United States Court of Appeals for the Federal Circuit

RONALD E. WHITE,
Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2024-1372

Appeal from the United States Court of Federal Claims in No. 1:20-vv-01319-TMD, Judge Thompson M. Dietz.

OPINION ISSUED: August 27, 2025
OPINION MODIFIED: December 22, 2025*

LISA A. ROQUEMORE, Law Offices of Lisa A. Roquemore, Rancho Santa Margarita, CA, argued for petitioner-appellant.

ALEC SAXE, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by C. SALVATORE

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* This opinion has been modified and reissued following a petition for rehearing filed by the appellant.

D'ALESSIO, VORIS EDWARD JOHNSON, JR., HEATHER LYNN PEARLMAN, YAAKOV ROTH, DARRYL R. WISHARD.

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

LOURIE, *Circuit Judge*.

Ronald E. White appeals from a decision of the United States Court of Federal Claims ("the Claims Court") sustaining a special master's denial of his claim for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 et seq. ("the Vaccine Act"). *White v. Sec'y of Health & Hum. Servs.*, 168 Fed. Cl. 660 (2023) ("*Claims Court Decision*"); *White v. Sec'y of Health & Hum. Servs.*, No. 20-1319V, 2023 WL 4204568 (Fed. Cl. June 2, 2023) ("*Special Master Decision*"). We affirm.

BACKGROUND

White received a flu vaccine on November 1, 2017. *Special Master Decision*, at *1. Over a month later, on December 5, 2017, he went to a clinic with a two-day history of dry cough, nasal congestion, runny nose, fatigue, and a fever. *Id.* While there, a "nurse practitioner diagnosed him with a viral infection." *Id.* Five days later, on December 10, 2017, White went to the emergency department complaining of sudden generalized weakness that began earlier that day and ongoing upper respiratory symptoms that he reported had lasted ten days without improvement. *Id.* at *2. The attending physician suspected his generalized weakness was a symptom of Guillain-Barré Syndrome ("GBS")—a neurologic condition in which the body's immune system mistakenly attacks the peripheral nerves—while continuing to note that White was also likely still experiencing a viral illness. *Id.*

That same day, White's healthcare providers transferred him to a different medical center and placed him in an intensive care unit ("ICU") for "close monitoring of his

respiratory status." *Id.* While there, White's providers continued to suspect that he had GBS "given his clinical presentation." *Id.* And throughout his hospitalization "many of his treating physicians opined or speculated that his neurologic, GBS-like symptoms were associated with his preceding/ongoing respiratory infection." *Id.*; *see id.* at *8 ("[A]t least 14 treaters associated [White's] upper respiratory infection with the development of his GBS."). Meanwhile, none of his providers "at this time proposed his more recent symptoms had anything to do with the flu vaccine he had received almost six weeks before." *Id.* at *2.

Four days later, "on December 14, 2017, a sputum sample from [White's] lungs was taken and the culture of it revealed an *H. influenzae* infection," *i.e.*, a bacterial infection. *Id.* at *3 (footnote omitted). Consistent with that test result, chest X-rays also showed worsening conditions in both lungs. *Id.* About a week later, on December 20, 2017, White's doctors transferred him from the ICU to another unit to conduct further testing to rule out GBS mimics. *Id.* White's providers "continued to repeat the hospital summary that [he] likely had experienced *H. influenza*[*e*] pneumonia" and upon discharge he was diagnosed with "GBS and *H. influenzae* pneumonia." *Id.*

On October 5, 2020, White sought compensation under the Vaccine Act by filing a petition at the Claims Court, which assigned his case to a special master. *Id.* at *1. White alleged that his GBS-related injury was caused by the flu vaccine that he received on November 1, 2017. *Id.* The special master determined that although White had established a *prima facie* case that the flu vaccine caused his alleged injury, *id.* at *15, he could not prevail because the government adequately showed that his unrelated *H. influenzae* infection was the "sole substantial factor" causing his GBS, *see id.* at *17–19. In so finding, the special master also explicitly eliminated the vaccine as a causal factor. *See, e.g.*, *id.* at *18 n.16.

