In the United States Court of Federal Claims

DONALD WINKLER,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

No. 18-203V
(Filed: May 13, 2022)*
*Opinion originally filed under seal on April 28, 2022

Michael Patrick Milmoe, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Ryan Daniel Pyles, U.S. Department of Justice, Civil Division, Vaccine/Torts Branch, Washington, DC, with whom were *Gabrielle M. Fielding*, Assistant Director, *Heather L. Pearlman*, Deputy Director, *C. Salvatore D'Alessio*, Acting Director, and *Brian M. Boynton*, Assistant Attorney General, for Respondent.

OPINION AND ORDER

LERNER, *Judge*.

Pending before the Court is Donald Winkler's ("Petitioner" or "Mr. Winkler") Motion for Review of the Special Master's Decision denying him compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300a-1 to -34 ("the Vaccine Act").[1] Petitioner argues that the tetanus/diphtheria ("Tdap") vaccine he received on April 26, 2017, caused him to develop Guillain-Barré Syndrome ("GBS").[2] The Special Master found that Petitioner was not entitled to compensation because he failed to establish by a preponderance of

[1] This Opinion will capitalize the first letter of the words "Petitioner" and "Respondent" to refer to the specific litigants in this case while keeping those letters in lower case when referring to generic petitioners and respondents. To avoid excessive use of brackets, this Opinion applies the same style within quoted material without further noting these alterations.

[2] GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection." *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 411 n.13 (2014) (quoting *Dorland's Illustrated Medical Dictionary* 1832 (32d ed. 2012)), *aff'd* 601 F. App'x 982 (Fed. Cir. 2015). "It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face." *Id.*

the evidence a logical sequence of cause and effect showing that the vaccination was the reason for his injury. In his Motion for Review, Petitioner contends that the Special Master's Decision dismissing his Petition was arbitrary, capricious, an abuse of discretion, and not in accordance with law. While the Court is sympathetic to Mr. Winkler's plight, for the reasons set forth below the Court finds that the Special Master acted within her discretion. Accordingly, the Motion for Review is **DENIED** and the Special Master's Decision is **AFFIRMED**.

I. Background

A. Factual Background

The Special Master's Decision contains a thorough and accurate account of this case's background facts, the most salient of which are as follows. *See* Decision ("Dec.") 4–11, ECF No. 61. Mr. Winkler was 66 years old and in generally good health when he received the Tdap vaccine on April 26, 2017, after stepping on a wire and receiving a painful wound. Pet. ¶ 1, ECF No. 1; Pet'r's Ex. ("Pet. Ex.") 3 at 9, ECF No. 7-3. Two days later, on April 28, 2017, Mr. Winkler visited a medical clinic and complained of "itchy, tingling legs," insomnia, and frequent urination as well as left knee pain. Pet. ¶ 2; Pet. Ex. 5 at 4, ECF No. 7-5. The physician found Mr. Winkler's leg symptoms most likely related to varicose veins and recommended that he see a specialist. Pet. ¶ 2; Pet. Ex. 5 at 6. He was given a pneumococcal conjugate ("Prevnar") vaccination during his examination. Pet. ¶ 2.

On May 3, 2017, Mr. Winkler returned to the clinic for "labs, fatigue[], & bloody stools," and presented with complaints of fatigue, aches, headaches, diarrhea, and frequent urination. Pet. ¶ 3 (quoting Pet. Ex. 5 at 2). He also reported chills, feeling feverish, sinus congestion, and a bloody nose. Pet. Ex. 5 at 2. Mr. Winkler reported abdominal pain but no dyspepsia, heartburn, nausea, vomiting, or constipation. He reported diarrhea three to six times daily and said there may have been melena or bright red blood with the diarrhea. *Id.* at 2. The doctor's assessment was fatigue, myalgia, urinary frequency, diarrhea, and a gastrointestinal ("GI") illness, specifically gastroenteritis. *Id.* at 3.

On May 11, 2017, Mr. Winkler visited an emergency room ("ER"), complaining of "2 weeks of progressively worsening weakness." Pet. Ex. 3 at 26. He reported instability, trouble standing, limping on his left leg, and difficulty using his hands. *Id.* at 7. Dr. Bruce A. Daniel in the ER documented that Mr. Winkler's symptoms "started after a [Prevnar] vaccine and a bout of diarrhea, which [Mr. Winkler] had about the same time 2 weeks ago." Pet. Ex. 3 at 26. Dr. Daniel opined that Mr. Winkler had GBS. Pet. ¶ 4. Mr. Winkler was admitted to the hospital. *Id.*

On May 12, 2017, after more testing, a lumbar puncture confirmed a GBS diagnosis. *Id.* Dr. Mitchell Melling assessed him with the acute inflammatory demyelinating polyneuropathy ("AIDP") variety of GBS. Pet. Ex. 3 at 15. Mr. Winkler was discharged on May 16, 2017, with a diagnosis of GBS and "proximal muscle weakness." Pet. ¶ 7 (quoting Pet. Ex. 3 at 13). He was advised to follow up with Dr. James D. White, who had collaborated in his in-patient treatment, within one week. *Id.*

Mr. Winkler saw Dr. White for a follow-up on May 23, 2017, at which time he reported some improvement but continued weakness, pain, and fatigue. Pet ¶ 8. Mr. Winkler stated that he believed his symptoms had started around May 6, 2017, or slightly earlier. Pet. Ex. 6 at 29, ECF No. 7-6. Dr. White noted that "the patient has symptoms strongly suggestive of AIDP" with a differential diagnosis of chronic inflammatory demyelinating polyneuropathy ("CIDP").[3] Pet. ¶ 8. He was advised to follow up on June 2, 2017. *Id.*

On June 2, 2017, Mr. Winkler visited Dr. White for an electro-neuro diagnostic study. Pet. ¶ 9. Dr. White noted that "[a]bout 4 weeks ago, [Mr. Winkler] developed diarrhea," and "3 weeks ago he developed weakness and was diagnosed with [GBS] (mostly likely AIDP)." Pet. Ex. 6 at 13. He noted that Mr. Winkler's medical history was "quite classic for [GBS]; he had a bout of diarrhea and one week later experienced significant weakness with suppressed reflexes." *Id.* at 14. Dr. White considered whether Mr. Winkler might have had acute motor axonal neuropathy ("AMAN") or acute motor-sensory axonal neuropathy ("AMSAN")—which are two sub-types of GBS—but decided that these types were less likely than GBS "of the AIDP variety." *Id.* at 14–15. However, he also wrote that the "possibility of CIDP cannot entirely be ruled out." *Id.* at 15.

