

NOTE: This disposition is nonprecedential.

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

MICHAEL MCCOLLUM,
Petitioner-Appellant

v.

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

2018-1623

Appeal from the United States Court of Federal Claims
in No. 1:14-vv-00790-LAS, Senior Judge Loren A. Smith.

Decided: February 25, 2019

RICHARD GAGE, Richard Gage, PC, Cheyenne, WY, 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 ALEXIS B. BABCOCK, C. SALVATORE D'ALESSIO, GABRIELLE M. FIELDING, CATHARINE E. REEVES, JOSEPH H. HUNT.

Before HUGHES, SCHALL, and STOLL, *Circuit Judges*.

SCHALL, *Circuit Judge*.

DECISION

Michael McCollum appeals the decision of the United States Court of Federal Claims in *McCollum v. Secretary of Health & Human Services*, 135 Fed. Cl. 735 (Dec. 21, 2017) (“*McCollum III*”). In that decision, the Court of Federal Claims denied Mr. McCollum’s motion for review of the decision of the special master denying his claim under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34, as amended (“Vaccine Act”), for compensation for narcolepsy. *See McCollum v. Sec’y of Health & Human Servs.*, No. 14-790V, 2017 WL 5386613 (Fed. Cl. Sept. 15, 2017) (“*McCollum I*”); *see also McCollum v. Sec’y of Health & Human Servs.*, No. 14-790V, Doc. 49 (Oct. 12, 2017) (denying reconsideration) (“*McCollum II*”). We *affirm*.

DISCUSSION

I.

Under the Vaccine Act, a petitioner seeking compensation may prove causation in one of two ways, depending upon whether the case involves a “Table injury” or an “off-Table injury.” *See Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). If the administered vaccine and injury are listed in the Vaccine Injury Table, and the injury manifests itself within the specified time period, a petitioner receives a presumption of a causal link between the vaccination and the injury. *See de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *see also* 42 U.S.C. § 300aa-11(c)(1)(C)(i) (not requiring a showing of causation for a Table injury). However, for an injury not listed in the Table, or for an injury which does not occur within the specified time period, a petitioner seeking compensation must prove causation in

fact. *See de Bazan*, 539 F.3d at 1351; *see also* 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (requiring a showing of causation for an off-Table injury). This appeal involves an off-Table injury.

A petitioner asserting an off-Table injury must file an affidavit and supporting documentation demonstrating that the vaccine-related injury for which compensation is sought was caused by a vaccine. *Cloer v. Sec’y of Health & Human Servs.*, 654 F.3d 1322, 1331 (Fed. Cir. 2011) (en banc). Causation must be proved by a preponderance of the evidence. *See* 42 U.S.C. § 300aa-13(a)(1) (“Compensation shall be awarded . . . to a petitioner if the special master or court finds . . . (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition.”). When a petitioner claims to have suffered an off-Table injury, we apply the test for causation in fact outlined in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005):

[The petitioner’s] burden is to show by preponderant evidence that the vaccination brought about [his or] 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.

418 F.3d at 1278.

II.

On August 29, 2014, Mr. McCollum filed a petition for compensation under the Vaccine Act, alleging that he suffered from narcolepsy as the result of an influenza vaccination he received in the fall of 2011. In *McCollum I*, the special master denied Mr. McCollum’s claim. 2017 WL 5386613, at *23. Weighing the evidence, the special master found that Mr. McCollum had “not offered preponderant

reliable medical and scientific evidence sufficient to satisfy the first *Althen* prong.” *Id.* at *19. The special master thus concluded that Mr. McCollum had failed to satisfy the requirement of providing a medical theory causally connecting the vaccination he received and his injury. Addressing the second *Althen* prong, the special master found that Mr. McCollum likely did receive an influenza vaccination in the fall of 2011. *Id.* at **19-20. The special master also found that, “given the ambiguity of the evidence purportedly showing [sleep problems relating to a variety of preexisting interrelated illnesses and medical problems,]” he could not conclude that Mr. McCollum’s narcolepsy “more likely than not predated his receipt of the flu vaccine.” *Id.* at *21. The special master nevertheless concluded that Mr. McCollum’s “failure to establish a persuasive causal theory [with respect to the vaccine he received] ultimately doom[ed]” his showing with respect to *Althen* prong two. *Id.* “Because the unadjuvanted H1N1 vaccine Mr. McCollum likely received has not been shown to cause narcolepsy,” the special master wrote, “it does not matter how consistent Petitioner’s arguments are with the causation theory proposed but rejected.” *Id.* Finally, turning to the third prong of *Althen*, the special master stated that “the deficiencies in [Mr. McCollum’s] causation theory ma[d]e it impossible for him to establish that onset of his narcolepsy was temporally reasonable.” *Id.* at *22. The special master stated that, “[a]bsent more compelling proof that the version of the H1N1 vaccine in question administered in the U.S. *can cause* narcolepsy, I cannot conclude that the proposed timeframe herein has preponderant support.” *Id.*

After the special master denied his motion for reconsideration, *see McCollum II*, Mr. McCollum moved for review. The Court of Federal Claims denied the motion. *See McCollum III*. Mr. McCollum now appeals. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

III.

