

NOTE: This disposition is nonprecedential.

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

**LAURA KALAJDZIC, BOJAN KALAJDZIC, ON
BEHALF OF A.K., A MINOR CHILD,
*Petitioners-Appellants***

v.

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

2023-1321

Appeal from the United States Court of Federal Claims
in No. 1:17-vv-00792-CNL, Judge Carolyn N. Lerner.

Decided: June 20, 2024

AMBER WILSON, Wilson Science Law, Washington, DC,
argued for petitioners-appellants.

ALEC SAXE, Torts Branch, Civil Division, United States
Department of Justice, Washington, DC, argued for re-
spondent-appellee. Also represented by BRIAN M.
BOYNTON, C. SALVATORE D'ALESSIO, TRACI PATTON,
HEATHER LYNN PEARLMAN.

Before CHEN, HUGHES, and STARK, *Circuit Judges*.

CHEN, *Circuit Judge*.

A.K.'s parents, Laura and Bojan Kalajdzic (collectively, the Kalajdzics), appeal a decision of the United States Court of Federal Claims under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), affirming a decision of Chief Special Master Brian H. Corcoran. The Chief Special Master denied compensation for narcolepsy with cataplexy allegedly caused by administration of the FluMist vaccine. *Kalajdzic ex rel. A.K. v. Sec'y of Health & Hum. Servs.*, No. 17-792V, 2022 WL 2678877 (Fed. Cl. June 17, 2022) (*Special Master Op.*), *aff'd* Dkt. No. 79 (Fed. Cl. Oct. 27, 2022).

We *affirm* because the Chief Special Master's decision applied the correct legal standard; was not arbitrary, capricious, or an abuse of discretion; and was otherwise in accordance with the law. *See* 42 U.S.C. § 300aa-12(e)(2)(B). We write for the parties and therefore omit the factual and procedural background from this opinion.

DISCUSSION

“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).

Under the Vaccine Act, a petitioner seeking compensation may prove causation in one of two ways, depending on whether the case involves a “Table injury” or an “off-Table injury.” *Id.* If the injury satisfies the criteria listed in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), and manifested within the specified time period, then causation is presumed. *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *see also* 42 U.S.C. § 300aa-11(c)(1)(C)(i). But if the injury is not listed in the

Table or did not manifest within the specified time period, then the petitioner must prove causation by a preponderance of the evidence. *de Bazan*, 539 F.3d at 1351; *see also* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), -13(a)(1)(A). This appeal involves an off-Table injury.

When a petitioner claims to have suffered an off-Table injury, we apply the test for causation articulated in *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274 (Fed. Cir. 2005):

[The petitioner’s] burden is to 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.

Id. at 1278.

A.

The Kalajdzics argue that the Chief Special Master erroneously applied a heightened evidentiary standard to their burden of proof under *Althen* prong one by viewing the evidence “through the lens of a laboratorian” rather than “from the vantage point of the [Vaccine] Act’s simple preponderance standard.” Appellants’ Br. at 58. Whether the Chief Special Master applied the correct standard is a legal question, which we review *de novo* under the “not in accordance with law” standard. *Althen*, 418 F.3d at 1277–78.

The Chief Special Master considered the evidence before him and determined that Dr. Ahmed’s causation theory was “too specific to Pandemrix, and thus cannot be then re-applied to [FluMist,] a different vaccine formulation.” *Special Master Op.*, 2022 WL 2678877, at *22. In the Chief Special Master’s view, Dr. Ahmed’s theory failed to explain

how evidence specific to Pandemrix, an adjuvanted vaccine, could be transitively applied to FluMist, a non-adjuvanted vaccine with lower nucleoprotein levels due to a different manufacturing process. *Id.* As for the Kalajdzics' reliance on Vaccine Adverse Event Reporting System (VAERS) data and case reports involving adverse events after receipt of live attenuated influenza vaccines (LAIVs)¹ as evidence connecting FluMist to narcolepsy, the Chief Special Master found that evidence "reflexive" and not especially probative. *Id.* at *23.

Contrary to the Kalajdzics' contention, the Chief Special Master did not impose a heightened standard of scientific certainty when evaluating Dr. Ahmed's theory. Before stating his findings, he correctly set forth the law pertinent to the inquiry before him:

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury.

Special Master Op., 2022 WL 2678877, at *17 (citations omitted).

