

NOTE: This disposition is nonprecedential.

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

MARY ORLOSKI,
Petitioner-Appellant

v.

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

2020-1754

Appeal from the United States Court of Federal Claims
in No. 1:17-vv-00936-LKG, Judge Lydia Kay Griggsby.

Decided: January 14, 2021

VERNE E. PARADIE, JR., Paradie & Rabasco, Lewiston,
ME, for petitioner-appellant.

KYLE POZZA, Vaccine/Torts Branch, Civil Division,
United States Department of Justice, Washington, DC, for
respondent-appellee. Also represented by JEFFREY B.
CLARK, C. SALVATORE D'ALESSIO, HEATHER LYNN
PEARLMAN, CATHARINE E. REEVES.

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

CHEN, *Circuit Judge*.

Ms. Mary Orloski appeals a decision of the United States Court of Federal Claims (Claims Court) affirming a decision of the Special Master finding that Ms. Orloski failed to meet her burden to show a causal link between her influenza (flu) and tetanus-diphtheria-acellular-pertussis (Tdap) vaccinations and her claimed autoimmune condition—Acute Disseminated Encephalomyelitis (ADEM). The Special Master considered and appropriately weighed all of the evidence presented by Ms. Orloski. We, thus, *affirm*.

BACKGROUND

On October 23, 2014, Ms. Orloski received a flu vaccination. Later that day, Ms. Orloski went to the emergency room with visual disturbances, however, her visual symptoms resolved that same day. Over the next few days, Ms. Orloski stated that she began to experience tingling and numbness in her limbs. On December 2, 2014, Ms. Orloski saw a doctor for her symptoms and he dismissed her symptoms as stress related. On November 18, 2015, Ms. Orloski received a Tdap vaccination. Ms. Orloski stated that subsequent to the Tdap vaccination, she started experiencing a number of neurological symptoms and other issues. The record in this case contains Ms. Orloski's medical records for doctors' visits between November 18, 2015 and May 4, 2017. During that time, Dr. Alexandra Degenhardt suggested that Ms. Orloski had ADEM resulting from her vaccinations. Ms. Orloski's other treating physicians, Dr. David Preston, Dr. Robert Stein, and Dr. Haatem Reda, all opined that either Ms. Orloski did not have ADEM or her symptoms were not caused by the vaccinations. Additionally, some of Ms. Orloski's medical records fail to mention her symptoms and/or vaccinations.

On July 13, 2017, Ms. Orloski filed a claim with the Claims Court for vaccine injury compensation under the National Vaccine Injury Compensation Program (Vaccine Program). Following receipt of a petition for compensation under the Vaccine Program, the Claims Court designates a Special Master to issue a decision on whether compensation should be provided and, if so, the amount of the compensation. 42 U.S.C. § 300aa-12(d).

When Ms. Orloski filed her petition, she included one exhibit consisting of her medical records. J.A. 1–2. On June 6, 2018, the Special Master directed Ms. Orloski to file an expert report and supporting medical literature by July 16, 2018. On July 16, 2018, Ms. Orloski filed seven pages of medical records from Dr. Degenhardt. On July 18, 2018, in response to an inquiry from the Special Master as to whether Ms. Orloski planned to submit an expert report, Ms. Orloski stated that she would request additional time to consult Dr. Degenhardt. Thus, on August 15, 2018, the Special Master ordered Ms. Orloski to file a formal expert report and supporting medical literature by October 22, 2018. The Special Master requested that the report discuss the expert’s qualifications, pertinent facts from Ms. Orloski’s medical records, background on Ms. Orloski’s alleged disease or injury, a theory of causation, and any non-vaccine potential causes. On October 2, 2018, Ms. Orloski filed a single page report from Dr. Degenhardt stating that there is a clear temporal relationship between ADEM and the vaccine. On October 15, 2018, the Special Master again ordered Ms. Orloski to file a formal expert report by no later than November 14, 2018, noting that the one-page report did not properly address the topics identified in the Special Master’s prior order. On October 17, 2018, Ms. Orloski indicated that she did not intend on submitting any further reports. During a November 13, 2018 status conference, Ms. Orloski requested additional time to supplement the record with medical literature and other evidence

related to her causation theory. The Special Master ordered that such evidence be filed by December 13, 2018.

On December 12, 2018, Ms. Orloski motioned for a ruling on the record and submitted five exhibits consisting of additional medical records, two pieces of medical literature, and an affidavit. In response, the government filed an expert report from Dr. Subramaniam Sriram who concluded that Ms. Orloski did not have ADEM and that the onset of Ms. Orloski's symptoms was too remote from either vaccination to support causation. On April 3, 2019, the Special Master contacted Ms. Orloski to inquire about whether she intended to file a responsive expert report. Ms. Orloski responded with a second affidavit and two photographs purporting to show an injection site reaction from her Tdap vaccination. On October 31, 2019, the Special Master issued a decision denying Ms. Orloski compensation under the Vaccine Program, finding that Ms. Orloski had failed to meet her burden of proof that the vaccines were the cause of her claimed injury. On March 17, 2020, the Claims Court affirmed the Special Master's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

DISCUSSION

We review an appeal in a vaccination case from the Claims Court de novo, applying the same standard to the Special Master's decision that the Claims Court applied. *Milik v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2016). We review the Special Master's legal conclusions without deference and discretionary rulings for abuse of discretion. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). We review the Special Master's factual findings using an "arbitrary or capricious" standard. *Id.*

To receive compensation under the Vaccine Program, Ms. Orloski must demonstrate either that: (1) she suffered a "Table injury" by receiving a covered vaccine and

subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table or (2) that she suffered an “off-Table injury,” one not listed on the Table, as a result of her receipt of a covered vaccine. *Moberly v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Ms. Orloski does not allege a Table injury and therefore she must prove that her injury was caused-in-fact by a covered vaccine. *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274 (Fed. Cir. 2015), sets forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury: (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. In this case, the Special Master found that Ms Orloski did not meet her burden of proof under any of the *Althen* prongs, and the Claims Court agreed.

