role is not to "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." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal citation and quotation marks omitted). However, the Court has "a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, 'considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [his] decision.'" Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373, 1380 (Fed. Cir. 2015) (quoting Hines ex rel. Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)) (alteration in original).

### **Burden of Proof Under the Vaccine Act**

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illness was actually caused by a vaccine (a "Non-Table Injury"). See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof, requiring a petitioner to offer evidence that leads the trier of fact to believe that the existence of a fact is more probable than not. Moberly, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321-22 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)).

### **Petitioner Failed to Establish That the Special Master Erred**

Petitioner contends that the Special Master erred in finding that Petitioner did not establish either a Table Vaccine Case or causation in fact for a non-Table injury.

#### **Petitioner's Table Case**

Petitioner argues that the Special Master applied the wrong legal standard by mandating that Petitioner demonstrate a clear diagnosis of a specific disease in order to prevail in a Table Vaccine case. Pet'r's Mot. 6. Petitioner asserts that he submitted sufficient evidence demonstrating he experienced GBS-like symptoms and that he satisfied his burden of proof through the testimony of Dr. Shackelford, who stated that regardless of whether Petitioner has GBS, "[a]ll symptoms can be blamed on the vaccine." Id. at 8-9.<sup>4</sup>

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<sup>4</sup> The Special Master correctly found that the Vaccine Table did not include GBS as a listed injury for the flu vaccine until March 21, 2017. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Delay of Effective Date, 82 Fed. Reg. 11,321 (Feb. 22, 2017). Because Petitioner filed his petition in 2015, and the amended Table does not apply retroactively, Petitioner could not establish a Table Vaccine injury. Nonetheless, the Special

The Special Master correctly ruled that to establish entitlement in a Table Vaccine case, Petitioner was required to establish by a preponderance of the evidence that he actually experienced the illness, disability, injury, or condition listed in the vaccine injury table. 42 C.F.R. 100.3(a). The Federal Circuit explained that for “Table injuries,” “causation is presumed when a designated condition follows the administration of a designated vaccine within a designated period of time.” Moberly, 592 F.3d at 1321 (citing 42 U.S.C. §§ 300aa–11(c), 300aa–14) (emphasis added).

The Special Master correctly concluded that Petitioner failed to establish that he in fact had GBS, the “designated condition” he claimed, as Petitioner has never been diagnosed with GBS. Merely claiming symptoms of GBS did not establish that Petitioner suffered from that table injury. See Pet’r’s Mot. 8; Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 960 (Fed. Cir. 1993) (“Although the symptoms of her death are among the statutory indicia of HHC listed in § 300aa-14(b)(1), these symptoms do not independently establish an HHC that is a table injury.”). The Special Master explained:

[t]he Vaccine Injury Table requires a petitioner alleging this kind of claim to establish onset of GBS within three to forty-two days post-vaccination (42 C.F.R. § 100.3(a)(XIV)(D)), and that in fact he suffered from GBS. In the present case, however, Petitioner was never affirmatively diagnosed with GBS, regardless of when his symptoms began. Furthermore, Petitioner’s treating physicians indicated that his symptoms were *not* related to GBS, despite some initial suspicions.

Harrington, 2018 WL 1125831, at \*12.

#### **Petitioner’s Non-Table Case**

Petitioner argues that he established causation in fact because he “had no significant physical problems prior to the vaccination and very significant problems after the vaccine” and his medical records “clearly show that no other factors have been found that could have caused petitioner’s medical problems.” Pet’r’s Mot. 5. Petitioner contends that the Special Master erred in concluding that Petitioner did not satisfy the three-part test set forth in Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under Althen, a petitioner must:

show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278.

Petitioner argues that the Special Master arbitrarily disregarded Petitioner’s evidence of “a medical theory causally connecting the vaccination and injury” because “the injuries have persisted since the time of the vaccination” and Petitioner’s expert, Dr. Shackelford, stated in his

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Master considered Petitioner’s claim “as if the claim itself had been filed after the amendment.” Harrington, 2018 WL 1125831, at \*6 n.5.

report that “[a]ll symptoms can be blamed on the vaccine” and “[n]o M.D. would give a diagnosis other than a vaccine reaction.” Pet.’r’s Mot. 8-9.

Contrary to Petitioner’s argument, the Special Master did consider Dr. Shackelford’s opinions. The Special Master found that Dr. Shackelford’s opinion was “unpersuasive, conclusory, and disjointed,” and was “unsupported by any corroborative literature.” Harrington, 2018 WL 1125831, at \*12. As such, the Special Master concluded that Petitioner failed to demonstrate that the symptoms he experienced post-vaccination could have been caused by the flu vaccine. Id. Conversely, the Special Master determined that Dr. Cohen “persuasively explained why Petitioner’s symptoms and test results did not satisfy the current clinical criteria for a GBS diagnosis” and that Dr. Cohen “credibly rebutted Petitioner’s allegations.” Id. at \*11, \*12. Special masters “are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” Moberly, 592 F.3d at 1326. Such findings “are virtually unchallengeable on appeal.” Broekelschen, 618 F.3d at 1345 (quoting Lampe, 219 F.3d at 1362); see also Paluck v. Sec’y of Health & Human Servs., 104 Fed. Cl. 457, 467 (2012) (“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.”) (internal citations and quotation marks omitted). There is no basis for this Court to disturb the Special Master’s assessment of the expert testimony or of Dr. Cohen’s credibility and the reliability of his opinion.

Second, Petitioner argues that he established “a logical sequence of cause and effect showing that the vaccination was the reason for the injury” because “there have been no other medical theories submitted” and Respondent “failed to establish any other explanation.” Pet.’r’s Mot. 8-9. It is well established that the lack of an alternate explanation for a petitioner’s injury does not establish that the injury was caused by a vaccine. See Lampe, 219 F.3d at 1367-68; Moberly, 592 F.3d at 1323 (“temporal association between a vaccination” and injury, “together with the absence of any other identified cause” for the injury does not on its own compel a finding of causation); Althen, 418 F.3d at 1278 (“neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation”).<sup>5</sup>

### **Conclusion**

Petitioner’s motion for review is **DENIED**. The Special Master’s decision denying compensation is **SUSTAINED**.

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<sup>5</sup> Petitioner also argues that “the proximate temporal relationship between the vaccine and the injury” is clear given that Petitioner “developed his first symptoms and went to the doctor and made multiple calls to his physician” three days after receiving the vaccine. Pet.’r’s Mot. 9. The Special Master acknowledged that there was a temporal connection between Petitioner’s claimed injuries and the vaccine. Harrington, 2018 WL 1125831, at \*13. This circumstance does not undermine the Special Master’s conclusion that Petitioner failed to establish that he had GBS or that his symptoms were caused by the flu vaccine.

The Clerk shall not disclose this decision publicly for 14 days.

s/Mary Ellen Coster Williams  
**MARY ELLEN COSTER WILLIAMS**  
**Judge**