Mr. Winkler then began a series of follow-up medical appointments. He visited Dr. White on June 14, July 12, and August 9, 2017. Pet. ¶ 10 (citing Pet. Ex. 6 at 3, 6–7, 11). Although his condition improved, Mr. Winkler remained "probably weak relative to his prior condition." *Id.* (quoting Pet. Ex. 6 at 3). Mr. Winkler also began a course of physical therapy treatments on August 18, 2017. *Id.* ¶ 11 (citing Pet. Ex. 2 at 8, ECF No. 7-2). This continued for five sessions, with the last occurring on September 20, 2017. Pet. Ex. 2 at 9. He reported some improvement by this last session. *Id.* at 4.

Mr. Winkler saw Dr. White again on September 11 and December 13, 2017. Pet. Ex. 6 at 1–2, 76–77. Dr. White noted that Mr. Winkler's lower body strength was improving, although his upper extremity strength was not satisfactory. *Id.* at 76. Dr. White's diagnostic impression remained GBS, most likely AIDP. *Id.* Mr. Winkler also saw Dr. White on January 10, 2018. *Id.* at 59–64. Dr. White documented steady improvement despite ongoing weakness, primarily in the upper extremities. *Id.* at 59. He opined that Mr. Winkler's persistent weakness was "secondary to the axonal nature of his condition" and noted that Mr. Winkler had been improving. *Id.* Mr. Winkler returned to Dr. White on January 29, 2018, complaining of pain and fatigue. *Id.* at 53–54. In Dr. White's evaluation, Mr. Winkler's clinical course was "most strongly reminiscent of AMSAN." *Id.* at 54.

[3] CIDP is a "slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid" that "occurs most commonly in young adults and is related to Guillain–Barré syndrome." *Semanski*, 115 Fed. Cl. at 412 n.15 (quoting *Dorland's Illustrated Medical Dictionary* 1491 (32d ed. 2012)).

On February 13, 2018, Mr. Winkler executed an affidavit documenting his experience. *See* Pet. Ex. 7, ECF No. 7-7. As of that date, he still had difficulty engaging in certain activities and suffered aches, numbness, and pain. *Id.* ¶ 4.

B. Procedural Background

1. Proceedings before the Special Master

Mr. Winkler filed his Petition in this case on February 9, 2018. *See* Pet. On February 15, 2019, after reviewing the Petition, Respondent, the Secretary of Health and Human Services ("Respondent" or "the Government"), recommended against compensation. *See* Resp't's Rule 4(c) Report, ECF No. 14. In an April 2, 2020 order, the Special Master encouraged the parties to attempt settlement. *See* Order at 2, ECF No. 31. On March 24, 2021, Petitioner filed a motion for a ruling on the record. *See* Mot. for Ruling on the R., ECF No. 49. Further briefing occurred through July 23, 2021, and on December 10, 2021, the Special Master issued a decision dismissing the Petition. *See* Dec. at 34. Mr. Winkler filed a motion for review and accompanying brief on January 10, 2022. *See* Mot. for Rev., ECF No. 62; Memo. of Objs. ("Pet'r's Br."), ECF No. 63. The Government filed a response on February 9, 2022. *See* Resp't's Resp. to Mot. for Rev. ("Resp."), ECF No. 65.

2. Expert Opinions

Both parties submitted expert reports for the Special Master's consideration. Petitioner submitted a report by Dr. John R. Rinker, a board-certified neurologist with a subspeciality in neuroimmunology and Associate Professor of Neurology at the University of Alabama, Birmingham, who opined that Mr. Winkler's vaccination most likely caused his GBS. *See* Pet. Ex. 9, ECF No. 19-1. Respondent submitted expert reports by Dr. J. Lindsay Whitton and Dr. Vinay Chaudhry. *See* Resp't's Ex. ("Resp. Ex.") A, ECF No. 27-1; Resp. Ex. C, ECF No. 28-1. Dr. Whitton is a professor in the Department of Immunology and Microbiology at Scripps Research Institute in California, and Dr. Chaudhry is a board-certified neurology professor at Johns Hopkins University School of Medicine and the Director of the Neurology EMG Laboratory at Johns Hopkins Hospital. *See* Resp. Ex. A at 1; Resp. Ex. C at 1. Both professors concluded that it was more likely that a GI infection had caused the GBS, and that the most likely source of the infection was a bacteria called Campylobacter jejuni ("*C. jejuni*"). *See* Resp. Ex. A; Resp. Ex. C.

a. Dr. Rinker's Report

Dr. Rinker opined that the vaccination likely caused Mr. Winkler's GBS through a process called "molecular mimicry." Pet. Ex. 9 at 4. He explained that this phenomenon occurs when the immune system fails to distinguish between foreign cells and the body's own cells, and "because of the structural resemblance, antibodies and auto-reactive T cells not only destroy the invading pathogen but can react with host tissues as well." *Id.* (quoting Pet. Ex. 37 at 3, ECF No. 55-1). He stated that "[a]n estimated 2/3 of GBS cases are preceded by an illness within 4 weeks before the onset of neurological symptoms," and that "[r]espiratory illnesses are the most common antecedent infections while diarrheal illnesses (esp. *C. jejuni*) are the next most

common." *Id.* at 3 (citation omitted). He added that "[a]nother potential immunological trigger for GBS is vaccination." *Id.*

Dr. Rinker explained his view that there is a causal relationship between vaccination and GBS. He pointed to a 1976 vaccination campaign against swine influenza, which resulted in vaccinated individuals reporting GBS at seven times the rate reported in unvaccinated individuals. *Id.* at 3. Dr. Rinker claimed that "[s]ubsequent epidemiological links between vaccination and GBS have found an excess GBS risk of 1.6 excess cases of GBS per 1 million vaccine recipients, without a strong signal coming from any specific vaccine types." *Id.* (citation omitted). He also pointed to four individual case reports of GBS after patients received tetanus-toxoid-containing vaccines, *see id.* at 5, and noted that these case studies led to a 1994 Institute of Medicine ("IOM") report and a 1996 Centers for Disease Control and Prevention ("CDC") report that both "caution[ed] against a possible causal relationship between tetanus toxoid and GBS," *id.* at 5 (first citing Pet. Ex. 24, ECF No. 23-15; and then citing CDC, *Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 45 Morbidity and Mortality Weekly Report: Recommendations and Reports RR-12 (1996)). He also referred to a report drawing from the Vaccine Adverse Event Reporting System concluding that vaccines other than influenza can be associated with GBS. *Id*.

