NOTE: This disposition is nonprecedential.

## United States Court of Appeals for the Federal Circuit

## DEIDRE HENKEL, ALEX HENKEL, AS PARENTS OF V.H., A MINOR,

Petitioners-Appellants

v.

## SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee

2023-1894

Appeal from the United States Court of Federal Claims in No. 1:15-vv-01048-LAS, Senior Judge Loren A. Smith.

Decided: August 20, 2024

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EDWARD KRAUS, Kraus Law Group, LLC, Chicago, IL, argued for petitioners-appellants. Also represented by BRYNNA GANG.

MADYLAN LOUISE YARC, 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, HEATHER LYNN PEARLMAN, RYAN D. PYLES, DARRYL R. WISHARD.

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Before Moore, *Chief Judge*, Prost, *Circuit Judge*, and Mazzant, *District Judge*. <sup>1</sup>

PROST, Circuit Judge.

V.H.'s parents, Deidre and Alex Henkel ("Appellants"), filed a petition with the U.S. Court of Federal Claims under the National Vaccine Injury Compensation Program, which was established by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"). The petition alleged that V.H. developed narcolepsy from the FluMist vaccine, and it sought compensation for that injury. A special master denied the petition; the Court of Federal Claims sustained that denial; and Appellants appeal, see 42 U.S.C. § 300aa-12(f). We have jurisdiction under 28 U.S.C. § 1295(a)(3).

For the reasons below, we affirm. Because we write for the parties, we omit from this opinion other details of the factual and procedural background.

T

In Vaccine Act cases, we review the Court of Federal Claims' decision de novo. *E.g.*, *Dupuch-Carron v. Sec'y of HHS*, 969 F.3d 1318, 1324 (Fed. Cir. 2020). Effectively, "we perform the same task as the Court of Federal Claims and determine anew whether the special master's findings were arbitrary or capricious." *Deribeaux ex rel. Deribeaux v. Sec'y of HHS*, 717 F.3d 1363, 1366 (Fed. Cir. 2013) (cleaned up); *see* 42 U.S.C. § 300aa-12(e)(2)(B) (providing that, when reviewing a special master's decision, the Court of Federal Claims may "set aside any findings of fact or

<sup>&</sup>lt;sup>1</sup> Honorable Amos L. Mazzant, III, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

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conclusion of law... found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

Because this case involves an off-Table injury, Appellants must prove causation by establishing each of the three *Althen* prongs with preponderant evidence. *Boatmon v. Sec'y of HHS*, 941 F.3d 1351, 1355 (Fed. Cir. 2019) (citing *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). The three *Althen* prongs are: (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 found that Appellants carried their burden of proof for *Althen* prong one but not prongs two or three. *See Henkel v. Sec'y of HHS*, No. 15-1048V, 2022 WL 16557979, at \*43–47 (Fed. Cl. Aug. 31, 2022). Because we conclude that the special master's finding on *Althen* prong three was not arbitrary or capricious (or otherwise erroneous), and because Appellants needed to prevail on all three prongs to have their petition granted, we affirm the petition's denial without reaching the prong-two finding.

П

Establishing *Althen* prong three "requires 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 v. Sec'y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

The special master found—and Appellants do not dispute—that V.H.'s narcolepsy symptom onset began approximately four-to-six weeks after the relevant FluMist

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vaccination.<sup>2</sup> Henkel, 2022 WL 16557979, at \*46. The special master also found, however, that this four-to-six-week timeframe lacked sufficient evidentiary support as an appropriate timeframe for symptom onset in this case. See id. In particular, the special master found that the study described in the Han article ("Han")<sup>3</sup> indicated that narcolepsy symptom onset possibly associated with H1N1 influenza infection began six months after such infection. The special master also found that the Ahmed article ("Ahmed")4—which Appellants' expert co-authored—characterized Han as indicating such a six-month timeframe. Six months, however, was "not the timeframe proposed by [Appellants] as appropriate in this case." Id. The special master further found that, although Appellants' expert had opined that four-to-six weeks was appropriate for a "recall response"—that is, a response to a subsequent vaccine dose after receiving an earlier one—the expert had "not explained how a recall response would impact the timing of disease onset" in a way relevant to this case. See id.