White sought review of the special master's decision in the Claims Court. *See Claims Court Decision*, 168 Fed. Cl. at 664. He argued there that the special master "erred by making arbitrary and capricious findings of fact and by failing to apply the correct burden of proof to the government." *Id.* The Claims Court rejected his arguments and sustained the special master's decision denying White entitlement to compensation under the Vaccine Act. *Id.* White timely appealed, and we have jurisdiction under 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

DISCUSSION

White argues that there were at least two errors in the special master's decision denying his petition for compensation. First, White argues that the special master's decision was not in accordance with the law because it failed to apply the appropriate legal standard. *See* Appellant Br. 19–23, 40–54. Specifically, he argues that the special master did not hold the government to its burden of proving that a factor unrelated to the vaccine was the sole substantial cause of his GBS-related injury. *Id.* If the special master had applied the correct legal standard, White contends, then the special master would have found that the evidence stands in "equipoise," and that White is thus necessarily entitled to compensation. *See id.* at 37–40. Second, White argues that the special master's findings under the first and third prongs of the *Althen* test were arbitrary and capricious.[1] *See id.* at 24–37; *Althen v. Sec'y of Health*

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[1] White also argues that the special master's finding under *Althen* prong two was flawed, but only to the extent that we agree with his arguments on *Althen* prongs one and three. *See* Appellant Br. 37. Because we affirm the special master's findings under *Althen* prongs one and three, we need not address *Althen* prong two.

& Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). For the following reasons, we disagree.

I

"In Vaccine Act cases, we review a ruling by the Court of Federal Claims *de novo,* applying the same standard that it applies in reviewing the decision of the special master." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). As such, we review the special master's factual findings under the "arbitrary and capricious standard," and we review his legal rulings to determine whether they are "not in accordance with law." *Id.*; *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). The "arbitrary and capricious [standard] is a highly deferential standard of review. If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of Dep't of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) (cleaned up).

"The Vaccine Act distinguishes between so-called 'Table injuries,' for which causation is presumed when a designated condition follows the administration of a designated vaccine within a designated period of time, *see* 42 U.S.C. §§ 300aa-11(c), 300aa-14, and all other injuries alleged to be caused by a vaccine, known as 'off-Table injuries,' for which causation must be proved in each case." *Moberly*, 592 F.3d at 1321; *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008). Thus, for Table cases, the Vaccine Act "removes the petitioner's difficult burden of proving actual causation by allowing the petitioner to rely on a table[-based] injury and a presumption of causation." *Knudsen ex rel. Knudsen v. Sec'y of Dep't of Health & Hum. Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994). And if petitioners can overcome their initial burden of establishing that presumption, "they are entitled to recover

unless the government shows . . . by a preponderance of the evidence[] that the injury was in fact caused by factors unrelated to the vaccine." *Id.* (cleaned up); *see* 42 U.S.C. § 300aa-13(a)(1)(B).

To prove actual causation for the factor unrelated to the vaccine, we apply the same standards that apply to a petitioner's proof of actual causation in fact in off-Table cases. *See Knudsen*, 35 F.3d at 549 ("[T]he standards that apply to a petitioner's proof of actual causation in fact in off-[T]able cases should be the same as those that apply to the government's proof of alternative actual causation in fact."). Therefore, the government must

> show by preponderant evidence that the [factor unrelated] brought about [petitioner's] injury by providing: (1) a medical theory causally connecting the [factor unrelated] and the injury; (2) a logical sequence of cause and effect showing that the [factor unrelated] was the reason for the injury; and (3) a showing of a proximate temporal relationship between [factor unrelated] and injury.

Althen, 418 F.3d at 1278. In addition to proving causation under *Althen*, the government must also establish that the factor unrelated is the agent "*principally responsible* for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C. § 300aa-13(a)(2)(B) (emphasis added). We have described this "principally responsible for" language as a requirement that the government "present[] sufficient evidence to establish that [the factor unrelated] was the *sole substantial factor* in bringing about the injury." *de Bazan*, 539 F.3d at 1354 (emphasis added).

A

White first argues that the special master erred by failing to hold the government to its burden of proof with respect to causation and therefore that his findings are arbitrary and capricious. *See* Appellant Br. 19–23. In

particular, White contends that the government failed to exclude the vaccine as causal and that the special master overlooked that failure in assessing whether the government had met its burden on alternative causation for the factor unrelated. *Id.* at 23. In doing so, White heavily relies on a Table case, *Knudsen*, 35 F.3d at 547. *See* Appellant Br. at 19–23.

White's case is distinct from *Knudsen,* however. Here, unlike in *Knudsen*, the special master *did* "specifically find" that the parties' competing "evidence preponderated in favor of alternative causation." *Knudsen*, 35 F.3d at 550–51; *compare id.* (explaining that "the special master did not specifically find" whether the evidence preponderated one way or the other), *with Special Master Decision*, at *17 ("[T]he record preponderantly supports [the government's] contention that [White's] demonstrated *H.* [*i*]*nfluenza*[*e*] infection was the more likely sole substantial factor causing [White's] GBS . . . ."), *and id.* at *18, n.16 ("I conclude it 'more likely than not' that the vaccine is excluded as causal.").

