

United States Court of Appeals for the Federal Circuit

JOSE GAMBOA-AVILA,
Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN
SERVICES,
Respondent-Appellee

2024-1765

Appeal from the United States Court of Federal Claims
in No. 1:18-vv-00925-DAT, Judge David A. Tapp.

Decided: February 11, 2026

CURTIS RANDAL WEBB, Monmouth, OR, argued for petitioner-appellant.

ALEC SAXE, 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, COLLEEN HARTLEY, HEATHER LYNN PEARLMAN.

Before DYK, CHEN, and STOLL, *Circuit Judges*.

DYK, *Circuit Judge.*

Petitioner-Appellant Jose Gamboa-Avila (“Mr. Gamboa”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to 34 (“Vaccine Program”), in the Court of Federal Claims (“Claims Court”), alleging that a pneumococcal conjugate vaccine (“PCV”) caused him to suffer from Guillain-Barré Syndrome (“GBS”).

Because this is an off-Table case, Mr. Gamboa was required to establish causation. A special master of the Claims Court found that Mr. Gamboa did not prove that PCV can cause GBS and was thus not entitled to compensation. On review, the Claims Court affirmed. Mr. Gamboa appeals, arguing that the special master effectively required him to produce medical literature explicitly establishing a link between PCV and GBS, which he argues is contrary to our holding in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005).

Because we conclude that the special master here applied the proper evidentiary standard, we affirm. At the same time, we note that in these PCV cases, different special masters appear to have reached inconsistent results on identical facts. The Office of Special Masters should consider recommending, and the Claims Court should consider adopting, uniform related-case or other procedures to avoid such inconsistencies.

BACKGROUND

Mr. Gamboa received an injection of Prevnar 13, a PCV, on November 13, 2017. As a PCV, Prevnar 13 is covered under the Vaccine Program. On November 27, 2017, he sought treatment for generalized body aches, a headache, night sweats, and numbness, all of which he reported experiencing since November 13. Mr. Gamboa continued to experience symptoms and seek medical care over the next few days, culminating in a hospitalization.

Mr. Gamboa was diagnosed with GBS, an autoimmune disease involving the loss of nerve-insulating myelin in the peripheral nervous system, *see App'x 226*,¹ and was treated during his hospitalization. He was discharged on December 10, 2017.

On June 27, 2018, Mr. Gamboa filed a petition for compensation under the Vaccine Program. Mr. Gamboa introduced several reports from an expert witness, Dr. Lawrence Steinman, advancing theories that components of PCV can cause GBS based on “molecular mimicry,” whereby certain PCV components mimic the molecules present in nerve myelin, causing an autoimmune response to the myelin. Dr. J. Lindsay Whitton, an expert witness on behalf of the Secretary of Health and Human Services, submitted expert reports countering Dr. Steinman’s theories.

A claimant must prove causation-in-fact for an off-Table injury by preponderant evidence of “(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. The special master determined that Mr. Gamboa failed to carry his burden of proof under *Althen* prong one. App'x 27, 35. The special master analyzed each expert’s report and made findings with respect to the applicability and soundness of the evidence and methodologies relied upon by each expert. The special master found that elements of Dr. Steinman’s theory were unsupported by “reputable publications or studies.” App'x 36. In particular, the special master noted the absence of literature specifically connecting the phospholipid components at the center of Dr. Steinman’s theory to GBS. The special master went on to analyze

¹ Citations to “App’x” refer to the Corrected Appendix filed by Mr. Gamboa. Dkt. No. 36.

Dr. Steinman's evidence in detail and concluded that his molecular-mimicry theory did not scientifically justify linking Prevnar 13 to GBS.

Finding no causation under prong one, the special master did not reach the other *Althen* prongs or whether Mr. Gamboa was correctly diagnosed with GBS. Mr. Gamboa sought review of the special master's decision by the Claims Court. The Claims Court affirmed.

Mr. Gamboa timely appealed. We have jurisdiction under 42 U.S.C. § 300aa-12(f).

DISCUSSION

I

We review de novo the Claims Court's denial of the motion to review the special master's decision. *Lozano v. Sec'y of Health & Hum. Servs.*, 958 F.3d 1363, 1368 (Fed. Cir. 2020). We review de novo any questions of law, but we uphold the special master's factual findings unless they are arbitrary or capricious. *Id.*; see 42 U.S.C. § 300aa-12(e)(2)(B).

A

A Vaccine Program claimant may establish a causal link between a vaccine and an injury in one of two ways. The first is by a presumption of causation, if the vaccine and injury combination is listed in the Vaccine Injury Table. *Althen*, 418 F.3d at 1278; see 42 U.S.C. § 300aa-14(a), (c); 42 C.F.R. § 100.3. The second is by proving causation-in-fact by a preponderance of the evidence. *Althen*, 418 F.3d at 1278; *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); see 42 U.S.C. § 300aa-13(a)(1). The operative Vaccine Injury Table does not list PCVs with GBS in combination. 42 C.F.R. § 100.3. Mr. Gamboa must therefore prove causation-in-fact under *Althen* by showing "(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. Only *Althen* prong one is at issue in this appeal.