Dr. Rinker noted that "*C jejuni* is the most common infectious trigger of GBS," but that "less than 0.1% of *C jejuni* infections result in a case of GBS." *Id.* In his view, "the rarity with which GBS occurs even following exposures to known triggers of the condition, should allow for the possibility that sporadic cases of GBS may occur following other immunological stimuli." *Id.* He stated that "[i]n Mr. Winkler's case, it is not possible to distinguish whether vaccination or the diarrheal illness alone was responsible for his GBS, or whether the two immunological stimuli worked in concert to provoke the immune response." *Id.* at 6. In Dr. Rinker's view, "there is insufficient evidence to claim that the illness was a more likely cause of GBS than the vaccine" because Mr. Winkler's treating physicians did not document any tests that could identify an organism as the cause of his GI illness and because it is possible that the illness was not infectious at all. *Id.*

Dr. Rinker concluded that the Tdap vaccine was the most likely cause of Mr. Winkler's GBS. *Id.* at 7. Citing a study of GBS cases from 1996–2004, Dr. Rinker claimed that median latencies between infection and GBS were 15 days for influenza, 10 days for *C. jejuni*, and 6.5 days for cases where infection was suspected but not identified. *Id.* at 5. The ranges for these latencies were 7–21 days, 5–12 days, and 4–8 days, respectively. *Id.* Dr. Rinker observed that Mr. Winkler's GBS symptoms began 9–10 days after his vaccination and 4–5 days after his diarrheal illness. *Id.* at 7. Based on this timing, he concluded that the evidence suggested the vaccination was the more likely cause of the GBS. *Id.* at 7.

b. Dr. Whitton's Report

In contrast, Dr. Whitton opined that Mr. Winkler's GI illness was the more likely cause of his GBS. He explained that approximately two-thirds of GBS cases are preceded by signs or symptoms of an infection—often of the respiratory or GI tracts—and that for GI infections, there

is a strong association between *C. jejuni* and GBS. Resp. Ex. A at 4. He stated that it is common for GBS to appear within a few days after the onset of symptoms because infectious diseases have an incubation period and the body's adaptive immune response begins to react to infection before GI symptoms appear. *Id.* Unlike these diseases, vaccinations do not have an incubation period, which led Dr. Whitton to determine that "a 2-day interval between diarrheal disease and GBS may be acceptable . . . but the same 2-day interval after a vaccination would not be similarly acceptable" as an explanation. *Id.* at 5. In his opinion, given the incubation period of *C. jejuni*, the infection that caused Mr. Winkler's diarrhea likely set in on or around the day that he received the vaccination. *Id.* at 6. He concluded that, factoring in this incubation period, Mr. Winkler's case likely fell well within the latency periods between GI infection and GBS cited in Dr. Rinker's report. *Id.* at 9–10.

Dr. Whitton challenged any causal connection between the Tdap vaccine and GBS. He observed that although the tetanus toxoid vaccine was developed in 1924 and has been in widespread use since the early 1940s, Dr. Rinker's report only cited to four case studies of GBS preceded by such a vaccine, only one of which concerned Tdap, the vaccine that Mr. Winkler received. *Id.* at 6 (citing Pet. Ex. 9, at 5). Dr. Rinker had referred to a patient mentioned in the 1994 IOM report as having developed GBS following a tetanus toxoid vaccination, but Dr. Whitton pointed out that the 2012 revision to the IOM report re-diagnosed the patient in question as having CIDP rather than GBS and found no link between that condition and the vaccination. *Id.* at 8. He added that the Tdap vaccine was not licensed until 2005, so the 1994 report on which Dr. Rinker relied did not address it. *Id.* Dr. Whitton also cited several reports finding no association between GBS and vaccines (although some of these papers concerned vaccines other than Tdap). *See id.* at 6–7.

In addressing Dr. Rinker's assertion that the rarity of post-vaccination GBS suggests a causal relationship between the vaccine and Mr. Winkler's illness, Dr. Whitton considered the incidence of Tdap vaccination and GBS in the population, noting that a certain amount of coincidental post-vaccination GBS is to be expected. *See id.* at 9. He explained that if there were an individual whose GBS was caused by the Tdap vaccine—assuming such a causal relationship could even exist—the epidemiological data would not treat that person differently from the larger number of coincidental cases, meaning that for any such individual, the data would actually suggest that their GBS was more likely than not unrelated to the vaccine. *Id.* at 11–12.