Appellants disagree with the special master's finding that they failed to carry their burden of proof for *Althen* prong three. But they have not persuaded us that this finding was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

For example, Appellants argue that the special master misinterpreted Han. They maintain that Han's six-month timeframe referred to the time from infection to a narcolepsy *diagnosis*—not, as the special master thought, the

<sup>&</sup>lt;sup>2</sup> The relevant FluMist vaccination occurred on September 24, 2012. V.H. had also received a FluMist vaccination nearly two years earlier, on September 29, 2010, without any recorded complications. *Henkel*, 2022 WL 16557979, at \*1, \*3.

<sup>&</sup>lt;sup>3</sup> J.A. 2145–50.

<sup>&</sup>lt;sup>4</sup> J.A. 1180–82.

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time to symptom onset. See Appellants' Br. 46–47. Yet, as the government persuasively notes, Han suggests that the latter is indeed the proper interpretation, in part because Han hypothesizes the reason for this timeframe as: "[A]pproximately 80% cell loss is needed to exhibit symptoms, possibly explaining the 4- to 6-month delay between winter airway infection and narcolepsy onset occurrence." J.A. 2150; see also J.A. 2147 (describing results in terms of onset, "when onset was defined by the appearance of either sleepiness or cataplexy, a more objective symptom"); J.A. 1182 (Ahmed: "The time to narcolepsy onset following influenza infection was six months [in Han]."). At the very least, we cannot say that the special master's interpretation of Han's six-month timeframe as the time to symptom onset reflects a decision that was arbitrary, capricious, or an abuse of discretion.

Appellants also cite Ahmed as showing that approximately two months is the proper timeframe from an influenza vaccination to any resultant narcolepsy symptom onset. See Appellants' Br. 42, 46 (citing J.A. 1182 (describing "an onset approximately two months after vaccination")). Setting aside that, as the special master observed, this passage of Ahmed was discussing an influenza vaccine different from FluMist, see Henkel, 2022 WL 16557979, at \*46 (observing that Ahmed was discussing the Pandemrix vaccine), the government notes that this timeframe is still longer than four-to-six weeks. Appellants reply that, "to the extent 4-6 weeks is on the quicker side of approximately two months," their expert testified that a recall response explained any quicker symptom onset. Appellants' Reply Br. 9 (citing J.A. 740); see also Appellants' Br. 43 (citing J.A. 663–64, 714–15). But the special master determined that Appellants' expert had "not explained how a recall response would impact the timing of disease onset" in a way relevant to this case. See Henkel, 2022 WL 16557979, at \*46. And, having reviewed Appellants' identified expert testimony, we are not persuaded

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that the special master's determination in this regard reflects a decision that was arbitrary, capricious, or an abuse of discretion.

Appellants finally argue that, in evaluating Althen prong three, the special master applied an improperly elevated standard of proof—one more demanding than the preponderance standard. See, e.g., Appellants' Br. 49 (arguing that the special master's prong-three finding was "against the weight of the evidence and based on an elevated burden of proof"). We see no indication that the special master held Appellants to an improperly elevated standard when assessing Althen prong three. The special master's decision accurately set forth the governing standard as preponderant evidence. See, e.g., Henkel, 2022 WL 16557979, at \*1, \*35. And, in discussing Althen prong three specifically, the special master found that, because Appellants had "provided insufficient evidence in this case of what an appropriate timeframe between V.H.'s second FluMist vaccination and narcolepsy onset would be," they had "not provided preponderant evidence of a proximate temporal relationship between V.H.'s vaccination and narcolepsy onset." Id. at \*46.

In this case, Appellants' standard-of-proof challenge simply reflects their disagreement with how the special master weighed their evidence. As discussed above, however, we do not deem the special master's assessment of the evidence to be arbitrary or capricious. See, e.g., Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1349 (Fed. Cir. 2010) ("This court does not reweigh the factual evidence] or assess whether the special master correctly evaluated the evidence. . . . These are all matters within the purview of the fact finder." (cleaned up)). And we otherwise see no abuse of discretion or legal error in the special master's ultimate determination regarding Althen prong three.

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III

We have considered Appellants' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm.

## **AFFIRMED**

Costs

No costs.