

**United States Court of Appeals
for the Federal Circuit**

**MADISON DERIBEAUX, a minor, by her parents
and natural guardians, GUS DERIBEAUX, AND
KIMBERLY BURSHIEM,**
Petitioners-Appellants,

v.

**SECRETARY OF HEALTH AND HUMAN
SERVICES,**
Respondent-Appellee.

2012-5127

Appeal from the United States Court of Federal
Claims in No. 05-VV-306, Judge George W. Miller.

Decided: June 7, 2013

CLIFFORD J. SHOEMAKER, Shoemaker, Gentry &
Knickelbein, of Vienna, Virginia, argued for petitioners-
appellants.

GLENN A. MACLEOD, Senior Trial Counsel, Torts
Branch, Civil Division, United States Department of
Justice, of Washington, DC, argued for respondent-
appellee. With him on the brief were STUART F. DELERY,

Principal Deputy Assistant Attorney General, RUPA BHATTACHARYYA, Director, VINCENT J. MATANOSKI, Deputy Director, and GABRIELLE M. FIELDING, Assistant Director.

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

LOURIE, *Circuit Judge*.

Petitioners Gus Deribeaux and Kimberly Burshiem, on behalf of their daughter, Madison Deribeaux (“Deribeaux”), appeal from the judgment of the United States Court of Federal Claims affirming a special master’s decision denying their claim for compensation under the National Vaccine Injury Compensation Program for injuries allegedly caused by the Diphtheria-Tetanus-acellular Pertussis (“DTaP”) vaccine. *Deribeaux ex rel. Deribeaux v. Sec’y of Health & Human Servs.*, 105 Fed. Cl. 583 (2012). Because the special master did not apply an incorrect legal standard and because her evaluation of the case was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, we *affirm*.

BACKGROUND

Deribeaux was born on August 19, 2001, and received the DTaP vaccination on March 28, 2002. The next day, she was taken to the emergency room having suffered from a prolonged seizure. She continued to seize, and her temperature was later recorded as 103.6 degrees Fahrenheit; but all other tests were reported normal and she did not suffer any additional seizures during several subsequent days that she remained at the hospital. *Deribeaux*, 105 Fed. Cl. at 585. Deribeaux continued to experience seizures throughout the following year, however, and she was again admitted to the hospital in April 2003 with recurrent convulsive episodes. Her discharge note from that instance stated that she had a seizure disorder that began two days after the DTaP vaccination, with subse-

quent admission and treatment for atypical Kawasaki disease (a rare, immune-mediated vasculitis); Deribeaux continued to experience seizures through 2005. *Id.* at 585–86.

In December 2005, genetic testing revealed that Deribeaux had a DNA sequence variation in her SCN1A gene, which was reportedly not inherited and arose spontaneously. *Id.* at 586. SCN1A mutations have been associated with several epilepsy syndromes, including Severe Myoclonic Epilepsy of Infancy (“SMEI”), also known as Dravet’s Syndrome. Following genetic testing, Deribeaux’s treating physicians consistently noted the diagnosis of SMEI and SCN1A mutation in association with her chronic seizures and developmental delays. *Id.*

This case was brought under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (“Vaccine Act”), as amended, which created the National Vaccine Injury Compensation Program through which claimants can petition the Court of Federal Claims to receive compensation for vaccine-related injuries or death. On March 11, 2005, before Deribeaux’s genetic mutation was discovered, a petition was filed alleging that the administration of the DTaP vaccine was a substantial cause of her seizure disorder and developmental delay. Pursuant to 42 U.S.C. § 300aa-12(d), a hearing was held before a special master on September 20, 2007.

At that hearing, Deribeaux presented expert testimony that she had a reaction to the vaccine as a result of her poor immune system, which triggered her initial seizure and subsequent condition. *Deribeaux*, 105 Fed. Cl. at 587. In contrast, the Secretary presented expert testimony that Deribeaux’s condition could be explained completely by Kawasaki disease or by enterovirus, that there was no evidence that her initial seizure resulted in brain damage, and that DTaP vaccination can cause febrile seizures but not chronic seizure disorders in children. *Id.* None of the

medical records of treating physicians who diagnosed Deribeaux with SMEI were filed into the record prior to the initial entitlement hearing and no evidence concerning Deribeaux's genetic mutation or her diagnosis of SMEI was presented. The special master concluded that Deribeaux had established causation and was entitled to compensation, and therefore directed the parties to begin the damages phase of the proceeding. *Id.*

During the damages phase, Deribeaux produced new medical records, including documentation of her genetic mutation and diagnosis of SMEI, which her treating physicians had noted was the cause of her neurological disorder. *Id.* In light of that new evidence, the Secretary moved to set aside the special master's decision and to reopen the issue of entitlement. The case was then transferred to a second special master, who determined that the evidence presented at the hearing conducted by the earlier special master was sufficient to set forth Deribeaux's prima facie case and therefore to shift the burden of proof to the Secretary to establish alternative causation. *Id.*

