United States Court of Appeals for the Federal Circuit

DONALD WINKLER,
Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2022-1960

Appeal from the United States Court of Federal Claims in No. 1:18-vv-00203-CNL, Judge Carolyn N. Lerner.

Decided: December 13, 2023

MICHAEL P. MILMOE, Law Offices of Leah V. Durant, PLLC, Washington, DC, argued for petitioner-appellant. Also represented by GLENN ALEXANDER MACLEOD.

NINA REN, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by BRIAN M. BOYNTON, C. SALVATORE D'ALESSIO, GABRIELLE M. FIELDING, HEATHER LYNN PEARLMAN, RYAN D. PYLES.

Before LOURIE, MAYER, and STARK, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Dissenting opinion filed by *Circuit Judge* MAYER.

LOURIE, *Circuit Judge*.

Donald Winkler appeals from a decision of the United States Court of Federal Claims sustaining a Special Master's denial of compensation under the National Vaccine Injury Compensation Program, pursuant to the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34, for the development of Guillain-Barré Syndrome ("GBS") following a Tdap vaccination. *Winkler v. Sec'y of Health & Hum. Servs.*, No. 18-203V, 2022 WL 1528779 (Fed. Cl. May 13, 2022); *Winkler v. Sec'y of Health & Hum. Servs.*, No. 18-203V, 2021 WL 6276203 (Fed. Cl. Spec. Mstr. Dec. 10, 2021) ("*Special Master Decision*"). For the following reasons, we affirm.

BACKGROUND

In 2017, Winkler stepped on rusted metal. Concerned about contracting tetanus, he received a Tdap vaccination on April 26, 2017. *Special Master Decision* at *3. Two days later, he visited a physician complaining of itchy, tingling legs. *Id.* The physician administered a Prevnar vaccine and assessed Winkler as having, among other things, daytime somnolence, varicose veins, and proteinuria. *Id.* The physician concluded that the itchiness was perhaps related to the varicose veins. *Id.* Winkler returned to his physician five days later on May 3, 2017, complaining of fatigue, muscle aches, headaches, diarrhea, and feeling feverish. *Id.* The physician assessed him as having gastroenteritis, an inflammation of the stomach and intestinal linings. *Id.*

Evidence in the record supports the general contention that gastroenteritis may be caused by a bacterial infection. In particular, the bacterium *Campylobacter jejuni* is known as an infectious agent that may cause gastroenteritis. *Special Master Decision* at *2. However, the physician treating Winkler did not order a laboratory test to confirm

whether or not Winkler's gastroenteritis was the result of such an infection. Known causes of gastroenteritis other than bacterial infections include food poisoning, viral infections, and consumption of irritating food or drink. *Id.* at *3 n.7. Rarely, a gastrointestinal infection, including those caused by *C. jejuni*, may subsequently trigger GBS, a type of acute monophasic peripheral neuropathy that often presents with rapidly progressive, ascending motor neuron paralysis. *Id.* at *2, *23.

On May 11, 2017, fifteen days after his Tdap vaccination and eight days after his gastroenteritis diagnosis, Winkler went to an emergency room complaining of diffuse weakness and calf pain. *Special Master Decision* at *3. His attending doctors suspected GBS. *Id.* at *3–5. A lumbar puncture performed the following day confirmed that diagnosis. *Id.*

In 2018, Winkler filed a petition for relief in the Court of Federal Claims' Office of Special Masters asserting that he should be compensated under the National Vaccine Injury Compensation Program for GBS allegedly resulting from the Tdap vaccination. On December 10, 2021, the Special Master issued a decision denying the requested relief. *See Special Master Decision* at *26. Winkler filed a timely Motion for Review in the Court of Federal Claims, which affirmed the Special Master's decision. He then timely appealed to this court. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

We review the Court of Federal Claims' review of the Special Master's decision without deference. *Hines ex rel. Sevier v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1523–24 (Fed. Cir. 1991). We examine the Special Master's legal determinations under a "not in accordance with the law" standard and factual determinations under an "arbitrary and capricious" standard. *Munn v. Sec'y of Dep't of*

Health & Hum. Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The parties agree that GBS is not listed in the Vaccine Injury Table as a covered condition for Tdap vaccines. Pet. Br. at 6; Resp. Br. at 1; *Special Master Decision* at *22. Winkler's GBS thus constitutes an off-Table injury, for which he had the burden to prove was actually caused by the Tdap vaccination. 42 U.S.C. §§ 300aa-13(a)(1), –11(c)(1)(C)(ii)(I). A showing of causation-in-fact is evaluated using the three-prong test set forth in *Althen v. Secretary of Health and Human Services* requiring that the petitioner show:

> (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 proximate temporal relationship between vaccination and injury.