Ultimately, Dr. Whitton said, GI infection "is known to incite GBS; indeed, it is one of its most frequent triggers," while, "[i]n contrast, . . . Tdap is *not known* to cause GBS (and studies indicate that it does not do so)." *Id.* at 11. He concluded that "these straightforward considerations tip the scales of probability extraordinarily heavily in favor of the known cause—GI infection." *Id.*

c. Dr. Chaudhry's Report

Dr. Chaudhry also noted that antecedent infection precedes two-thirds of GBS cases. Resp. Ex. C at 10. He stated that the "presence of [Mr. Winkler's] diarrheal illness [w]as one of the factors in making the diagnosis of GBS as noted by Dr. White, Dr. Melling, and other

physicians." *Id.* at 11. He also observed that while *C. jejuni* is the predominant infection, found in 25–50 percent of adult patients, several other infections are similarly associated with GBS. *Id.* Dr. Chaudhry added that while both AIDP and AMAN are associated with *C. jejuni* infection, AMAN is more likely. *Id.*

Dr. Chaudhry's review of the medical record led him to conclude that Mr. Winkler "had more features for the AMAN subtype than the AIDP subtype of GBS." *Id.* at 10. In particular, he noted that Mr. Winkler had hyperreflexia and suffered an antecedent diarrheal illness, and that Mr. Winkler's follow-up electromyography study showed axonal damage, all of which would suggest AMAN rather than AIDP. *Id.* at 10–11. He also noted that Mr. Winkler did not have indications of AIDP, such as cranial nerve or sensory involvement, autonomic dysfunction, or significant change in his sensory or motor nerves. *Id.* Dr. Chaudhry observed that, although Mr. Winkler's diagnosing physician, Dr. White, raised the possibility of AMAN before concluding that sensory involvement ruled it out as a diagnosis, Dr. White did not refer to any such sensory involvement in his clinical or electrophysiological findings. *Id.* at 11.

Dr. Chaudhry considered reports and studies regarding the possibility of an association between either the Prevnar or Tdap vaccine and GBS and found no likely association. *Id.* at 11–13. Regarding Tdap in particular, he explained that the IOM considered epidemiological studies as well as publications assessing mechanistic evidence and the IOM report itself concluded that evidence was insufficient to determine an association. *Id.* at 12. In fact, the "[n]umber of GBS cases after administration of tetanus toxoid vaccines in both children and adults is not greater than the number expected by chance alone." *Id.* at 13.

Dr. Chaudhry also addressed shortcomings in Dr. Rinker's report. Like Dr. Whitton, he considered Dr. Rinker's focus on instances of other vaccines being associated with GBS "not [to be] appropriate." *Id.* at 14. He noted several places in which Dr. Rinker appeared to have misquoted or misinterpreted the medical record. *See, e.g.*, *id.* at 13 (noting that "Dr. Rinker mentions that Mr. Winkler had multifocal demyelinating neuropathy" but that "[t]his was not the case"). Similar to Dr. Whitton, Dr. Chaudhry also took issue with Dr. Rinker's reliance on the CDC's 1996 report, rather than a follow-up report that found only one case of GBS within six weeks of Tdap vaccination, when two such cases were expected by chance alone. *Id.* at 14. Dr. Chaudhry also joined Dr. Whitton in dismissing a study that the 1994 and 1996 reports examined—and on which Dr. Rinker relied—because the IOM's revised report from 2012 re-diagnosed the subject of the study as suffering from CIDP rather than GBS. *Id.*

Regarding the timing issue, Dr. Chaudhry disagreed with Dr. Rinker's assessment that the time between diarrheal illness and GBS is four to five days. Instead, like Dr. Whitton, he pointed to studies showing a wide array of times between the onset of diarrheal illness and subsequent onset of weakness. *Id.* In Dr. Chaudhry's view, "[e]xcluding a well-known and established cause of GBS on an arbitrarily [sic] basis of time for which there is no support, is not rational." *Id.* at 15.

d. Supplemental Reports

Dr. Rinker submitted a supplemental report in which he addressed Dr. Chaudhry's report. Pet. Ex. 31, ECF No. 39-1. In this short response, he argued that *C. jejuni* causes only a small fraction of known instances of gastroenteritis, the vast majority of which do not result in GBS. *Id.* at 1. He claimed that norovirus is a more likely cause of gastroenteritis and stated that "while Mr. Winkler *may* have been affected by *C. jejuni* in the days leading up to the onset of his GBS, there is no confirmatory laboratory evidence to support this possibility as the organism was never identified, despite testing." *Id.* He also noted that diarrhea is a possible adverse effect of the Tdap vaccine. *Id.* at 1–2. Dr. Rinker opined that "there is insufficient evidence to claim that Mr. Winkler's diarrheal illness was the immunological trigger which initiated his GBS." *Id.* at 2. Based on his view that "*C. jejuni* is an uncommon cause of gastroenteritis, and there is nothing in the record that links *C. jejuni* to Mr. Winkler's GBS," Dr. Rinker concluded that "the mere presence of diarrhea before the onset of GBS, especially when *C. jejuni* was never identified, provides an unlikely cause of Mr. Winkler's GBS in comparison to the Tdap vaccination." *Id.* at 2.

Dr. Chaudhry submitted a supplemental report addressing Dr. Rinker's response. Resp. Ex. E, ECF No. 42-1. He cited reports by the CDC and World Health Organization, as well as additional studies finding that infection with *C. jejuni* is one of the most common causes of gastroenteritis. *Id.* at 1–2. He disputed Dr. Rinker's suggestion that Mr. Winkler's infection might have been caused by norovirus, arguing that "[b]loody stools are not a feature of norovirus infection but are a feature of bacterial gastroenteritis" and that there was no evidence Mr. Winkler came into contact with any person infected with norovirus. *Id.* at 2. Dr. Chaudhry cited several publications to demonstrate that infection with *C. jejuni* frequently precedes GBS, with 25–40 percent of GBS patients worldwide suffering from such an infection 1–3 weeks prior to the illness. *Id.* at 2–3.

In response to Dr. Rinker's assertion that no *C. jejuni* infection was found despite testing, Dr. Chaudhry stated that he did not see any such testing in Mr. Winkler's record. *Id.* at 3. However, he did not give the absence of testing much weight because a "majority of incident cases of C. *jejuni* infection are likely undiagnosed but an antecedent history of diarrhea followed by development of acute motor form of GBS and the known molecular mimicry are highly suggestive if not indicative of C. jejuni causing GBS." *Id.* at 3 (citation omitted). Ultimately, Dr. Chaudhry concluded that "[i]t is more likely than not that [Mr. Winkler's] GBS was caused by C. jejuni associated diarrhea, a proven association, rather than caused by Tdap vaccine, an unproven association." *Id.* at 4.

