

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

CHRISTINA OSENBACH, BRYAN OSENBACH,
PARENTS OF, B.O.,
Petitioners-Appellants

v.

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

2024-1663

Appeal from the United States Court of Federal Claims
in No. 1:16-vv-00419-LAS, Senior Judge Loren A. Smith.

Decided: August 18, 2025

SYLVIA CHIN-CAPLAN, Law Office of Sylvia Chin-Caplan LLC, Boston, MA, argued for petitioners-appellants. Also represented by NICOLE ANNE CAPLAN-MASON.

FELICIA LANGEL, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by ALEXIS B. BABCOCK, BRIAN M. BOYNTON, C. SALVATORE D'ALESSIO, HEATHER LYNN PEARLMAN.

Before HUGHES, LINN, and CUNNINGHAM, *Circuit Judges*.
HUGHES, *Circuit Judge*.

Christina Osenbach and Byran Osenbach, on behalf of their minor child, “B.O.”, appeal the judgment of the United States Court of Federal Claims affirming a special master’s denial of their petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa–1 to –34. Because the special master applied the correct legal standard to assess B.O.’s off-table aggravation claim, and his factual findings were not arbitrary or capricious, we affirm.

I

B.O. was born in March 2012. J.A. 2, 10. On April 17, 2013, B.O. received the pneumococcal and inactive poliovirus (IPV) vaccines. J.A. 2, 156–58. The following day, B.O. experienced four seizures and was taken to an emergency room where he received critical care, including intubation. J.A. 2, 225–29. He was discharged from intensive care on April 20, 2013. J.A. 221–22. The discharge summary noted B.O.’s history of complex seizures and a history of seizures associated with immunizations. J.A. 221.

Over the next several months, B.O.’s pediatrician addressed concerns about his development, including speech delay, and his pediatric neurologist treated him for a seizure disorder. J.A. 150–58, 173–79, 185–88, 191–94. In August 2013, B.O. was diagnosed with developmental delay. J.A. 2, 151. Due to his persistent seizures, B.O.’s parents sought further treatment. J.A. 143–48, 180–84, 210–11; *see also* J.A. 180–81 (B.O.’s mother reporting that he was “having more than 100 episodes [of] absence seizures a day.”).

Extensive genetic testing to determine the cause of B.O.’s seizures revealed that B.O. had a “variant of uncertain significance in the SCN1A gene” that was not

inherited from either parent. J.A. 270–72. The testing report explained that the SCN1A gene encodes part of the “sodium channel that regulates the excitability of neurons;” “variants in SCN1A cause a variety of epilepsy phenotypes;” and “[t]he most common phenotypes include severe myoclonic epilepsy of infancy (Dravet syndrome).” J.A. 271. B.O.’s medical records later reflected Dravet syndrome due to SCN1A mutation as his diagnosis. J.A. 15.

II

The Osenbachs filed a petition under the Vaccine Act’s National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa–10, alleging that B.O.’s underlying epilepsy disorder was significantly aggravated by the pneumococcal and IPV vaccines he received on April 17, 2013.

“The Vaccine Act provides two separate mechanisms to obtain benefits: table claims and causation in fact claims.” *Andreu ex rel. Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009). Petitioners can obtain recovery by demonstrating that they sustained or significantly aggravated an illness, disability, injury, or condition listed on the Vaccine Injury Table within a set time period of receiving the vaccine (a table injury), or by demonstrating by a preponderance of the evidence that the vaccine caused or significantly aggravated an off-table illness, disability, injury, or condition. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1355–56 (Fed. Cir. 2013); 42 U.S.C. §§ 300aa–13(a)(1), –11(c)(1)(C). The Osenbachs did not allege that B.O. sustained a table injury. J.A. 35.

To receive compensation for an off-table significant-aggravation claim, a petitioner must demonstrate by preponderant evidence all six factors established in *Loving v. Sec’y of Dept. of Health & Hum. Servs.*:

- (1) the person’s condition prior to administration of the vaccine, (2) the person’s current condition (or the condition following the vaccination if that is

also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccine, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

86 Fed. Cl. 135, 144 (2009); *see W.C.*, 704 F.3d at 1357 (adopting this standard).

Following an entitlement hearing held on September 19, 2022, the Chief Special Master assigned to the Osenbachs' petition denied B.O.'s claim. J.A. 9–53. He determined that the Osenbachs could not establish by preponderant evidence that the pneumococcal and IPV vaccines significantly aggravated B.O.'s Dravet syndrome. J.A. 10. The Chief Special Master's decision denying entitlement turned on *Loving* factors four and five.

