

NOTE: This disposition is nonprecedential.

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

MYKELLE JIVON D'TIOLE,
Petitioner-Appellant

v.

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

2017-1982

Appeal from the United States Court of Federal Claims in No. 1:15-vv-00085-EJD, Senior Judge Edward J. Damich.

Decided: April 12, 2018

CURTIS RANDAL WEBB, Twin Falls, ID, argued for petitioner-appellant.

ROBERT PAUL COLEMAN, III, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by CHAD A. READLER, C. SALVATORE

D'ALESSIO, CATHARINE E. REEVES, GABRIELLE M. FIELDING, LARA A. ENGLUND.

Before MOORE, LINN, and CHEN, *Circuit Judges*.

LINN, *Circuit Judge*.

The parents and relatives of Mykelle Jivon D'Tiole (collectively "D'Tiole") appeal from the decision of the Court of Federal Claims under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), affirming the determination by Special Master Brian H. Corcoran denying compensation for narcolepsy with cataplexy allegedly caused by administration of the FluMist vaccine. *D'Tiole v. Sec'y of Health & Human Servs.*, ("Special Master Op.") No. 15-85, 2016 WL 7664475, 2016 U.S. claims LEXIS 2003 (Fed. Cl. Nov. 28, 2016), *aff'd* 132 Fed. Cl. 421 (2017).

Because the Special Master's decision was not arbitrary, capricious, or an abuse of discretion, was legally proper, *see* 42 U.S.C. § 300aa-12(e)(2)(B), and was based on a plausible analysis of the record evidence, we affirm. We write for the parties, and therefore omit the factual and procedural background from this opinion.

A.

In *Althen v. Sec'y of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005) and *Capizzano v. Sec'y of Health and Human Services*, 440 F.3d 1317 (Fed. Cir. 2006), this court made clear that the Vaccine Act mandates proof of causation by a "preponderance of the evidence," 42 U.S.C. § 300aa-12(a)(1), "substantiated by medical records or medical opinion," *Althen*, 418 F.3d at 1279, but does not "require" medical documentation to prove causation. *Id.* at 1280, 1281 ("To require *Althen* to provide medical documentation would contravene the

plain language of the statute.”). *See also Capizzano*, 440 F.3d at 1325.

D'Tiole argues that the Special Master violated *Althen* and *Capizzano* by de facto requiring epidemiological evidence because the Special Master gave undue weight to Duffy¹ and did not give enough weight to the Han² studies.

The Special Master considered Duffy as strong evidence against Dr. Steinman's theory that the evidence linking Pandemrix (a vaccine using an inactivated form of H1N1) to narcolepsy via molecular mimicry also established a medical theory causally connecting FluMist (a Live Attenuated Influenza Vaccine (“LAIV”)) to narcolepsy. In coming to that conclusion, the Special Master explained the baseline deficiency in Dr. Steinman's theory. The scientific literature indicated that the form of manufacture of the inactive flu vaccine was likely involved in the association of Pandemrix with narcolepsy. Dr. Steinman's theory fails to explain how this evidence applies to the FluMist vaccine, which has a distinct formulation and manufacturing process.

The consideration of *Duffy* did not de facto improperly require D'Tiole to provide epidemiological data to prove causation. The Special Master explicitly wrote that he was *not* requiring epidemiological evidence. *Special Master Op.* at 29 (“As a general matter, it is true that Program petitioners need not offer epidemiological evidence to establish their causation burden under *Althen*.”)

¹ Duffy J., et al., “Narcolepsy and Influenza A(H1N1) pandemic 2009 in the United States,” *Neurology*, 83: 1823–1830 (2014) (“Duffy”)

² Han F, et al., “Narcolepsy onset is seasonal and increased following the H1N1 pandemic in China,” *Ann. Neurol.*, 70(3): 410-417 (September 2011).

Indeed, because vaccine injuries are rare events, the fact that a particular epidemiological study suggests a vaccine is generally safe should not prevent a claimant from prevailing.”); *id.* at 27 (“By petitioner’s admission, there is no direct evidence of [causation] (although that fact does not mean the claim could not succeed, given the acceptance in the [Vaccine] Program of the notion that vaccine injuries are rare and otherwise need not be proven with scientific certainty.”)). Indeed, the Special Master noted possible probative evidence that would render D’Tirole’s case stronger. *Id.* at 31 (“Petitioner’s theory could well become more reliable once there is stronger proof linking the LAIV form of the H1N1 flu vaccine, or better and more consistent evidence linking the H1N1 wild virus alone, to narcolepsy. Studies measuring the nucleoprotein antibody levels in individuals vaccinated with FluMist would also be useful in supporting the theory.”). The Special Master’s acceptance of Duffy’s finding of a lack of a correlation between an LAIV vaccine and narcolepsy as undermining Dr. Steinman’s theory, *id.* at 29 (“[T]he Duffy epidemiologic study stood as very strong evidence rebutting an association between an LAIV containing the H1N1 strain and narcolepsy.”) did not directly or implicitly require epidemiological proof of causation. To the contrary, it simply reflects the Special Master’s assessment of the record presented.

Nothing in *Althen* or *Capizzano* requires the Special Master to ignore probative epidemiological evidence that undermines petitioner’s theory. See *Andreu v. Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (“Although *Althen* and *Capizzano* make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, *where such evidence is submitted*, the Special Master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.” (emphasis added)); *Grant v. Health & Human*

Servs., 956 F.2d 1144, 1148-49 (Fed. Cir. 1992) (considering negative epidemiological studies). The Special Master's reliance on Duffy did not improperly raise the standard in *Althen* beyond a preponderance of the evidence.

The Special Master also adequately explained that there were “facial difficulties with giving [*Han*] too much weight.” The Special Master noted specifically that, as recognized in Dr. Steinman's co-authored *Ahmed II* article, the results in *Han* were not duplicated outside of China and may have been the result of the high residential density in Hong Kong rather than the virus itself. *Special Master Op.* at 28. “[W]e do not sit to reweigh the evidence.” *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000) (explaining that where the Special Master's “conclusion was based on evidence in the record that was not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.”).

B.

D'Tiole also argues that the Special Master abused his discretion by deciding the case without an evidentiary hearing. We do not agree.

The decision to hold an evidentiary hearing is statutorily committed to the discretion of the Special Master. *See* 42 U.S.C. § 300aa-12(d)(3)(B)(v) (Special Master “may conduct such hearings as may be reasonable and necessary”). Nothing obliges the Special Master to hold such a hearing. *Id.* Here, the Special Master afforded D'Tiole a full and fair opportunity to present its case as required by Vaccine Rule 3(b) by accepting and considering seven expert reports, which addressed each of the arguments presented by both parties. *See Special Master Op.* at 37. D'Tiole does not point to any particular issues that the expert reports did not cover. The Special Master adequately explained that the primary issue—the presence or

absence of a reasonable theory of causation between the LIAV FluMist vaccine and narcolepsy—would be determined wholly based on the strength of the scientific evidence and the content of the seven expert reports, and not on any credibility determinations for which an evidentiary hearing could be helpful. D'Tiole has simply failed to show any abuse of discretion in this determination.

The Special Master's determination was not arbitrary, capricious or an abuse of discretion, was legally proper, *see* 42 U.S.C. § 300aa-12(e)(2)(B), and was based on a plausible analysis of the record evidence.

AFFIRMED

COSTS

No costs.