Addressing the first prong of *Althen* before the special master, Mr. Gamboa presented molecular-mimicry theories supported by Dr. Steinman’s expert reports. A related molecular-mimicry theory linking seasonal influenza vaccines to GBS became widely accepted, and Health and Human Services included the flu-vaccine–GBS combination in the Vaccine Injury Table. App’x 33; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294, 6295 (Jan. 19, 2017). But Dr. Steinman cited no articles directly linking pneumococcal conjugate vaccines to GBS. He instead put forward several studies as offering indirect support for his theory, such as a study linking the phospholipid components at the center of his molecular-mimicry theory to an autoimmune response in multiple sclerosis and another study showing that the blood of GBS patients contained antibodies that are reactive to those phospholipid components.

The special master concluded that Mr. Gamboa failed to satisfy *Althen* prong one by preponderant evidence.

B

Mr. Gamboa argues that the special master applied a higher evidentiary standard than *Althen* permits, requiring him to provide medical literature explicitly confirming that PCVs are causally linked to GBS. In *Althen*, we considered a special master’s rejection of a Vaccine Program claim “because [the claimant] did not provide peer-reviewed literature that demonstrated a suspected or potential association between the tetanus toxoid vaccine and the alleged injuries.” *Althen*, 418 F.3d at 1277 (emphasis removed) (internal citations and quotations omitted). We held that the peer-reviewed literature requirement was

contrary to the Vaccine Program statute, as it “prevent[ed] the use of circumstantial evidence envisioned by the preponderance standard and negat[ed] the system created by Congress.” *Id.* at 1280 (citing 42 U.S.C. § 300aa-13(a)(1)). “[T]he purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Id.*

We do not read the special master’s decision here to require support of a causation theory with medical literature and conclude the special master’s analysis is consistent with *Althen*. To be sure, the special master relied on the absence of support in the medical literature for Dr. Steinman’s theories. But *Althen* does not prohibit a special master from considering medical literature when weighing the scientific evidence underlying a claimant’s causation theory. Cases following *Althen* have confirmed that a “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *Boatmon*, 941 F.3d at 1360. A special master may weigh the fact that a “proposed mechanism had never been tested in any peer-reviewed study” and may properly consider the weakness of medical literature support when evaluating the overall reliability of scientific evidence. *Moberly*, 592 F.3d at 1324; see *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1350–51 (Fed. Cir. 2010) (affirming a special master’s no-causation determination where the claimant’s supporting evidence, “a literature review based on two papers from the early 1950s,” was “quite weak”).

The special master here, as permitted by our cases, only relied on the absence of medical literature as one feature in his analysis, relying on other core “foundational deficiencies” in the theory unrelated to the absence of medical literature. App’x 36–39. For example, he remarked that “Dr. Steinman cannot explain convincingly why the [PCV]

would be more likely to cause GBS than its wild bacterial infectious analog (which unquestionably is *not* so associated).” App’x 36 (emphasis in original). He noted that Dr. Steinman could only show that his proposed autoimmune targets were present in myelin without demonstrating why they were more likely than other structures to cause autoimmune responses. *See id.* (“It is simply speculative to propose that GBS could be *mediated by an attack on this target*, based solely on the logic that the myelin *contains* it—and the degree of speculation is highlighted by the comparatively larger amount of evidence that associate gangliosides as a likely target.” (emphasis in original)) And the special master observed that much of Dr. Steinman’s evidence was related to multiple sclerosis, not GBS. *Id.*

We conclude that the special master did not apply a standard inconsistent with *Althen*.

II

At oral argument, Mr. Gamboa noted that the special master’s findings in this case are inconsistent with those reached by other special masters on identical evidence in other cases and argued that this somehow established an *Althen* violation. In *Boatmon*, we held that it was not arbitrary and capricious for a special master to “ma[ke] no attempt to distinguish the instant case” from “the other cases reaching opposite conclusions.” *Boatmon*, 941 F.3d at 1358 (internal quotations omitted). While we reject Mr. Gamboa’s theory as unsupported, we are troubled by inconsistent findings on identical facts by different special masters. The special master here noted that his analysis in Mr. Gamboa’s case “recapitulates” his earlier findings in other cases alleging a PCV-GBS link based on the same studies cited here. App’x 42 (citing *Bielak v. Sec’y of Health & Hum. Servs.*, No. 18-761V, 2022 WL 18058244, at *15–17, 32 (Fed. Cl. Spec. Mstr. Dec. 9, 2022), released publicly as 2023 WL 35509 (Fed. Cl. Spec. Mstr. Jan. 3, 2023)); *Trollinger v. Sec’y of Health & Hum. Servs.*, No. 16-473V,