C. The Special Master's Decision

On December 10, 2021, the Special Master issued a decision denying Petitioner compensation under the Vaccine Act. Dec. at 34. The Special Master concluded, based on her review of the expert testimony and medical records, that "Petitioner has not established by preponderant evidence that his vaccinations caused his GBS." *Id.* The Special Master explained that Petitioner was required to prove by a preponderance of the evidence that the vaccine caused the injury. *Id.* at 28 (citing *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2

(Fed. Cir. 2010)). Petitioner was not required to demonstrate medical certainty or to make a specific evidentiary showing but did have to "prove that the vaccine was 'not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Id.* (quoting *Moberly*, 592 F.3d at 1321) (alteration in original). The framework for establishing causation is laid out in *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In order to show causation-in-fact, a petitioner must provide "(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." *Id.*

The Special Master explained that if a petitioner satisfies this burden, they are entitled to compensation "unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is 'due to factors unrelated to the administration of the vaccine.'" Dec. at 28–29 (quoting 42 U.S.C. § 300aa-13(a)(1)(B)). But "[r]egardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case." *Id.* at 29 (quoting *Flores v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 157, 162–63 (2014)).

Here, the Special Master applied the three *Althen* prongs to Petitioner's case. Regarding the first prong, the Special Master stated that "the experts agree that molecular mimicry is not a disputed theory as it relates to GBS." *Id.* at 30. However, she stated that while they "did not dispute that a GI illness can cause GBS," they did "dispute whether the vaccines at issue here can cause GBS." *Id.* Ultimately, the Special Master did not reach a conclusion as to whether Petitioner met his burden under *Althen* prong one. Instead, she decided that "[d]ue to the facts and circumstances of this case, specifically the fact that Petitioner had a preceding GI illness prior to his GBS, the [Special Master's] determination as to causation turns on an analysis of *Althen* Prong Two." *Id.* The Special Master concluded that, "[a]ssuming that Petitioner has proven a sound and reliable causal mechanism under *Althen* Prong One, . . . Petitioner did not provide preponderant evidence of a logical sequence of cause and effect under the facts of this case." *Id.*

In assessing the claim under *Althen* prong two, the Special Master gave "some weight" to the opinions and views of Mr. Winkler's treating physicians. *Id.* at 31 (first citing *Andreu v. Sec'y of Health & Hum. Servs.*, 569. F.3d 1367, 1367 (Fed. Cir. 2009); and then citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006)). She noted that "Dr. Melling did not associate Petitioner's vaccinations with his GBS," *id.*, and observed that Dr. White, who conducted follow-up appointments with Mr. Winkler, "found [Mr. Winkler's] medical history 'quite classic for [GBS]; he had a bout of diarrhea and one week later experienced significant weakness with suppressed reflexes,'" *id.* (quoting Pet. Ex. 6 at 14).

The Special Master also considered the experts' analysis of causation. She observed that while the record did not show any testing was completed to confirm whether Mr. Winkler had a specific infection, such as *C. jejuni*, Respondent's experts considered a lack of testing to be common with GBS cases. *Id.* at 32. She gave weight to Dr. Chaudhry's assertions that Mr. Winkler's symptoms were consistent with typical symptoms of *C. jejuni* infection and that the treating physicians had considered his history of diarrhea relevant to treatment and diagnosis. *Id.*

The Special Master explained that she found Dr. Rinker's reasoning regarding causation unpersuasive. *Id.* She stated that the medical literature he cited is consistent with the Respondent's experts' findings, particularly regarding the incubation period for *C. jejuni* infections, which "would place the date of infection before or approximately the date of Petitioner's vaccination." *Id.* The Special Master concluded that the temporal association between the vaccination and GBS onset thus did not favor vaccination as the more likely cause. *Id.* She also noted that, although Dr. Rinker argues that "the mere presence of diarrhea before the onset of GBS . . . provides an unlikely cause" of the illness in comparison to the vaccine, *id.* (quoting Pet. Ex. 31 at 2), "[t]his argument does not explain how the Tdap vaccine is the more likely cause of Petitioner's GBS," *id.*

The Special Master stated that she was "not persuaded by Petitioner's arguments, given Petitioner's clinical course, treating physician statements, and the experts' opinions and supporting medical literature." *Id.* She "acknowledge[d] that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation," but found it "reasonable to consider 'evidence of other possible sources of injury'. . . in determining 'whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.'" *Id.* at 32–33 (quoting *Stone ex rel. Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012)). The Special Master decided that, "[i]n this case, 'the presence of multiple potential causative agents makes it difficult to attribute "but for" causation to the vaccination,'" and that, as such, "Petitioner failed to prove that the Tdap and/or Prevnar vaccines were the 'but for' cause of Petitioner's GBS." *Id.* at 33 (quoting *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1358–59 (Fed. Cir. 2006)).

Regarding *Althen* prong three, the Special Master's examination of the record demonstrated that "Petitioner's GBS onset of May 5 or 6, 2017 was 9–10 days after Petitioner's Tdap vaccination, 7–8 days after Petitioner's Prevnar vaccination, and 5–6 days after his diarrheal illness onset." *Id.* at 34. She determined that "[a]ll of these intervals are appropriate" and that Petitioner had satisfied the third *Althen* prong. *Id.*

D. The Motion for Review

Petitioner filed his Motion for Review and accompanying Memorandum of Objections. Mot. for Rev.; Pet'r's Br. He argues that the Special Master erred by applying an incorrect burden of proof, Pet'r's Br. at 11, 20, and by considering irrelevant or unreliable evidence, *id.* at 13–20. In particular, he argues that the Special Master erred in considering evidence concerning a *C. jejuni* infection when no such infection was ever proven to have occurred and in inappropriately considering statistical evidence. *Id.* at 16, 18–19. He also challenges the way in which the Special Master weighed the evidence. *Id.* at 17.