418 F.3d 1274, 1278 (Fed. Cir. 2005). The evidence set forth for those prongs "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

In evaluating Winkler's claim for relief, the Special Master made separate holdings for each *Althen* prong. First, she assumed that Winkler had established the first prong, without fully evaluating whether he had in fact done so. *Special Master Decision* at *23. She then held that he had not established the second prong but had established the third. *Id.* at *23–26. She subsequently denied relief because of a failure to show, by preponderant evidence, that the Tdap vaccine was the reason for Winkler's GBS. *Id.* at *26.

In reaching her conclusion on the second *Althen* prong, the Special Master thoroughly reviewed evidence relating to Winkler's May 3, 2017 visit to his physician during which he was diagnosed with gastroenteritis. *See Special Master Decision* at *23–25. Although the physician did not probe further to determine whether or not the gastroenteritis was due to a gastrointestinal infection, expert testimony submitted on behalf of the government supported a conclusion that Winkler likely suffered from such an infection. *Id.* at *24. In particular, a medical expert testifying on behalf of the government reviewed Winkler's complaints of "fatigue, bloody stools, chills, and feeling feverish" and found that that particular constellation of symptoms was consistent with a *C. jejuni* infection. *Id.* at *20, *24. The Special Master thus considered two potential triggers of the GBS: the Tdap vaccine and the diarrheal illness that was consistent with a *C. jejuni* infection.

Winkler argues on appeal that the Special Master erred by requiring him to disprove that he suffered from a *C. jejuni* infection. Pet. Br. at 6. However, Winkler mischaracterizes the burden that he was required to meet. In asserting an off-Table injury, Winkler needed to show, by preponderant evidence, that his Tdap vaccination was a substantial factor in causing his GBS. He did not need to show that he did not suffer from a gastrointestinal infection, or that said gastrointestinal infection did not contribute to his GBS. Nor did he have to show that the Tdap vaccination was the only cause of his GBS. The Special Master made that clear, explaining that "petitioner is not required to eliminate other potential causes in order to be entitled to compensation." *Special Master Decision* at *25 (citing *Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1149–52 (Fed. Cir. 2007)). Here, the Special Master did not conclude that Winkler was not entitled to relief because he did not disprove evidence of an infection. Rather, the Special Master held that Winkler was not entitled to relief because he did not establish a prima facie case of

causation of his GBS by the Tdap vaccine. As explained in *Doe v. Secretary of Health and Human Services*, 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." 601 F.3d 1349, 1356–58 (Fed. Cir. 2010) (discussing 42 U.S.C. § 300aa-13(a)(1)).

Winkler further argues that the Special Master erred in failing to make a factual finding as to whether or not he actually suffered from a *C. jejuni* infection. Pet. Br. at 6. He also contends that, without said factual finding, it was error for the Special Master to consider "irrelevant evidence" of a *C. jejuni* infection. *Id.* We disagree.

As set forth in *Stone v. Secretary of Health and Human Services*, "evidence of other *possible* sources of injury can be relevant . . . to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." 676 F.3d 1373, 1379 (Fed. Cir. 2012) (emphasis added). There is no dispute that Winkler's diarrheal illness was a possible source of injury. Indeed, an expert testifying on Winkler's behalf acknowledged that "it is not possible to distinguish whether . . . the diarrheal illness alone was responsible for [the] GBS." *Special Master Decision* at *24. Nor is there a dispute that the diarrheal illness could have been due to a *C. jejuni* infection and that such an infection could have caused Winkler's GBS. *Id.* at *10, *12–13. Especially given that lack of dispute regarding *C. jejuni* as a possible source of injury, evaluating the strength of Winkler's prima facie case did not require an explicit finding that Winkler actually suffered from a *C. jejuni* infection. The Special Master was free to consider evidence relating to whether or not Winkler suffered from a *C. jejuni* infection, as well as the likelihood that said infection triggered Winkler's GBS. Such contemplation of a potential causative agent when evaluating whether or not a petitioner has established a prima facie case is in accordance with the law.