Ms. Orloski argues that the evidence she submitted was sufficient to establish prong one of *Althen*. Appellant’s Br. at 18. Under the first *Althen* prong, Ms. Orloski must offer a scientific or medical theory that the vaccine at issue can cause the type of injury alleged. *Althen*, 418 F.3d at 1278. “Simply identifying a ‘plausible’ theory of causation is insufficient of a petitioner to meet her burden of proof.” *LaLonde v. Sec’y of Health & Human Servs.*, 746 F.3d 1334, 1338 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1332).

Ms. Orloski primarily relies on Dr. Degenhardt’s opinions, but they fail to address a mechanism for how either or both vaccines could cause ADEM. Although Dr. Degenhardt diagnosed Ms. Orloski with ADEM as a reaction to her vaccinations, she did not provide any reasoning for how or why they would cause such a reaction. J.A. 147. Under the deferential review standard we must apply, we see no reversible error as to the Special Master’s evaluation of Dr. Degenhardt’s opinions. Ms. Orloski argues that the

Special Master refused to consider Dr. Degenhardt's opinions, but we disagree. A review of the Special Master's opinion shows that the Special Master considered Dr. Degenhardt's opinions but found them too conclusory and underdeveloped to be persuasive. J.A. 16. Next, Ms. Orloski argues that the Special Master incorrectly required her to provide an outside expert opinion to prove her claim (Appellant's Br. at 17–18), but we read the Special Master's statements differently. To be sure, the Special Master gave Ms. Orloski several opportunities to bolster her case and provide a more detailed expert report than what Ms. Orloski had provided. But nothing in the Special Master's opinion demands that a petitioner must submit an expert report in order to prove her case.

Ms. Orloski also submitted two articles purporting to establish a medical theory as required by the first *Althen* prong. The first article, "The spectrum of post-vaccination inflammatory CNS demyelinating syndromes," by Dimitrios Karussis and Panayiota Petrou, discusses inflammatory central nervous system diseases related to vaccines. J.A. 148–57. With respect to ADEM, the article provides the following information: (1) "ADEM can occur in any age but is mainly a disease of children and young adults with a mean age of onset of 5–6 years and a higher incidence in males"; (2) "[e]ncephalopathy, occurring in up to 74% of patients, is considered mandatory for definite diagnosis"; and (3) "despite a close temporal relation to vaccinations, there is no concrete evidence of a clear pathogenetic correlation." J.A. 149–50. The article also discusses two hypothetical pathogenic hypotheses, but fails to review each to discuss the reasonableness of the hypotheses and is ultimately a discussion of frequency of ADEM with respect to vaccines, rather than a study showing causation. The second article cited by Ms. Orloski, "Acute Disseminated Encephalomyelitis following Vaccination against Hepatitis B in a Child: A Case Report and Literature Review," by Yuan et al., is a case study of a twelve-

year-old child who suffered from ADEM three weeks after receiving a hepatitis B vaccination. J.A. 158. The article contains a single relevant sentence: “Postvaccination ADEM has been associated with several vaccines such as rabies, diphtheria-tetanus-polio, smallpox, measles, mumps, rubella, Japanese B encephalitis, pertussis, influenza, hepatitis B, and the Hog vaccine.” J.A. 159–60. The article, however, fails to address the causation between the flu and Tdap vaccines and Ms. Orloski’s ADEM. Thus, the Special Master’s conclusion that Ms. Orloski failed to prove the first *Althen* prong with the two submitted articles by preponderance of the evidence is supported by the evidentiary record.

Lastly, as to *Althen* prong one, Ms. Orloski contends that the immediate onset of her symptoms after her vaccinations helps establish her burden under this prong. But as the Special Master correctly noted, “a proximate temporal association alone does not suffice to show a causal link between vaccination and injury.” J.A. 17 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). In view of the foregoing, we affirm the Special Master’s analysis as to *Althen* prong one, which properly considered the evidence “taken separately or in the aggregate.”¹ J.A. 16

¹ Ms. Orloski also noted that there were instances in the Vaccine Program in which other special masters had established that the flu vaccine could cause ADEM or similar injuries. Appellant’s Br. at 22; *see e.g.*, *Caruso v. Sec’y of Health & Human Servs.*, No. 13-700V, at *14 (Fed. Spec. Mstr. Sept. 26, 2017). As we have previously stated, Special Masters are not bound by the decisions of other special masters and further, special masters are not required to distinguish non-binding decisions of other Special Masters. *Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1358-59 (Fed. Cir. 2019).

Because Ms. Orloski must prevail as to all three *Althen* prongs, our decision upholding the Special Master's decision as to prong one is sufficient to affirm her decision.

CONCLUSION

We have considered Ms. Orloski's remaining arguments and find them unpersuasive. For the reasons set forth above, we affirm the Special Master's denial of entitlement under the Vaccine Program.

AFFIRMED

COSTS

No costs.