We review de novo decisions of the Court of Federal Claims arising under the Vaccine Act, applying the same standard as the Court of Federal Claims applied in its review of the special master's decision. *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1248-49 (Fed. Cir. 2011). We owe no deference to the Court of Federal Claims or the special master on questions of law. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). At the same time, we uphold the special master's findings of fact unless they are arbitrary or capricious. *Porter*, 663 F.3d at 1249 (citing *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010)). "Thus, although we are reviewing as a matter of law the decision of the [Court of Federal Claims] under a non-deferential standard, we are in effect reviewing the decision of the special master under the deferential arbitrary and capricious standard on factual issues." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1350 (Fed. Cir. 2011) (quoting *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1369 (Fed. Cir. 2000)).

The arbitrary and capricious standard affords a fact finder considerable deference. Under that standard, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences, and articulated a rational basis for the decision, 'reversible error will be extremely difficult to demonstrate.'" *Hazlehurst v. Sec'y of Health & Human Servs.*, 604 F.3d 1343, 1349 (Fed. Cir. 2010) (quoting *Hines v. Sec'y of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). Thus, as long as a special master's factual finding is based upon evidence that is "not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." *Lampe*, 219 F.3d at 1363.

Mr. McCollum makes two arguments on appeal. We address them in turn.

IV.

Mr. McCollum's first argument is that the special master "impermissibly heightened the substantive law of what needs to be proven under prong one of *Althen*." Pet'r's Br. 13. Mr. McCollum states that, in order to satisfy prong one, a Vaccine Act petitioner "need only show a medically plausible theory of how a vaccine theoretically can cause the injury at issue." *Id.* According to Mr. McCollum, however, "[t]he special master erred by demanding scientific certainty." *Id.*

A.

Relevant to prong one of *Althen*, the medical theory Mr. McCollum advanced before the special master was that influenza vaccines administered in the United States (containing the H1N1 influenza strain) can provoke an autoimmune process that (via the mechanism of molecular mimicry) results in blockage of the hypocretin receptors in the brain responsible for sleep regulation, thereby producing narcolepsy. *McCollum I*, 2017 WL 5386613, at *15.

In support of his theory, Mr. McCollum presented the testimony of Dr. Marcel Kinsbourne. Dr. Kinsbourne opined that the flu vaccine Mr. McCollum received caused him to develop narcolepsy. *McCollum I*, 2017 WL 5386613, at *6. Dr. Kinsbourne proposed that this occurred by way of molecular mimicry. *Id.* In support of his theory, Dr. Kinsbourne relied upon epidemiologic evidence involving Pandemrix. Pandemrix is an inactivated, adjuvanted H1N1 flu vaccine¹ administered in Europe and associated

¹ A vaccine's adjuvant enhances the effect of the vaccine's antigen, here the H1N1 antigen, to increase the adaptive immune response created by that antigen. *McCollum I*, 2017 WL 5386613, at *7 n.18.

with a high rate of narcolepsy in a number of countries, such as Finland. *Id.* at *7.

Before the special master, Mr. McCollum also pointed to various studies and articles in the medical literature to support his claim that his narcolepsy was the result of his influenza vaccination. Among these were two articles by S. Sohail Ahmed, et al.: (1) *Narcolepsy, 2009 A (H1N1) Pandemic Influenza, and Pandemic Influenza Vaccinations: What is Known and Unknown About the Neurological Disorder, the Role for Autoimmunity, and Vaccine Adjuvants*, 50 *J. Autoimmunity* 1, 7 (2014) (“Ahmed I”); and (2) *Antibodies to Influenza Nucleoprotein Cross-React with Human Hypocretin Receptor 2*, 7 *Sci. Translational Med.* 294 (2015) (“Ahmed II”). The Ahmed I authors proposed that autoantibodies generated in response to a cross reaction with the H1N1 components (via a molecular mimicry process) contained in Pandemrix likely blocked hypocretin receptors to an extent sufficient to trigger narcolepsy in those individuals susceptible to it. The work of Ahmed II’s authors, in turn, led them to begin to suspect that the nucleoprotein (“NP”) antibody content of the H1N1-based flu vaccines they studied was a more likely causal factor for narcolepsy than the adjuvant in Pandemrix, as was previously suspected. *McCollum I*, 2017 WL 5386613, at *7.