With regard to *Loving* factor four, the Chief Special Master found that the Osenbachs' causation theory was unreliable and that record evidence did not demonstrate it was "more likely than not that vaccines could worsen a case of Dravet syndrome attributable to an SCN1A mutation." J.A. 49 (internal quotation marks omitted). Although the Osenbachs "did credibly establish that environmental factors can play some role in the course of an otherwise genetically-caused illness," the Chief Special Master concluded that "[n]ot enough evidence . . . was offered to show that the peripheral, temporary inflammatory impact of vaccination will likely also worsen a seizure disorder emanating from the brain." J.A. 47 (emphasis omitted). The Chief Special Master added that the evidence put forward by the Osenbachs "does not mean that the impact of a vaccine on a person with Dravet 'more likely than not' wholly alters the

course of their disease, or that ‘but for’ vaccination Dravet syndrome will be less catastrophic.” J.A. 47 (emphasis omitted).

With regards to *Loving* factor five, the Chief Special Master found it was unlikely that the vaccines actually worsened B.O.’s Dravet syndrome because (1) “[n]o contemporaneous treaters” made such a conclusion; (2) “there is no identifiable record evidence that B.O.’s post-vaccination seizure event caused some identifiable form of brain injury that later played a role in the course of his Dravet syndrome;” and (3) “the record does not more broadly support the conclusion that the vaccine-induced seizures B.O. experienced in April 2013 constituted an inflection point, after which time his overall course worsened due to those vaccines.” J.A. 49–50 (emphasis omitted).

Because the Chief Special Master did not find that the Osenbachs satisfied their prima facie burden for demonstrating significant aggravation, “the burden of proof never shifted to [the Secretary of Health and Human Services] to prove a ‘factor unrelated’ to vaccination.” J.A. 50. Nonetheless, the Chief Special Master explained that in the hypothetical case where the Osenbachs had made their prima facie case of causation, he would find that the Secretary had established by preponderant evidence that a “factor unrelated” to the vaccinations—the SCN1A mutation—was responsible for B.O.’s epilepsy disorder. J.A. 50–52.

On February 5, 2024, the Court of Federal Claims denied the Osenbach’s Motion for Review of the Chief Special Master’s decision, concluding that the Chief Special Master “neither acted arbitrarily, capriciously, or contrary to law, nor abused his discretion.” J.A. 8.

The Osenbachs appealed, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

III

When reviewing the decision of a special master, the Court of Federal Claims may “set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]” 42 U.S.C. § 300aa–12(e)(2)(B). “Thus, the Claims Court judge reviews the special master’s decision essentially for legal error or factual arbitrariness.” *Bradley v. Sec’y of Dep’t of Health & Hum. Servs.*, 991 F.2d 1570, 1574 (Fed. Cir. 1993).

“We review de novo decisions of the Claims Court arising under the Vaccine Act, applying the same standard of review.” *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1248–49 (Fed. Cir. 2011). The special master’s “[f]act findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the ‘not in accordance with law’ standard; and discretionary rulings under the abuse of discretion standard.” *Munn v. Sec’y of Dep’t of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). “In general, reversible error is ‘extremely difficult to demonstrate’ if the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Hines v. Sec’y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

IV

We affirm the Claims Court’s judgment because the Chief Special Master’s findings with respect to *Loving* factor five were not arbitrary, capricious, or contrary to law. To satisfy *Loving* factor five, appellants must prove, by preponderant evidence, “a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation[.]” *Loving*, 86 Fed. Cl. at 144. The Chief Special Master correctly applied the law in requiring the

Osenbachs to demonstrate by preponderant evidence that the pneumococcal and IPV vaccines caused significant aggravation of B.O.'s epilepsy disorder, which is frequently referred to in the record as Dravet syndrome. See J.A. 35–38 (section of decision denying entitlement and outlining the applicable legal standard for establishing a *prima facie* off-table claim). The Chief Special Master evaluated all evidence of record, including B.O.'s medical records and expert testimony, see J.A. 13–46, and concluded that the record did not support the Osenbachs' asserted theory of specific causation. J.A. 49. We agree with the Claims Court that the Chief Special Master's weighing of the evidence was not arbitrary or capricious.