II. Legal Standards

The Vaccine Act created the National Vaccine Injury Compensation Program, which provides compensation for vaccine-related injuries or deaths. 42 U.S.C. § 300aa. This Court has jurisdiction to review the decisions of a special master in a Vaccine Act case upon a motion from the petitioner. 42 U.S.C. § 300aa-12(e)(2). The Court applies three distinct standards of review

in Vaccine Act cases: whether findings of fact are "arbitrary and capricious," whether conclusions of law are "not in accordance with law," and whether discretionary rulings are an "abuse of discretion." *Masias v. Sec'y of Health & Hum. Servs.*, 634 F.3d 1283, 1287–88 (Fed. Cir. 2011); *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see* 42 U.S.C § 300aa-12(e)(2)(B). However, the 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." *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871). If a special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision," then "reversible error is extremely difficult to demonstrate." *Id*. at 1360 (quoting *Hines ex rel. Sevier v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

To be compensated, a petitioner must prove they have an injury that was caused by a vaccine. There are two types of claims under the Vaccine Act: claims based on injuries listed in the Vaccine Injury Table ("Table claims") and claims based on injuries not listed in the Table ("off-Table claims"). *See* 42 U.S.C.§ 300aa-14; *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (describing Table and off-Table cases). In a Table claim, a petitioner is granted a presumption of causation if they show that they received a vaccine listed in the Table, suffered a corresponding injury listed in the Table, and the injury occurred within the prescribed time limitations. 42 U.S.C.§ 300aa-14; *see Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009) (describing Table cases). This presumption satisfies the petitioner's burden to establish a prima facie case for compensation. *Andreu*, 569 F.3d at 1374.

In an off-Table case, a petitioner who received a vaccine listed in the Table but suffered an injury not listed in the Table must prove causation by a preponderance of the evidence without the benefit of any favorable presumption. *See Moberly*, 592 F.3d at 1321 (describing off-Table cases). To prove causation in an off-Table case, a petitioner must show that the injury "was caused by a vaccine" listed in the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). The Federal Circuit uses the *Althen* test to evaluate causation in vaccine injury cases. 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 at1278.

Once the petitioner satisfies their burden, either through a favorable presumption in a Table case or through satisfying the *Althen* test in an off-Table case, they are "entitled to recover unless [the respondent] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1151–52 (Fed. Cir. 2007) (quoting *Whitecotton v. Sec'y of Health & Hum. Servs.*, 17 F.3d

374, 376 (Fed. Cir. 1994), *rev'd on other grounds sub nom*. *Shalala v. Whitecotton*, 514 U.S. 268 (1995)) (citing *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 547 (1994)).

III. Discussion

A. Whether the Special Master Applied the Appropriate Burden of Proof

Petitioner alleges two errors regarding the Special Master's application of the burden of proof; he argues that the Decision applied a heightened burden of proof and that it failed to shift the burden onto the Government. Because the appropriate burden of proof is a question of law, the Court applies the "not in accordance with law" standard. 42 U.S.C. § 300aa-12(e)(2)(B); *Althen*, 418 F.3d at 1277–78.

1. Heightened Burden

Petitioner states that the Special Master erred in "finding that because Petitioner could not eliminate the other 'potential causative agent' in the record for GBS, to wit: a previous GI infection," Petitioner failed to establish but-for causation under *Althen* prong two. Pet'r's Br. at 11 (quoting Dec. at 33). Petitioner alleges that in doing so, "the Special Master raised Petitioner's burden of proof and committed legal error in deciding this question." *Id.*

Respondent argues that because this is not a Table case, Petitioner enjoys no favorable presumption and is instead required to show that the vaccine was "the 'but for' cause of his harm, and the 'reason for the injury.'" Resp. at 8 (quoting *Pafford*, 451 F.3d at 1356). Respondent notes that the Special Master "specifically 'acknowledge[d] that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation.'" *Id.* (citing Dec. at 32). The Government argues that Petitioner's objection, though couched in terms of legal standards, merely amounts to a disagreement with how the Special Master weighed the evidence, a matter that is entitled to substantial deference. *Id.* at 9.

Respondent quotes the Federal Circuit for the proposition that a petitioner could satisfy the first and third prongs of the *Althen* test, but still fail to satisfy the second prong "when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence." *Id.* (emphasis omitted) (quoting *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326–27 (Fed. Cir. 2006)).

The Special Master did not erroneously impose on Petitioner a heightened burden of proof. The Vaccine Act requires that a petitioner prove by a preponderance of the evidence that a vaccination caused her to "sustain[ ] . . . any illness, disability, injury, or condition." 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I); 300aa-13(a). The Secretary of Health and Human Services may raise a "factors unrelated" defense. *Id.* § 300aa-13(a)(1)(B). This defense provides that if the petitioner establishes a prima facie case, but the government proves by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, the petitioner will not be entitled to compensation. *See id.* Where the government submits evidence in support of an alternative theory of causation, the special master may consider that evidence in determining

whether a petitioner has made a prima facie case. In other words, a special master's consideration of the government's evidence does not necessarily impose on a petitioner an improperly heightened burden to disprove the government's alternative theory of causation.

In *Stone*, the Federal Circuit considered the question of whether, in assessing an off-Table petitioner's case, "a special master may consider evidence of other possible causes for the injury in question, or whether evidence of other possible causes may be considered only in connection with the 'factors unrelated' defense on which the government has the burden of proof." 676 F.3d at 1379. The Court determined that its "decisions support the common-sense proposition that evidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." *Id.* at 1379–80 (first citing *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008), and then citing *Pafford*, 451 F.3d at 1358–59).

As the *Stone* court stated, "in some cases a sensible assessment of causation cannot be made while ignoring the elephant in the room—the presence of compelling evidence of a different cause for the injury in question." *Id.* at 1380. *See also de Bazan*, 539 F.3d at 1353 ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case[-]in-chief."); *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1356–58 (Fed. Cir. 2010) (citing 42 U.S.C. § 300aa-13(a)(1)) (stating that "[a]llowing the special master to consider evidence of [an alternative theory of causation] did not improperly shift the burden to [the petitioner] to rule out alternative causes"; evidence of an alternative theory of causation was "just one factor among many that the special master relied on in concluding that 'the facts of the case' did not support [the petitioner's] theory of causation, and thus failed to establish a prima facie case"; and that "[a] petitioner's failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternative cause").