To the extent that Winkler challenges the way in which the Special Master weighed evidence relating to *C. jejuni* infections in the absence of an express finding that he suffered from one, we find no abuse of discretion. "We do 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) (citing *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)). As explained in *Hodges v. Secretary of Health and Human Services*, "[t]hat level of deference is especially apt in a case in which the medical evidence of causation is in dispute." 9 F.3d 958, 961 (Fed. Cir. 1993). That makes reversible error and abuses of discretion "extremely difficult to demonstrate" when, as is the case here, the Special Master "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision." *Hines*, 940 F.2d at 1528. Using that discretion, the Special Master found that Winkler "failed to provide preponderant evidence of a logical sequence of cause and effect required under *Althen* Prong Two." *Special Master Decision* at *25. We see no abuse of discretion in the Special Master's evaluation of the evidence that would mandate overturning her holding.

Ultimately, while, based on the record before us, the Special Master could have gone either way, it was not arbitrary or capricious for her to conclude that Winkler did not prove his case. And the failure to prove an alternate cause does not obviate the need for proof of causation by the vaccine.

CONCLUSION

We have considered Winkler's remaining arguments and do not find them persuasive. For the foregoing reasons, we affirm the Special Master's holding that Winkler

failed to prove causation of GBS by the Tdap vaccine by preponderant evidence.

AFFIRMED

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Appeal from the United States Court of Federal Claims in No. 1:18-vv-00203-CNL, Judge Carolyn N. Lerner.

MAYER, *Circuit Judge*, dissenting.

The special master here improperly required the petitioner, Donald Winkler, to eliminate other potential causes of his Guillain-Barré syndrome ("GBS") and permitted the government to defeat his claim without producing any credible evidence that he was afflicted with a *Campylobacter jejuni* ("*C. jejuni*") infection or that it, rather than vaccination, triggered his GBS. *See* J.A. 30–34. Under the special master's reasoning, the government can defeat a claim for compensation under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 ("Vaccine Act"), simply by speculating—rather than establishing—that an agent other than vaccination caused a petitioner's

illness. Such an approach will make it nearly impossible for claimants—even those who, like Winkler, can provide cogent medical evidence linking their vaccination to their injury—to prevail in off-Table claims for compensation.

The special master's approach has no place in the pro-claimant compensation system designed by Congress, a system where awards are to "be made to vaccine-injured persons quickly, easily, and with certainty and generosity," H.R. Rep. No. 99–908, 99th Cong., 2d Sess. 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344, where a link between vaccination and an injury can be found "in a field bereft of complete and direct proof of how vaccines affect the human body," *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005), and where "close calls regarding causation [must be] resolved in favor of injured claimants," *id*. I therefore respectfully dissent.

I.

The special master's initial order, issued pursuant to Vaccine Rule 5, was correct. *See* J.A. 103–04. She determined that because Winkler's expert, John R. Rinker, M.D., a neurologist with subspecialty training in neuro-immunology, J.A. 63, had done "a good job explaining" why Winkler could meet all three prongs for vaccine causation set out in *Althen*,[1] she "would not be opposed to finding" that Winkler satisfied his burden to demonstrate that the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine he

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[1] In an off-Table case, the petitioner must show by preponderant evidence that the vaccination caused his 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.

received on April 26, 2017, led to the development of his GBS. J.A. 103. The special master further stated that while the government alleged that a *C. jejuni* infection, rather than vaccination, caused Winkler's GBS, it could "have difficulty proving the [gastrointestinal] infection was more likely than not the cause of [Winkler's] GBS." J.A. 104. Citing to precedent from this court, the special master emphasized that because there were at least two potential independent causes of Winkler's GBS, it was the government's burden to demonstrate that it was a *C. jejuni* infection, rather than vaccination, which caused Winkler's condition. J.A. 104 (citing *Walther v. Sec'y of HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007)).

Inexplicably, however, when the special master issued her final decision, she reversed course, absolving the government of any duty to establish either that Winkler had been afflicted with a *C. jejuni* infection or that it was the likely trigger for his GBS. *See* J.A. 32–33. Indeed, the special master denied Winkler's claim without making a finding that he ever experienced a *C. jejuni* infection. *See* J.A. 32–33. Nor could she have made such a finding on the record presented.