In finding that the government had shown that the vaccine was not a substantial factor contributing to White's injury, the special master first noted that White's expert merely stated in "conclusory form" that "the flu vaccine was still likely . . . a substantial factor in [White's] injury," *id.* at *5, and that the expert relied on the vaccine being "presumed causative," *id.* at *6 (citation omitted). The special master then reviewed the relevant evidence to determine whether the government established a factor unrelated actually caused White's injury. Specifically, he reviewed the medical literature and expert reports. *See, e.g.*, *id.* at *17 (explaining that the "risk" of developing a GBS-related injury from vaccination "is consistently deemed lesser in comparison [to infection] (and in some studies

unfounded).");[2] *id.* (explaining that in some cases "[i]t has even been documented that vaccination might play a protective role against GBS.").[3] Based on his review of that medical literature, the special master drew the plausible inference that the government "has also shown that in the general context of vaccination and infection, vaccination will *usually* be less likely causal (thus helping [the government] to exclude the vaccine in this case as part of his enhanced burden to show factor unrelated)." *Id.* at *17.

In addition to the medical literature, the special master also reviewed White's medical records, which "establish[ed] that the infection . . . occurred far closer in time than vaccination." *Id.* at *18. From that, he drew the plausible inference that "[t]his medical history is not consistent with the vaccine playing even a contributory role to [White's] GBS." *Id.* We therefore conclude that the special master's decision to exclude the vaccine as a substantial causal factor is grounded in the relevant record evidence and supported by plausible inferences and thus it is not arbitrary and capricious.

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[2] F. DeStefano et al., *Principal Controversies in Vaccine Safety in the United States,* CLINICAL INFECTIOUS DISEASES 1, 4 (2019), J.A. 499–504.

[3] J. Stowe et al., *Investigation of the Temporal Association of Guillain-Barré Syndrome with Influenza Vaccine and Influenza like Illness Using the United Kingdom General Practice Research Database,* 169 AM. J. EPIDEMIOLOGY OF 382, 385–86 (2008), J.A. 466–67; L. Grimaldi-Bensouda et al., *Guillain-Barré Syndrome, Influenzalike Illnesses, and Influenza Vaccination During Seasons With and Without Circulating A/H1 N1 Viruses*, 174 AM. J. OF EPIDEMIOLOGY 3, 326, J.A. 473.

B

White next argues that the special master's findings under the first and third prongs of *Althen* are arbitrary and capricious. Regarding prong one, the government's burden was to show by preponderant evidence "a medical theory causally connecting the [factor unrelated] and the injury," *i.e.*, that the factor unrelated can cause the injury suffered. *Althen*, 418 F.3d at 1278. White argues that the government did not provide a "sound and reliable medical or scientific explanation." Appellant Br. 26 (citation omitted). Specifically, he argues that the government did not offer "sufficient evidence specific to the infection in question, [and] how it could cause GBS." *Id.* at 29 (emphasis omitted). White contends that for the government to have preponderantly established *Althen* prong one, it "needed to provide evidence of the biological mechanism of how the *H*[.] [*i*]*nfluenza*[*e*] could cause GBS." *Id.* We disagree.

"*Althen* makes clear that a claimant's theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). Whether a theory of causation is "reputable" can depend on the scientific evidence. *Id.* at 1380. But medical studies and data "must be viewed . . . not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard," which does not require "scientific certainty" or disproving "every possible ground of causation." *Id.* (citation omitted); *see Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010); *Moberly*, 592 F.3d at 1325; *see also Lobo v. Dep't of Just.*, 139 F.4th 1311, 1317 (Fed. Cir. 2025) (noting that "'medical certainty' . . . is more demanding than the preponderance standard of more likely than not"). The government, like a petitioner when the burden is on him, is therefore "not required to present proof of causation to the level of scientific certainty," *Moberly*, 592 F.3d at 1324, or

to "provide conclusive evidence in the medical literature," *Andreu*, 569 F.3d at 1377. Nor is "identification and proof of specific biological mechanisms" required. *Knudsen*, 35 F.3d at 549. Rather, "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture." *Id.* (citation omitted). White's argument is therefore premised on an incorrect articulation of our case law.

Moreover, White has failed to demonstrate that the special master's decision was arbitrary and capricious under the appropriate requirements for *Althen* prong one. The special master considered the relevant record evidence, *see, e.g.*, *Special Master Decision*, at *17 (relying on an article stating that "[m]olecular mimicry and cross-reactive immune responses have also been identified after some types of preceding infection, including *H. influenzae*.");[4] *id.* at *7, *17 (relying on a study that determined that six GBS patients had elevated anti-*H. influenzae* antibodies compared with only one in normal controls, suggesting an association),[5] and drew plausible inferences from said evidence, *see, e.g.*, *id.* (finding that the evidence "demonstrat[ed] an association between the risk of GBS following infection generally," as well as a risk of GBS "specific to the *H. influenza*[*e*] infection."). We therefore see no reversible error regarding the special master's analysis of the first prong of *Althen*. *See Hines*, 940 F.2d at 1528 ("If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be

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[4] P. van Doorn et al., *Clinical Features, Pathogenesis, and Treatment of Guillain-Barré Syndrome*, 7 LANCET 939, 941 (2008), J.A. 522.