Thus, evidence supporting alternative theories of causation is relevant to the assessment of whether a petitioner has made a prima facie showing that the vaccination caused the injury. In considering this evidence, the Special Master applied the correct burden and did not require that Petitioner disprove other theories of causation. Indeed, the Special Master expressly "acknowledge[d] that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation." Dec. at 32 (citing *Walther*, 485 F.3d at 1149–52). The Special Master also correctly "consider[ed] 'evidence of other possible sources of injury'—here, Petitioner's GI illness—in determining 'whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.'" *Id.* at 33 (quoting *Stone*, 676 F.3d at 1379).

The Federal Circuit has recognized that "a petitioner as a practical matter may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient." *Walther*, 485 F.3d at 1149–50. However, while "a petitioner need not show the asserted vaccine was the predominant cause," a petitioner still "must show that it was substantial." *Id.* at 1151 n.4. The Federal Circuit added that "[w]here multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial cause may require

the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine." *Id.*

This aptly describes the present case. The Special Master noted that Petitioner's expert opined that it was impossible to determine whether the vaccination or diarrheal illness alone caused his GBS, or whether they worked in concert. Dec. at 32. However, the expert "did not explain how the vaccines and GI illness could work together in concert to cause GBS" and "did not support this statement with medical literature or other evidence." *Id.* The Special Master gave little weight to Dr. Rinker's argument that "the mere presence of diarrhea before the onset of GBS . . . provides an unlikely cause of Mr. Winkler's GBS in comparison to the Tdap vaccination." Dec. at 23 (quoting Pet. Ex. 31 at 2). She concluded that even if that is true, it "does not explain how the Tdap vaccine is the more likely cause of Petitioner's GBS." Dec. at 32. Because the Special Master found Petitioner's evidence of causation to be insufficient, particularly in light of the evidence supporting an alternative theory of causation, she determined that Petitioner failed to make a prima facie case for causation. *See Walther*, 485 F.3d at 1151 n.4.

2. Assignment of the Burden

Petitioner further argues that the vaccination and GI illness may have worked in concert and that the burden is not on Petitioner to establish that the vaccination was the predominant cause. He states that "[t]he legal doctrines of legal causation do not require that a substantial cause be a predominant cause," and that "[w]here there are multiple independent potential causes, where harm has been caused by only one of them but there is uncertainty as to which one, the burden is upon Respondent to prove that it was their proposed cause and not the vaccination which caused the harm." Pet'r's Br. at 20. He concludes that "Respondent has failed to show that the unidentified gastrointestinal infection played any role in causing Petitioner's GBS." *Id.*

The Special Master did not erroneously fail to shift the burden onto Respondent. The type of burden-shifting that Petitioner describes only applies "once the petitioner has established a prima facie case." *Walther*, 485 F.3d at 1151. "Once a petitioner establishes her prima facie case by satisfying the *Althen* test, the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing 42 U.S.C. § 300aa–13(a)(1)(B)); *see also de Bazan*, 539 F.3d at 1354 (holding that to "prov[e] by preponderant evidence that a *particular* agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause" is "the government's burden *once the petitioner has met her burden*" (second emphasis added)). The Special Master concluded that Petitioner failed to establish a prima facie case that the vaccination caused the injury, which ended the inquiry. Dec. at 32–33. There was no need to shift the burden to Respondent.

B. Whether the Special Master Erred in Considering Evidence Concerning a GI Infection

Petitioner argues that the Special Master's consideration of evidence of a *C. jejuni* infection was harmful error because the Special Master never found, and the record does not support, that Mr. Winkler suffered from a *C. jejuni* infection. Pet'r's Br. at 13–20. He couches his objections in two ways. The first is to challenge the relevance of Respondent's evidence and the second challenges the Special Master's assessment of that evidence.

1. Relevance

The question of "what evidence is relevant to determining under the Vaccine Act that a condition or injury is unrelated to administration of the . . . vaccine [is] a question of law," which is reviewed under the "contrary to law" standard. *See, e.g.*, *Deribeaux*, 717 F.3d at 1366–67. Petitioner claims that "[b]ecause AIDP and AMAN are separate diagnoses that affect different parts of the nervous system, and are not equally caused by C. jejuni, the Special Master committed reversible error by failing to address this important diagnostic issue of whether Petitioner suffered from AIDP or AMAN." Pet'r's Br. at 17 n.7.

Petitioner also states that, in discussing the prevalence of *C. jejuni* infections in the general population and among GBS patients, Dr. Chaudhry introduced statistical evidence. *See* Pet'r's Br. at 18. Relying on *Knudsen v. Secretary of Health and Human Services*, 35 F.3d 543, 550 (1994) and *Boatmon v. Secretary of Health and Human Services*, 941 F.3d 1351, 1363 (2019), Petitioner insists that "[e]vidence discussing probability, generalizations, and statistical likelihoods cannot be utilized in the instant case to show that Petitioner followed a general trend" and that "such statistics are not germane" to the question of causation. Pet'r's Br. at 18. Additionally, Petitioner argues that the Special Master's reliance on Dr. Whitton's opinion regarding the latency between diarrheal illness and the onset of GBS is "legally inapt absent a concomitant finding that Petitioner likely suffered a C. jejuni illness." *Id.* at 19.

Respondent counters that, because the burden of proof is on Petitioner, the validity of evidence concerning *C. jejuni* does not depend on a finding that Petitioner more likely than not had a *C. jejuni* infection. Resp. at 13. Respondent notes that in *Knudsen*, the Federal Circuit held that a viral infection can be an alternative cause, "even though the viral infection is not in the particular case specifically identified by type or name." *Id.* at 13–14 (quoting *Knudsen*, 35 F.3d at 549). Although Petitioner took issue with Dr. Chaudhry's statements regarding *C. jejuni*, Respondent notes that he addressed other types of infection in his report as well. *Id.* at 14–15. The Government adds that regardless of any finding regarding *C. jejuni*, it is undisputed that Mr. Winkler had a GI infection, diagnosed as gastroenteritis, and Dr. Whitton's testimony on incubation periods was not limited to that of *C. jejuni*. *Id.* at 15–16.