Also before the special master was an observational epidemiologic study filed by both Mr. McCollum and the Secretary: Jonathan Duffy et al., *Narcolepsy and Influenza A (H1N1) Pandemic 2009 Vaccination in the United States*, 83 *Neurology* 1823 (2014) (“Duffy”). Duffy’s authors studied the association between narcolepsy and the unadjuvanted version of the H1N1 vaccine utilized in the United States, retrospectively surveying 650,995 individuals vaccinated with an H1N1 strain flu vaccine in 2009. The study failed to find an increase in narcolepsy. The Duffy authors hypothesized that the H1N1 antigens in the version of the vaccine they studied were themselves not sufficient to

increase the incidence of narcolepsy. *McCollum I*, 2017 WL 5386613, at *8.

B.

As noted above, the special master found that Mr. McCollum had “not offered preponderant reliable medical and scientific evidence sufficient to satisfy the first *Althen* prong.” *McCollum I*, 2017 WL 5386613, at *19. Before stating his findings, the special master 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. [citing *Andreu*, 569 F.3d at 1378–79]. 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.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) (“[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one” (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner’s ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

Id. at *12 (footnote omitted).

The special master began his analysis by recognizing that “the proposition that narcolepsy is an immune-mediated condition is fairly well-established” and that “the decrease in, or complete disappearance of, hypocretin caused by autoantibodies produced via the mechanism of molecular mimicry likely results in a disruption in a person’s wake cycle leading to narcolepsy.” *McCollum I*, 2017 WL 5386613, at *16. The special master also recognized the literature associating narcolepsy with Pandemrix, as well as “persuasive studies suggesting that the NP content of Pandemrix-like versions of the flu vaccine may be an important causal factor.” *Id.*

The special master turned next to what he regarded as the two points upon which Mr. McCollum relied in his argument that the H1N1 vaccine that he received caused his narcolepsy. The first point, based upon Ahmed II, was that H1N1 flu vaccines administered in the United States during the relevant time period contained levels of NP almost comparable to that of Pandemrix, “allowing,” the special master wrote, “for the conclusion that the vaccine [Mr. McCollum] received could have the same cross-reactive capacity.” *Id.* at *17. The second point was that, according to Mr. McCollum, there was reliable evidence suggesting that the wild H1N1 virus can cause narcolepsy. In support of this point, Mr. McCollum relied upon two articles: (1) Fang Han, et al., *Narcolepsy Onset is Seasonal and Increased Following the 2009 H1N1 Pandemic in China*, 70 *Am Neurological Ass’n* 410, 410-17 (2011); and (2) Fang Han, et al., *Genome-Wide Analysis of Narcolepsy in China Implicates Novel Immune Loci and Reveals Change in Association Prior to Versus after the 2009 H1N1 Influenza Pandemic*, 9 *PLOS Genetics*, no. 10, (2013). *Id.* at **8, 17.

As far as the first point was concerned, the special master noted that there were “limits to the conclusiveness of the Ahmed II findings about NP content.” *McCollum I*, 2017 WL 5386613, at *17. The special master also noted that, “while Ahmed II shifts the focus on the likely primary

cause of narcolepsy away from the adjuvants contained in the Pandemrix-like vaccines, it does not wholly eliminate the adjuvant as possibly playing an important role (thus reducing the applicability of its findings to the proposed causal effects of unadjuvanted vaccines).” *Id.* Addressing the second point, the special master concluded that, in view of inconsistencies in the Han findings and the circumstances unique to the countries studied, “[t]he findings in Han and similar articles may . . . only establish that the development of narcolepsy requires a confluence of factors (an H1N1 vaccine containing an adjuvant, coupled with an ongoing pandemic involving the wild virus) – strengthening the conclusion that the capacity of the vaccine’s NP content to spark narcolepsy still requires other boosting factors if it is to occur.” *Id.*

The most important consideration for the special master, however, was Duffy, which the special master regarded as “the sole relevant epidemiologic evidence regarding the impact of the version of the H1N1 flu vaccine administered in the [United States].” *McCollum I*, 2017 WL 5386613, at *17. The special master noted that Duffy involved forms of flu vaccine administered in the United States (unadjuvanted H1N1 flu vaccines), but yet Duffy observed no increase in the occurrence of narcolepsy after receipt of the vaccine by thousands of individuals. The special master noted that, in a prior case, he had found Duffy “to be a reliable and persuasive piece of evidence.” *Id.* at *18.² The special master stated that he viewed Duffy “as reasonable evidence that calls into doubt Petitioner’s theory.” *Id.* The