The Osenbachs argue that the Chief Special Master erred in his analysis of *Loving* factor five “by requiring direct proof of a brain injury in B.O.” Opening Br. 37; see also *id.* at 43–44. Although the Chief Special Master noted that testimony from the Osenbachs' expert was not “corroborated with imaging proof, such as MRI results confirming the existence of active inflammation close-in-time to vaccination,” J.A. 49, he did not impermissibly suggest that imaging proof was required over circumstantial evidence to establish specific causation.

Earlier in his decision, the Chief Special Master explained that a logical sequence of cause and effect under *Loving* factor five is usually supported by a petitioner's medical records, J.A. 36, but that to meet the preponderant evidence standard, the Osenbachs would only have to “offer evidence that leads ‘the trier of fact to believe that the existence of a fact is more probable than its nonexistence.’” J.A. 35 (quoting *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n. 2 (Fed. Cir. 2010) (internal quotation marks omitted)). Applying the correct standard, he found that “testing performed around the time of the vaccinations at issue does not corroborate [the Osenbachs' specific causation] theory”; not because imaging proof, in particular, was lacking, but because there was “no

identifiable record evidence” and no “contemporaneous treater opinions” suggesting that the vaccines significantly aggravated B.O.’s Dravet syndrome. J.A. 49.

The Osenbachs’ response is essentially that the Chief Special Master must have erred in weighing the evidence, because both their testifying expert and B.O.’s medical records offered some circumstantial evidence of brain injury following B.O.’s post vaccination seizure. Opening Br. 38–41. This court “do[es] 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*, 663 F.3d at 1249; *see also* J.A. 7 (Claims Court declining to reweigh the evidence for the same reason). Here, the fact finder articulated his reasons for finding that “the medical record does not support the conclusion that B.O.’s Dravet syndrome was impacted negatively by the April 2013 [vaccines],” J.A. 49, and we do not disturb this finding of fact.

Failure to satisfy any one *Loving* factor is dispositive of a significant-aggravation claim, thus we need not evaluate the Chief Special Master’s analysis under *Loving* factor four to affirm the decision denying the Osenbach’s petition.

With regard to *Loving* factor four, though, we note that to the extent the Chief Special Master’s decision might be read as requiring a petitioner to demonstrate that the vaccines at issue “wholly alter[ed] the course of their disease,” J.A. 47, we agree with the Osenbachs that such a requirement would conflict with our precedent. *See* Opening Br. 26. Although a merely plausible theory of causation is insufficient to meet a petitioner’s burden of proof, *LaLonde v. Sec’y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014), “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.” *Knudsen v. Sec’y of Dep’t of*

Health & Hum. Servs., 35 F.3d 543, 548–49 (Fed. Cir. 1994). This “allow[s] the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Requiring a petitioner to demonstrate that vaccination “wholly altered” their pre-vaccination condition would be at odds with our holding in *Sharpe v. Sec’y of Health & Hum. Servs.* that the *Loving* test does not require petitioners to provide conclusive evidence linking their vaccines to their significant aggravation. 964 F.3d 1072, 1083–85 (Fed. Cir. 2020). Thus, to the extent that the Chief Special Master imposed a higher burden, it was legal error, albeit harmless given our affirmance of his findings regarding *Loving* factor five. *Hines*, 940 F.2d at 1526 (Fed. Cir. 1991) (explaining that when “the special master’s decision was based on a number of factors” and the petitioner cannot show reliance on the improperly considered information “was likely critical to the result,” such a mistake constitutes harmless error.).

The Osenbachs also take issue with the Chief Special Master’s extraneous analysis of a “factor unrelated” cause for B.O.’s epilepsy disorder. Opening Br. 28–34. The Chief Special Master did not, as the Osenbachs allege, find that B.O.’s SCN1A mutation was the sole cause of his Dravet syndrome. Instead, in the hypothetical scenario where the Osenbachs had established their prima facie case of causation, the Chief Special Master explained that he would nonetheless have found the Secretary’s evidence established “a genetic explanation for the course of B.O.’s epileptic condition.” J.A. 50. This exploration of whether the Secretary could have established an alternative cause for B.O.’s disorder by a preponderance of the evidence was not the basis for denying the Osenbach’s petition and therefore is not grounds for reversal.

V

We have considered the Osenbachs' remaining arguments and find them unpersuasive. Because the Chief Special Master correctly applied the law with respect to *Loving* factor five, and his findings of fact were not arbitrary or capricious, we do not find reversible error, and we affirm the judgment of the Claims Court.

AFFIRMED

COSTS

No costs.