A limited supplemental hearing was held on June 28, 2011, focused on whether the Secretary could rebut Deribeaux's prima facie case by showing that her disorder was caused by her SCN1A gene mutation, a factor unrelated to vaccination, pursuant to 42 U.S.C. § 300aa-13(a)(1)(A)–(B). The Secretary acknowledged that a vaccine-induced fever likely triggered Deribeaux's first febrile seizure because individuals with SMEI are prone to suffer seizures in the context of any temperature elevation, and presented additional expert testimony showing that the sole cause of Deribeaux's neurological disorders was her genetic mutation and that the vaccination neither caused nor aggravated her condition. *Deribeaux*, 105 Fed. Cl. at 587. The Secretary's position was thus that the course of Deribeaux's disorder was not altered by her initial seizure and that the disabilities caused by her

genetic mutation would have been the same with or without the vaccine-induced seizure. Deribeaux contended that, notwithstanding her genetic mutation and diagnosis of SMEI, it was the DTaP vaccination that caused her condition by triggering an immune deficiency that led to additional disorders, including the atypical Kawasaki disease, and further neurological damage.

After considering the record as a whole, the special master determined that the Secretary had carried the burden of demonstrating alternative causation by establishing that an unrelated factor, namely, genetic mutation, caused Deribeaux's seizures and other neurological disorders, and concluded that SMEI provided a complete, alternative explanation for Deribeaux's condition. *Id.* at 588. Accordingly, the special master set aside the previous entitlement decision and dismissed Deribeaux's claim. Deribeaux timely moved for review of that decision by the Court of Federal Claims.

The Court of Federal Claims denied the motion for review and affirmed the decision, holding that the special master did not abuse her discretion or act arbitrarily, capriciously, or contrary to law in determining that the Secretary had met the burden of proving by a preponderance of the evidence that a substantial factor unrelated to the DTaP vaccine caused Deribeaux's injury. *Id.* at 596. In particular, the court held that the special master: (i) applied the correct legal standard as set forth in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005), *id.* at 590; (ii) acted properly within her discretion to rely on the testimonial evidence of experts and to determine the persuasiveness of experts, *id.* at 593; and (iii) did not err or act arbitrarily or capriciously in determining that Deribeaux's genetic mutation was the sole substantial cause of her condition despite the fact that the vaccine triggered her initial seizure, *id.* at 594–95.

This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(3).

DISCUSSION

We review without deference a ruling by the Court of Federal Claims on a special master's decision to grant or to deny entitlement to compensation under the Vaccine Act. *Lampe v. HHS*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Hines v. HHS*, 940 F.2d 1518, 1523–24 (Fed. Cir. 1991). Accordingly, we “perform[] the same task as the Court of Federal Claims and determine[] anew whether the special master's findings were arbitrary or capricious.” *Lampe*, 219 F.3d at 1360; *see also Hines*, 940 F.3d at 1524 (holding that we review without deference the Court of Federal Claims's “determination as to whether or not the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”).

Whether the special master applied the appropriate standard of causation is a legal determination that we review without deference under the “not in accordance with law” standard. *Munn v. HHS*, 970 F.2d 863, 870–73 (Fed. Cir. 1992). We apply the arbitrary and capricious standard when reviewing findings of fact, and review the special master's discretionary rulings for abuse of discretion. *Id.* at 870 n.10. As we have noted:

Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That

level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Hodges v. HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted).

We have similarly held that “we do not sit to reweigh the evidence. [If] the special master’s conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.” *Lampe*, 219 F.3d at 1363. Thus, on review, 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/Knight v. HHS*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

On appeal, Deribeaux contends that she has satisfied the statutory requirements of the Vaccine Act in having shown by a preponderance of the credible evidence that her DTaP vaccination, not an unrelated factor, likely caused her seizure disorder and subsequent developmental delays. Deribeaux argues that both the special master and the Court of Federal Claims applied an evidentiary standard not in accordance with law in finding that her genetic mutation was the cause of her neurological condition by applying the *Althen* test to the Secretary’s burden of proof, rather than the legal standard contained in the Restatement (Second) of Torts, as announced in *Shyface v. HHS*, 165 F.3d 1344 (Fed. Cir. 1999).

The Secretary responds that the special master applied the correct evidentiary standard and stated a rational basis for the conclusion that Deribeaux’s genetic abnormality caused both her susceptibility to a post-vaccine seizure and her numerous subsequent seizures and other neurological problems.

In this case, because Deribeaux's injury is not listed on the Vaccine Injury Table, she was required to prove causation in fact by a preponderance of the evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(A). In *Althen*, we established a three-prong test that petitioners alleging an off-Table injury must satisfy in order to prove causation. Specifically, a petitioner must

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

Althen, 418 F.3d at 1278.

To prove causation, a petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface*, 165 F.3d at 1352–53.

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. 42 U.S.C. § 300aa-13(a)(1)(B). In order to meet that burden, the respondent must “identify[] a particular . . . factor (or factors) and present[] sufficient evidence to establish that it was the sole substantial factor in bringing about the injury.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *accord Althen*, 418 F.3d at 1278.