[5] Y.Y. Ju et al., *Haemophilus Influenzae as a Possible Cause of Guillain-Barré Syndrome,* 149 J. NEUROIMMUNOLOGY 160, 165–66 (2004) ("Ju"), J.A. 552–53.

extremely difficult to demonstrate."); *see also Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992) ("[I]t is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence.").

Regarding *Althen* prong three, the government's burden was to show by preponderant evidence that there was a "proximate temporal relationship between [the factor unrelated] and injury." *Althen*, 418 F.3d at 1278. White argues that the "temporal association was determined, *without any evidence* proffered by [the government]." Appellant Br. 35–37. He also takes issue with the special master's analogy to another Claims Court case finding that 12 days was a medically acceptable immune response time. *Id.* at 35–36 (citing *Randolph v. Sec'y of Health & Hum. Servs.*, No. 15-146V, 2021 WL 5816271, at *23 (Fed. Cl. Nov. 12, 2021)). He argues that because "the case the [special master] relies upon does not support his conclusion," since the onset here is only 10 days, and because "no discussion by [the government's] expert exists about an 'adaptive immune response' in this case," the special master could not "properly determine the temporal association in this case." *Id.* at 36. Once again, we disagree.

The burdened party must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352 (citing *Althen*, 418 F.3d at 1281 (equating "proximate temporal relationship" with the phrase "medically-acceptable temporal relationship")). White's argument that the special master made a finding based on "no evidence," Appellant Br. 36, is not accurate and mischaracterizes the special master's decision.

The special master reviewed White's clinical course and found that "[t]he medical records establish that the

infection (which first manifested 10 days before [White's] neurologic symptoms on December 10, 2017) occurred far closer in time than vaccination—but within a timeframe that would be reasonable for an antibody-driven, adaptive immune system autoimmune process to occur." *Special Master Decision*, at *18. The special master also found "no record evidence of any close-in-time vaccine reaction." *Id.* Furthermore, the special master reviewed the relevant medical literature offered by both experts, *see id. at* *6–7 (citing Ju, J.A. 547), and offered a reasoned explanation analogizing a 12-day timeframe for an onset of symptoms to the 10-day timeframe in this case, *see id.* at *18 (citing *Randolph*, 2021 WL 5816271, at *23). Again, we will not second guess the special master's reasoned assessment of the evidence and expert reports. *See Munn*, 970 F.2d at 871.

Finally, White argues that the special master erred by using the term "likely" in describing White's "likely infection." Appellant Br. 35–36 (citing *Special Master Decision*, at *18). He contends that "[l]ikely[] does not meet the 'more likely than not' standard of proof." *Id.* at 35 n.9. But White takes the use of "likely" out of context. The special master used the term "likely" to account for the uncertainties inherent in medical diagnoses, not to draw a causal comparison between the infection and vaccine. That is evident elsewhere in his decision, where he makes clear that he found that White did have an *H. influenzae* infection. *See Special Master Decision*, at *17 (explaining that "the medical records also establish that [White's] *H. influenzae* infection likely 'did cause' his GBS"); *id.* (explaining that the evidence—that White experienced a URI with a ten-day history of symptoms, his sputum findings positive for *H. influenzae* and that his chest X-ray findings showed worsening lung conditions—were persuasive); *id.* at *8 ("[A]t least 14 treaters associated [White's] upper respiratory infection with the development of his GBS."). He also clearly articulated and applied the "more likely than not" standard

to the government's evidence and argument. *See, e.g.*, *Special Master Decision*, at *18 n.16 ("I emphasize again: this determination is the result of the preponderance standard. I conclude it 'more likely than not' that the vaccine is excluded as causal.").

In sum, the special master's conclusion that "the record preponderantly supports [the government's] contention that [White's] demonstrated *H. [i]nfluenza*[*e*] infection was the more likely sole substantial factor causing [White's] GBS," *id.* at *17, reflects a careful review of the record evidence, including the medical literature and expert reports, and is therefore not arbitrary and capricious.

CONCLUSION

We have considered White's remaining arguments and find them unpersuasive. For the foregoing reasons, we conclude that the special master's decision is in accordance with the law and his findings are not arbitrary and capricious. Accordingly, we affirm the Claims Court's upholding of the special master's denial of White's claim for compensation under the Vaccine Act.

AFFIRMED

COSTS

No costs.