The Chief Special Master then weighed the evidence before him and found that the Kalajdzics' theory had "too

¹ FluMist and Pandemrix are both LAIVs.

many omissions and gaps to conclude ‘more likely than not’ that FluMist can cause narcolepsy.” *Id.* at *24. In doing so, he specifically noted his “rejection of a FluMist-narcolepsy association” did “not reflect a mistaken substitution of a standard of scientific certainty in place of the [Vaccine Act]’s lower standard of preponderance.” *Id.* We see no legal error in this analysis, as we have repeatedly explained that a petitioner must prove a medical theory by a preponderance of the evidence that a vaccination can cause a particular injury. *See, e.g., Althen*, 418 F.3d at 1278; *de Bazan*, 539 F.3d at 1351; *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013).

Nothing in the cases the Kalajdzics cite requires otherwise. In *Andreu*, although we noted at one point that the petitioner’s expert presented a “biologically plausible theory,” *Althen* prong one was not disputed, and we thus could not have endorsed a lower standard of proof than the preponderance standard. *See Andreu ex rel. Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009). Moreover, neither *Kottenstette v. Secretary of Health and Human Services*, 861 F. App’x 433, 439–40 (Fed. Cir. 2021), nor *Capizzano v. Secretary of Health and Human Services*, 440 F.3d 1317, 1324 (Fed. Cir. 2006), undercuts the requirement that a petitioner’s medical theory must be proven by preponderant evidence.

While the Kalajdzics acknowledged during oral argument that *Althen* prong one requires proof by a preponderance of the evidence, Oral Arg. at 3:12–3:43, available at https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-1321_04042024.mp3, they appear to be arguing that the requirements of the preponderance standard are more relaxed than what the law mandates. To the extent they argue for a less than preponderance standard, that is plainly inconsistent with our precedent. *See, e.g., Moberly*, 592 F.3d at 1322.

B.

The Kalajdzics next contend that the Chief Special Master improperly found that they failed to satisfy *Althen* prong one by placing undue weight on his prior decision in *D'Tiole v. Secretary of Health and Human Services*, No. 15-085V, 2016 WL 7664475 (Fed. Cl. Nov. 28, 2016). We disagree.

In *D'Tiole*, then-Special Master Corcoran found that the petitioner failed to establish preponderant evidence that FluMist could cause narcolepsy under *Althen* prong one. *Id.* at *20, *28. In rejecting the Kalajdzics' theory, the Chief Special Master expanded upon his analysis in *D'Tiole* to address “more recent scientific or medical studies” filed in A.K.'s case regarding “the Pandemrix-narcolepsy association and distinguishable versions of the flu vaccine like FluMist.” *Special Master Op.*, 2022 WL 2678877, at *22–23 (“Nothing published or determined since the time of my prior decisions has been identified in this case that would alter the analysis.”). He specifically addressed the Sarkanen² meta-analysis and the IABS Report³—two reports published after *D'Tiole* issued—and found “neither at all suggest that a FluMist-narcolepsy association has become any more likely than it was” when *D'Tiole* was decided. *Id.* at *23.

Contrary to the Kalajdzics' assertion, the Chief Special Master rejected Dr. Ahmed's expert testimony based on case-specific reliability grounds, not based on another

² T. Sarkanen et al., *Incidence of Narcolepsy After H1N1 Influenza and Vaccinations: Systematic Review and Meta-Analysis*, 38 *Sleep Med. Revs.* 177 (2018).

³ K. Edwards et al., *Narcolepsy and Pandemic Influenza Vaccination: What We Know and What We Need to Know Before the Next Pandemic? A Report from the 2nd IABS Meeting*, 60 *Biologicals* 1 (2019).

expert's testimony from *D'Tiole*. For example, in rejecting Dr. Ahmed's contention that FluMist's LAIV character may mimic an adjuvant's immunologic effect, the Chief Special Master relied on the IABS Report. *Id.* at *23. Similarly, the Chief Special Master relied on other evidence filed in A.K.'s case to reject Dr. Ahmed's other contentions. *See, e.g., id.* (“[I]t is not at all clear from the studies or other evidence filed in this case that narcolepsy is as rare an occurrence in children under the age of ten as Dr. Ahmed proposed . . .”).

To succeed on their claim, the Kalajdzics must satisfy all three *Althen* prongs. Our decision upholding the Chief Special Master's decision as to prong one is thus sufficient to affirm his decision.

CONCLUSION

We reject the Kalajdzics' remaining challenges to the Chief Special Master's specific fact findings because those findings are neither arbitrary nor capricious, and he acted within his discretion. We have considered the Kalajdzics' arguments and find them unpersuasive. For the reasons set forth above, we *affirm* the Chief Special Master's denial of entitlement under the Vaccine Act.

AFFIRMED

COSTS

No costs.