In support of its assertion that it was a *C. jejuni* infection that led to Winkler's GBS, the government relied heavily on the testimony of its expert, Vinay Chaudhry, M.D. Chaudhry's testimony, however, rested upon conjecture stacked upon speculation after speculation and was therefore wholly inadequate to derail Winkler's strong prima facie case of causation.

As a preliminary matter, none of Winkler's laboratory tests showed any indicia of a *C. jejuni* infection, J.A. 32, 43, 105, and there was no evidence that any physician who treated him for his non-specific diarrheal illness considered it to have been caused by such an infection, J.A. 4–5. The record shows, moreover, that the overwhelming majority of diarrheal illnesses are *not* the result of a *C. jejuni* infection.

As the special master acknowledged, "[c]auses of gastroenteritis include food poisoning, viral infections, and consumption of irritating food or drink." J.A. 5 n.7. Notably, Rinker pointed to medical literature showing that while "[e]stimates for annual incidence of diarrheal illnesses in the United States range from 179 million to 350 million," the Centers for Disease Control and Prevention ("CDC") estimates that only "approximately 1.5 million instances of gastroenteritis are caused by *Campylobacter* each year (including unconfirmed cases)." J.A. 105 (citations omitted). This means that *Campylobacter* accounts for less than 1% of all cases of gastroenteritis in the United States.[2] J.A. 105.

By contrast, "among gastroenteritis cases in which the pathogen was identified, norovirus is the most common pathogen, accounting for 12–16% of cases." J.A. 105 (citation omitted). Notably, moreover, Chaudhry acknowledged that while *C. jejuni* infection has been linked to the development of GBS, a diarrheal illness caused by certain other agents, such as one caused by *Campylobacter coli*, "does not trigger GBS." J.A. 98.

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[2] In his rebuttal report, Chaudhry stated that "infection with [*C. jejuni*] is one of the most common causes of gastroenteritis worldwide," J.A. 108 (citation and internal quotation marks omitted), but he did not dispute Rinker's claim that there were less than 1.5 million instances of gastroenteritis caused by *Campylobacter* each year in the United States, J.A. 109. To the contrary, Chaudhry cited to a CDC report stating that there were only "about 1.3 million cases" of *Campylobacter* infection each year in this country. J.A. 109. Further, while Chaudhry pointed to an article stating that *C. jejuni* infections are a common cause of "*bacterial* gastroenteritis," J.A. 137 (emphasis added), there is no evidence demonstrating that Winkler's non-specific diarrheal illness was caused by a bacterial infection.

Further, "the CDC's Tdap Vaccine Information Statement lists diarrhea as a possible adverse reaction." J.A. 17 (footnote omitted); *see* J.A. 105. Given that: (1) no laboratory tests showed Winkler had a *C. jejuni* infection; (2) reports indicate that less than 1% of diarrheal illnesses in the United States are the result of such an infection; (3) Chaudhry acknowledged that diarrheal illness from other agents, such as *Campylobacter coli*, do not trigger GBS; and (4) the Tdap vaccine Winkler received in April 2017 could well have been responsible for his gastrointestinal symptoms, the government's effort to defeat Winkler's prima facie case by showing that he had been afflicted with a *C. jejuni* infection fell woefully short.

Even assuming *arguendo* that the government had made a more robust showing that Winkler had experienced a *C. jejuni* infection, moreover, its evidence linking such an infection to the development of GBS was anemic. In this regard, it is noteworthy that "less than 0.1% of *C. jejuni* infections result in a case of GBS." J.A. 13 (citation and internal quotation marks omitted); *see* J.A. 105. Further, there are various subtypes of GBS, including acute inflammatory demyelinating polyneuropathy ("AIDP") and acute motor axonal neuropathy ("AMAN"), and Winkler's physicians repeatedly diagnosed him with the AIDP subtype. *See* J.A. 90 (noting that Winkler's "[h]istory, electrodiagnostic studies, and spinal tap [were] consistent with AIDP"); *see also* J.A. 37, 118, 121. While there is an established connection between a *C. jejuni* infection and AMAN, the link between a *C. jejuni* infection and AIDP is significantly weaker. *See* J.A. 41, 138; *Isaac v. Sec'y of HHS*, No. 08-601V, 2012 WL 3609993, at *22 (Fed. Cl. Spec. Mstr. July 30, 2012), *aff'd,* 108 Fed. Cl. 743 (Fed. Cl. 2013), *aff'd,* 540 F. App'x 999 (Fed. Cir. 2013) (noting that "AIDP . . . has been found not to be caused by cross-reaction with *C. jejuni*"); *Garcia v. Sec'y of HHS*, No. 05-0720V, 2008 WL 5068934, at *7 (Fed. Cl. Spec. Mstr. Nov. 12, 2008), *adhered to on reconsideration*, No. 05-0720V, 2010 WL 2507793