As the Court of Federal Claims noted in this case, the special master determined that the evidence presented at the initial entitlement hearing, which did not include evidence of Deribeaux's genetic disorder, established a

prima facie case of causation. *See Deribeaux*, 105 Fed. Cl. at 589. Because the burden then shifted to the Secretary to rebut the prima facie case, the special master accordingly limited the proceedings before her to the specific issue of whether the Secretary met the burden of establishing alternative causation. *Id.*

Under the provisions of the Vaccine Act, it was incumbent upon the special master to consider whether a preponderance of the evidence demonstrated that Deribeaux's SCN1A genetic mutation was such an alternative cause once that evidence came to light. The Secretary was "required not only to prove the existence of [a factor unrelated], but *also* to prove by a preponderance of the evidence that the [factor unrelated] actually *caused*" the injury alleged. *Knudsen v. HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). Furthermore, the Secretary also had to present sufficient evidence to prove that the alternative factor was the sole substantial factor in bringing about the injury. *de Bazan*, 539 F.3d at 1354.

Based upon the record as a whole, including a balance of all available expert testimony, medical evidence, and test results, the special master determined that the Secretary carried her burden and that the SCN1A gene mutation was the sole substantial cause of Deribeaux's seizure disorder and developmental delays. Specifically, the special master found that the evidence presented supported: (i) an association between mutation of the SCN1A gene, especially a missense mutation arising *de novo* (*i.e.*, not inherited) in a biologically conserved region, as in this case, and SMEI; (ii) a logical sequence of cause and effect between mutation of the SCN1A gene and Deribeaux's SMEI as corroborated by her genetic testing and diagnoses of her treating physicians; (iii) a finding that the time frame in which Deribeaux's symptoms developed was consistent with the diagnosis of SMEI, which was not contradicted; and (iv) an analysis that the SCN1A mutation was the sole substantial factor unrelat-

ed to the DTaP vaccine in causing Deribeaux's SMEI. *Deribeaux ex. rel. Deribeaux v. Sec'y of Health & Human Servs.*, No. 05-306V, 2011 WL 6935594 (Fed. Cl. Dec. 9, 2011).

The special master correctly identified that the Secretary's burden was to show a sequence of cause and effect that is logical and legally probable, although causation by the unrelated factor need not be established to a medical or scientific certainty. See *Deribeaux*, 105 Fed. Cl. at 596; see also *Knudsen*, 35 F.3d at 548–49 (“The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is ‘logical’ and legally probable, not medically or scientifically certain.”). Moreover, we have held that “the standards that apply to a petitioner’s proof of actual causation in fact in off-table cases should be the same as those that apply to the government’s proof of alternative actual causation in fact.” *Knudsen*, 35 F.3d at 549.

Both the Court of Federal Claims and the special master therefore applied the correct legal standards for proving actual causation set forth in *Althen* to the Secretary’s theory of alternative causation. As the Court of Federal Claims correctly noted, “The Restatement standard, as adopted in *Shyface*, is not at odds with the *Althen* factors; rather, those factors are themselves derived from the Restatement standard.” *Deribeaux*, 105 Fed. Cl. at 589; see also *Stone/Hammitt v. HHS*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[T]he causation standard in off-Table Vaccine Act cases is to be applied consistently with the principles set forth in the Second Restatement of Torts.” (citing *Walther v. HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007)); *Walther*, 485 F.3d at 1150 (explaining that, in the context of vaccine cases, *Shyface* “adopted the actual causation standard of the Restatement (Second) of Torts” and that “precedent has established that a petitioner satisfies this standard by” meeting the three-part *Althen* test).

In every case in which the Secretary asserts that an unrelated factor caused the injury, there is necessarily an allegation that a vaccine was the cause of the same injury. Thus, the Vaccine Act requires the Secretary to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. Such a showing establishes that the factor unrelated, not the vaccination, was “principally responsible” for the injury. *See* 42 U.S.C. § 300aa-13(a)(2)(B). In making this showing, the Secretary refutes the prima facie finding that the vaccination is both the “but for” cause and a “substantial factor” in bringing about an alleged injury. *Shyface*, 165 F.3d at 1352; *de Bazan*, 539 F.3d at 1354 (stating that the factor unrelated must be the “sole substantial factor” that caused the injury). Because the factor unrelated must be the “sole substantial factor,” the Secretary must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan*, 539 F.3d at 1354. The Secretary did so here.

Accordingly, the special master did not act contrary to law when she employed the *Althen* factors to analyze whether, after Deribeaux established a prima facie case, the Secretary carried her burden to prove that a factor unrelated to the vaccine was the sole substantial cause of Deribeaux’s injuries. We find no error in the special master’s application of the preponderance standard under the Vaccine Act and no basis to disturb her factual findings as arbitrary or capricious in view of both the record before us and the highly deferential standard of review under which we must conduct such an evaluation.

CONCLUSION

For the reasons stated above, the special master did not apply an incorrect legal standard and her evaluation of the case was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Accordingly, the judgment is affirmed.

AFFIRMED