² See *D’Tirole v. Sec’y of Health & Human Servs.*, No. 15-85, 2016 WL 7664475 (Fed. Cl. Nov. 28, 2016), *aff’d* 132 Fed. Cl. 421 (2017). We affirmed the decision of the Court of Federal Claims denying review of the special master’s decision. *D’Tirole v. Sec’y of Health & Human Servs.*, 726 Fed. Appx. 809, 810-12 (Fed. Cir. 2018).

special master brought his analysis to a close with the following statement:

Weighing all of the above together, I find that Petitioner has not offered preponderant reliable medical and scientific evidence sufficient to satisfy the first *Althen* prong. The concept that an adjuvanted version of the H1N1 vaccine comparable to Pandemrix could cause narcolepsy finds support in the Ahmed articles plus other literature offered by Dr. Kinsbourne. If Pandemrix were the version of the vaccine at issue, none of the foregoing analysis would be necessary. But the contention that the NP content of an unadjuvanted H1N1 vaccine administered in the U.S. is enough by itself to cause narcolepsy is far weaker, and rebutted by reliable and relevant epidemiologic evidence.

Id. at *19.

C.

We are unable to agree with Mr. McCollum that the special master “impermissibly heightened the substantive law of what must be proven under prong one of *Althen*.” Pet’r’s Br. 13. Contrary to Mr. McCollum’s contention, Pet’r’s Br. 20-23, the special master’s consideration of Duffy did not amount to a de facto requirement of epidemiological evidence to find this prong met. *See Andreu*, 569 F.3d at 1379 (“Although *Althen* and *Capizzano* [*v. Sec’y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006),] 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.”).

Moreover, after correctly setting forth the pertinent law, *see* the quotation above from page *12 of *McCollum I*,

the special master weighed the evidence before him and arrived at the conclusion that Mr. McCollum had failed to satisfy the requirement of providing a medical theory causally connecting the vaccine he received and his injury. Because Mr. McCollum does not challenge the special master's fact findings, *see* Pet'r's Reply Br. 2, his complaint is with the way the special master weighed the evidence. This argument cannot succeed, however. As we stated in *Porter*, “[w]e 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.” 663 F.3d at 1249 (citations omitted). Having thoroughly reviewed the decision of the special master, and given the constraints upon the scope of our review of that decision, we are unable to say that the special master erred by imposing any kind of an improper burden upon Mr. McCollum. We therefore decline to disturb the special master's finding that Mr. McCollum failed to satisfy prong one of *Althen*.

VI.

Mr. McCollum's second argument on appeal is that the special master acted arbitrarily in “[i]gnoring [p]roof” of a challenge-rechallenge specific to him. Pet'r's. Br. 24. *See Capizzano*, 440 F.3d at 1322 (“A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine.”). Mr. McCollum claims that the special master failed to address and analyze evidence in the record to the effect that he experienced increased symptoms of narcolepsy after receiving a second influenza vaccination in the fall of 2012. Pet. Br. 24-27.

We do not agree. To begin with, the record hardly contains “proof” of challenge-rechallenge. It appears, at most, the special master had before him Mr. McCollum's references to certain “post-vaccination symptoms.” *McCollum*

I, 2017 WL 5386613, at *21. The special master, however, did not ignore this evidence. Rather, in finding that Mr. McCollum had failed to meet the requirements of *Althen* prong two, the special master stated:

I also note the testimony of the McCollums that Petitioner received a *second* flu vaccine sometime during his treatment at the Stanford Sleep Clinic as somewhat suggestive of the uncertainty surrounding the link between vaccination and his condition (since it is not likely his treaters would have been cavalier about exacerbating his condition had they been certain of a causal connection), although this evidence on this matter is fairly vague in the record.

Id. at *21 n.29. Furthermore, as the Court of Federal Claims noted in its review of the special master's decision, not only did the record not provide evidentiary support for a challenge-rechallenge argument, but "Petitioner never raised the challenge-rechallenge issue during the proceedings before the Special Master, either in the expert testimony or during trial testimony." *McCollum III*, 135 Fed. Cl. at 740-41. In short, we see no merit in Mr. McCollum's challenge-rechallenge argument.

CONCLUSION

For the foregoing reasons, we affirm the decision of the Court of Federal Claims denying Mr. McCollum's motion for review of the decision of the special master.

AFFIRMED

No costs.