(Fed. Cl. Spec. Mstr. May 19, 2010) (concluding that the petitioner established that the tetanus vaccine he received led to his GBS, notwithstanding the fact that the petitioner had also experienced a diarrheal illness, and citing expert testimony that "the most prevalent form of GBS in America is the AIDP form" and "*C. jejuni* is more commonly associated in sources of medical literature with the AMAN form").

In short, the government failed to produce any reliable evidence that Winkler ever had a *C. jejuni* infection, much less that it triggered his GBS. Winkler, by contrast, produced credible evidence linking his GBS to vaccination. Before the special master, there was little dispute that Winkler presented evidence sufficient to meet prongs one and three of the *Althen* test.[3] As to *Althen* prong two, Rinker provided a reasoned explanation of the logical sequence of cause and effect between Winkler's vaccination and his GBS. Rinker stated that "GBS is thought to result when an immunological trigger provokes an autoimmune reaction in an affected person that leads to widespread demyelination of the peripheral nerves" and that vaccination can cause GBS by provoking the immune system to attack healthy tissues. J.A. 66; *see also* J.A. 12–13. Rinker supported his testimony by citing to medical literature indicating that vaccination, in general, and the tetanus vaccine,

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[3] The special master here correctly "assum[ed]" that Winkler had "proven a sound and reliable causal mechanism" linking his receipt of the Tdap vaccine to the development of GBS so as to satisfy *Althen* prong one, given that "the experts agree[d] that molecular mimicry is not a disputed theory as it relates to GBS." J.A. 30. She further correctly concluded that he had satisfied *Althen* prong three by demonstrating an appropriate temporal association between his April 26, 2017, vaccination and his development, approximately ten days later, of GBS. J.A. 34.

in particular, can trigger GBS.[4] *See* J.A. 14–15. Indeed, even Chaudhry cited to medical literature acknowledging that "epidemiological studies" had "reported development of GBS following vaccinations, including those containing tetanus toxoid." J.A. 24–25 (citation and internal quotation marks omitted).

Such evidence was more than ample to satisfy Winkler's burden under *Althen* prong two. In this regard, causation can be established with "circumstantial evidence," *Althen*, 418 F.3d at 1280, and Winkler was not required to "submit conclusive proof in the medical literature linking" his vaccination to his illness, *Andreu ex rel. Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1375 (Fed. Cir. 2009). *See Althen*, 418 F.3d at 1277–80 (concluding, based on the testimony of the petitioner's expert, that the petitioner's central nervous system injury was caused by the tetanus toxoid vaccine she received).

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[4] Notably, one large-scale study concluded that there was "strong evidence" that a specific flu vaccine had "incited the onset of GBS in many adult vaccinees." J.A. 14 (citation and internal quotation marks omitted); *see also* J.A. 70. Another article examined reports of GBS following vaccination, finding that 1000 cases of GBS had occurred post-vaccination. J.A. 14, 71. While the development of GBS was most strongly associated with the flu vaccine, there were twenty-eight cases of GBS following tetanus and diphtheria toxoid vaccination and fourteen cases of GBS after a pneumococcal polyvalent vaccination. *See* J.A. 14, 71. Rinker further noted that there had been at least four individual case reports in the medical literature of persons developing GBS following inoculation with vaccines containing tetanus toxoid. J.A. 15–16, 67.

II.

The text and structure of the Vaccine Act create a two-stage framework for evaluating causation in off-Table cases. *See* 42 U.S.C. § 300aa-13(a)(1); *Walther*, 485 F.3d at 1150. In the first stage, the petitioner has the burden of establishing a prima facie case by demonstrating, by a preponderance of the evidence, that his injury was "caused in fact by the vaccine or vaccines he received." *Paluck ex rel. Paluck v. Sec'y of HHS*, 786 F.3d 1373, 1379 (Fed. Cir. 2015) (internal quotation marks omitted); *see Andreu*, 569 F.3d at 1374. The petitioner, however, "need not show that the vaccine was the sole or predominant cause of [an] injury, just that it was a substantial factor." *de Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008). If the petitioner establishes a prima facie case of causation, the inquiry moves to the second stage, where the government is given the opportunity to demonstrate, by a preponderance of the evidence, that the petitioner's illness was in fact caused by "factors unrelated" to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); *Walther*, 485 F.3d at 1150–51.