2023 WL 2521912, at *28–29 (Fed. Cl. Spec. Mstr. Feb. 17, 2023). Recognizing that his findings were outliers as compared to other special masters, he further observed that the same scientific evidence he rejected had successfully persuaded other special masters of a PCV-GBS causal link. *See id.* (citing *Gross v. Sec'y of Health & Hum. Servs.*, No. 17-1075V, 2022 WL 9669651, at *15–17, 28 (Fed. Cl. Spec. Mstr. Sept. 22, 2022); *Pierson v. Sec'y of Health & Hum. Servs.*, No. 17-1136V, 2022 WL 322836 (Fed. Cl. Spec. Mstr. Jan. 19, 2022)). The special master acknowledged the inconsistency in assessments by different special masters of the same causation theory and that he is the only special master to find no causation.² In other words, for a claimant such as Mr. Gamboa, the identity of the special master assigned to his case determines the outcome, a result that is both arbitrary and unfair. As *Boatmon* demonstrates, this is not an isolated example of that problem. *See Boatmon*, 941 F.3d at 1358–59.

Generally, in federal civil litigation, there are mechanisms designed to minimize inconsistent results on identical facts. For example, for related cases filed within the same district, district courts have established local rules that require the assignment of related cases to the same judge. *See, e.g.*, D.D.C. L. Civ. R. 40.5; E.D. Tex. L. Civ. R. 42.³

² The special master stated: “And while special masters often take refuge in the legal truism that their colleagues’ determinations do not bind them, [Mr. Gamboa] not-unreasonably notes the fact that I am (so far) alone in my negative assessment of this causation theory.” App’x 42.

³ Where actions are brought in different districts sharing common questions of fact, a party may seek

The Office of Special Masters (“OSM”) is empowered by statute to recommend rules to the Claims Court for adoption under its rulemaking authority to “provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions.” 42 U.S.C. § 300aa-12(d)(2)(A); *see* 28 U.S.C. § 2071. The special masters have recommended, and the Claims Court has established, Vaccine Rules that govern proceedings under the Vaccine Program. *See generally* Vaccine Rules, Rules of Ct. of Fed. Claims app. B.

Although the Claims Court has not adopted a related-case rule, the OSM has consolidated omnibus proceedings to promote consistency in related cases. *See, e.g., Snyder v. Sec'y of Dep't of Health & Hum. Servs.*, No. 01-162V, 2009 WL 332044, at *2 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (discussing the basis of the OSM’s authority to conduct omnibus proceedings in its authority to “develop expertise in the complex medical and scientific issues involved in actual causation claims” and to “apply this expertise to the

transfer under 28 U.S.C. § 1404(a), under which courts consider whether the potential for consolidation with a related case is “in the interest of justice.” *See, e.g., Cont'l Grain Co. v. The FBL-585*, 364 U.S. 19, 20, 26 (1960); *In re Volkswagen of Am., Inc.*, 566 F.3d 1349, 1351 (Fed. Cir. 2009) (“In this case, the existence of multiple lawsuits involving the same issues is a paramount consideration when determining whether a transfer is in the interest of justice.”).

Multidistrict litigation (MDL) also allows common pre-trial issues to be consolidated in a single court. 28 U.S.C. § 1407(a); *see also* 15 Wright & Miller, Federal Practice & Procedure §§ 3861–3868 (4th ed.) For example, MDL is often useful to resolve common factual issues related to causation. *See, e.g., In re Welding Rod Prods. Liab. Litig.*, 269 F. Supp. 2d 1365, 1366–67 (J.P.M.L. 2003).

resolution of other cases"). For example, in 2002, the OSM instituted an "Omnibus Autism Proceeding" to "inquire into the general causation issues involved in these cases" and to enter the evidentiary record into an "Autism Master File." *Autism General Order #1*, 2002 WL 31696785, at *3 (Fed. Cl. Spec. Mstr. July 3, 2002); see, e.g., *Cedillo v. Sec'y of Health & Hum. Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); *King v. Sec'y of Health & Hum. Servs.*, No. 03-589V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

In light of the admitted inconsistencies in the types of cases involved here, the OSM should consider recommending, and the Claims Court should consider adopting, a related-case rule or other mechanisms to avoid inconsistent rulings of the special masters.

CONCLUSION

Although we are troubled by the inconsistent factual findings among the special masters on central issues presented in this case, we conclude that the special master here did not impose an improper evidentiary burden on Mr. Gamboa. Accordingly, we affirm.

AFFIRMED

COSTS

No costs.