On the matter of statistical evidence, Respondent distinguishes *Knudsen*. For that Table case, "bare statistical fact" was insufficient to overcome the presumption that a vaccine had caused an injury, but Respondent notes that the burden in the present case is on Petitioner. Resp. at 11 (quoting *Knudsen*, 35 F.3d at 547). Respondent further argues that the evidence in the present case is epidemiological, rather than merely statistical. *See* Resp. at 11–13. It quotes

Holmes v. Secretary of Health and Human Services for the proposition that "[s]tatistics, after all, are in large part what epidemiology is all about, and causation can without question be based on epidemiological evidence." *Id.* at 12 (quoting *Holmes*, 115 Fed. Cl. 469, 485 (2014)). Respondent further claims that the experts' opinions regarding the latency of bacterial infections were relevant, particularly because "the only evidence in this case linking the Tdap vaccine to Petitioner's GBS . . . is temporal proximity," which is "insufficient as a matter of law." *Id.* at 16 (citing *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The Special Master's consideration of evidence concerning a GI infection was not contrary to law. The relevance of this evidence is not predicated on the Special Master first establishing "that Petitioner likely suffered a C. jejuni illness." Pet'r's Br. at 19. Rather, this evidence is part of the inquiry into whether Petitioner made a prima facie case for causation. To hold that such evidence is irrelevant unless the Special Master first finds that alternative causation was likely would inappropriately force the Special Master to ignore "the elephant in the room—the presence of compelling evidence of a different cause for the injury in question." *Stone*, 676 F.3d at 1380. Doing so would require the Special Master to find that Petitioner has made a prima facie case when in fact he has not.

Further, the Government may establish causation by a preponderance of the evidence without identifying the precise alternative cause. *See Knudsen*, 35 F.3d at 549 (stating that "there is nothing in the Vaccine Act that requires a *per se* rule that alternative causation cannot be proved when the specific virus is not identified" and "hold[ing] that a 'viral infection' *can* be an alternative causation, even though the viral infection is not in the particular case specifically identified by type or name"). It follows that similar evidence would be relevant and reliable when the party offering it does not carry the burden of proof.

Similarly, the Special Master did not err by failing to address the "diagnostic issue" of whether Mr. Winkler suffered from the AIDP or AMAN subtype of GBS. "[T]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused [the petitioner's] injury.'" *Andreu*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549); *see also Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (citing *Kelley v. Sec'y of Health & Hum. Servs.*, 68 Fed. Cl. 84, 100–01 (2005) for the proposition that "the petitioner [is] not required to categorize his injury where the two possible diagnoses [are] 'variants of the same disorder'").

Nor did the Special Master err in considering statistical and epidemiological evidence. Bare probabilities are insufficient, but "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture." *Knudsen*, 35 F.3d at 549. Petitioner's reliance on *Boatmon* is also unavailing. In that case, the Court held that relying on statistics "[i]n the absence of actual evidence" cannot prove causation. 941 F.3d at 1362–63. But in this case, Respondent's epidemiological evidence supplements "actual evidence" of a GI infection, which is the basis offered as an alternative cause.

2. Discretion

The question of how to evaluate evidence is a discretionary matter for which special masters are entitled to substantial deference. *See Munn*, 970 F.2d at 871 (stating that the 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"). The Court reviews "discretionary rulings under the abuse of discretion standard." *Id.* at 870–73 & n.10. Special masters have wide latitude to decide what evidence to consider, as well as how to weigh that evidence. *See id.* at 871.

Petitioner claims that because the record does not indicate whether he was ever tested to determine the cause of his GI illness, Dr. Chaudhry's opinion discussing the possibility that the GI illness was caused by *C. jejuni* is "inherently unreliable." Pet'r's Br. at 17. In his view, this affects "how much weight to afford the offered opinion." *Id.* at 16 (citing *Broekelschen*, 618 F.3d at 1347). Respondent counters that the Special Master's consideration of evidence regarding GI illnesses that cause GBS was appropriate and relevant. Resp. at 11–14. The Government further states that the Special Master "properly considered" evidence of Mr. Winkler's GI illness and adds that weighing evidence is "a matter well within the Special Master's purview that is entitled to substantial deference on review." Resp. at 9.

The Special Master did not abuse her discretion in considering this evidence. "Where both sides offer expert testimony, a special master's decision may be 'based on the credibility of the experts and the relative persuasiveness of their competing theories.' As such, the special master's credibility findings 'are virtually unchallengeable on appeal.'" *Lozano v. Sec'y of Health & Hum. Servs.*, 958 F.3d 1363, 1370 (Fed. Cir. 2020) (citation omitted) (quoting *Broekelschen*, 618 F.3d at 1347). If the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision," then "reversible error is 'extremely difficult to demonstrate.'" *Lampe*, 219 F.3d at 1360 (Fed. Cir. 2000) (quoting *Hines*, 940 F.2d at 1528).

The Special Master's analysis, including her assessment of the experts' reliability, meets these standards. She "weighed the conflicting evidence and concluded that Petitioner[] had not carried [his] burden of demonstrating" a causal relationship between the Tdap vaccine and Mr. Winkler's GBS. *See Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1254 (Fed. Cir. 2011). It is not the role of this Court to "reweigh the factual evidence or assess whether the special master correctly evaluated the evidence," or to "examine the probative value of the evidence or the credibility of the witnesses," because "[t]hese are all matters within the purview of the fact finder." *Id.* (first citing *Broekelschen*, 618 F.3d at 1349; and then citing *Lombardi*, 656 F.3d at 1354).

In this case, the Special Master provided a "thorough and careful evaluation of all of the evidence including records, tests, reports, and medical literature, as well as the experts' opinions and their credibility." *Id.* Under the applicable standard of review, this is enough. Accordingly, the Special Master's determination that Petitioner failed to prove causation in fact by a preponderance of the evidence was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

IV. Conclusion

The Court is sympathetic to Mr. Winkler, who has suffered from GBS and placed private medical information into the public record in pursuing this action. However, he has not demonstrated that his illness was caused by the vaccination he received in 2017. Because the Special Master's Decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, Petitioner's Motion for Review is **DENIED** and the Decision is **AFFIRMED**. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Carolyn N. Lerner
CAROLYN N. LERNER
Judge