In certain circumstances, the special master can consider evidence of alternative causative agents not only when evaluating the government's "factors unrelated" defense, but also when assessing whether the petitioner has established a prima facie case. *See Stone ex rel. Stone v. Sec'y of HHS*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) (explaining that "the special master is entitled to consider the record as a whole in determining causation, especially in a case involving multiple potential causes acting in concert, and no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute"). This can be appropriate where the petitioner's evidence linking his injury to a vaccine is unusually weak and the government's evidence of an alternative cause, by contrast, is compelling. *See id.* (stating that "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"); *see also Doe ex rel. Doe v. Sec'y of HHS*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (affirming a denial of compensation where a special master determined that the claimants had failed to establish a prima facie case because their daughter's symptoms did not correspond to their theory of causation and "not because [the claimants] failed to eliminate [Sudden Infant Death Syndrome] as an alternative cause of [their daughter's] death").

Importantly, however, we have made clear that in assessing a potential alternative cause, a special master: (1) "may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order [to] establish a prima facie case"; and (2) "may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence." *Stone*, 676 F.3d at 1380; *see Walther*, 485 F.3d at 1151 (explaining that "when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm"). The special master violated both of these prohibitions here.

Even though the special master paid lip service to the notion that a petitioner need not eliminate other potential causes in order to establish a prima facie case, *see* J.A. 32, the crux of her analysis was that because Winkler could not conclusively demonstrate that he did not have a *C. jejuni* infection, he could not establish the requisite causal link between vaccination and his GBS. *See* J.A. 32–33. She stated that while Rinker argued that "the mere presence of diarrhea before the onset of GBS, especially when *C. jejuni* was never identified, provides an unlikely cause of [Winkler's] GBS in comparison to the Tdap vaccination," Winkler was not tested for the presence of a *C. jejuni* infection and therefore could not "explain how the Tdap vaccine [was] the more likely cause of [his] GBS." J.A. 32. In other words, because no test had ruled out a *C. jejuni* infection,

Winkler could not eliminate such an infection as the cause of his illness. This analysis has it backwards—Winkler was not required to rule out a *C. jejuni* infection, but it was instead the government's burden to "rule in" such an infection. *See Walther*, 485 F.3d at 1152 ("[W]e have specifically recognized that the government bears the burden on alternative causation when, as here, the petitioner attempts to establish a prima facie case through the off-Table path of proving actual causation.").

Relatedly, despite the rule that a special master "may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence," *Stone*, 676 F.3d at 1380, the special master here never determined that there was preponderant evidence showing that Winkler had been afflicted with a *C. jejuni* infection. *See* J.A. 30–33. Instead, she simply concluded that because there were two "potential" causes of his GBS, he could not establish that vaccination was the "but for" cause of his illness. J.A. 33. In effect, under the special master's approach, the government can derail a petitioner's prima facie case simply by identifying a "potential" alternative cause for his condition.

III.

"There is . . . a fine line between a court properly considering evidence in the record and improperly placing the burden on the petitioner to prove that" an illness was not caused or exacerbated by a factor unrelated to vaccination. *Sharpe ex rel. Sharpe v. Sec'y of HHS*, 964 F.3d 1072, 1082 (Fed. Cir. 2020) (citation omitted). The special master here crossed this line by a wide margin. Instead of holding the government to its burden, she required Winkler to demonstrate that he did *not* have a *C. jejuni* infection and that it did *not* trigger his GBS.

Despite ongoing research, the etiologies of many diseases and disorders remain poorly understood. *See, e.g.*, *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)

("[M]edicine is scientific, but not entirely a science."). Given that there is frequently no consensus on the factor or factors likely to trigger a particular illness or disorder, the government will, in the great majority of cases, be able to speculate about a potential alternative cause for a malady that emerges in the wake of vaccination. Thus, to the extent that this court sanctions the approach to causation relied upon by the special master here—an approach which countenances the use of mere speculation regarding alternative causes to defeat a petitioner's prima facie case—it will erect a nearly insurmountable barrier to the successful pursuit of an off-Table claim. I would reverse and remand for a calculation of the compensation to which Winkler is entitled.