

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

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**CARMEN MORENO LOZANO,**  
*Petitioner-Appellee*

v.

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

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2019-2138

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Appeal from the United States Court of Federal Claims  
in No. 1:15-vv-00369-LAS, Senior Judge Loren A. Smith.

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Decided: May 18, 2020

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RONALD C. HOMER, Conway Homer, PC, Boston, MA,  
for petitioner-appellee. Also represented by CHRISTINA  
CIAMPOLILLO.

LOWELL STURGILL, JR., Appellate Staff, Civil Division,  
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respondent-appellant. Also represented by ABBY  
CHRISTINE WRIGHT, ROBERT PAUL COLEMAN, III, JOSEPH H.  
HUNT.

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Before MOORE, O'MALLEY, and TARANTO, *Circuit Judges*.

O'MALLEY, Circuit Judge.

The Secretary of Health and Human Services (“the government”) appeals from a final judgment of the United States Court of Federal Claims, which denied the government’s motion for review and affirmed the special master’s decision granting entitlement to compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa–1 and –34 (“Vaccine Act”). See *Lozano v. Sec’y of Health & Human Servs.*, 143 Fed. Cl. 763 (2019); *Lozano v. Sec’y of Health & Human Servs.*, No. 15-369V, 2017 WL 3811124 (Fed. Cl. Spec. Mstr. Aug. 4, 2017). We affirm.

#### BACKGROUND

On July 14, 2012, Carmen Lozano (“Lozano”) gave birth to a baby girl at Community Memorial Hospital (“CMH”) in Ventura, California. The next day, while she was still hospitalized, Lozano received a tetanus-diphtheria-acellular-pertussis (“Tdap”) vaccination. Two weeks later, on July 30, 2012, Lozano reported to Ventura County Obstetrics and Gynecology, complaining of a low-grade fever, body aches, and breast tenderness. The nurse practitioner suspected that Lozano had early mastitis, and prescribed medication. Lozano’s symptoms persisted and she began to experience fatigue.

On August 9, 2012, Lozano went to the emergency room with complaints of abdominal pain and difficulty urinating. After the laboratory tests showed no signs of infection, she was discharged, but returned later that same day, reporting fever, weakness, loss of balance, vision changes, neck pain, headache, vomiting, and dizziness. A brain MRI revealed “numerous focal and patchy high signal intensity lesions involving the brainstem, cerebellopontine angles, right cerebellum, basal ganglia, corpus callosum and subcortical white matter,” which suggested to the radiologist that Lozano possibly had multiple sclerosis (“MS”), acute disseminated encephalomyelitis (“ADEM”), or vasculitis. *Lozano*, 2017 WL 3811124, at \*1.

Lozano was admitted to the hospital for further evaluation, including a consultation with a neurologist, Dr. Francisco Torres. Dr. Torres opined that Lozano had possibly experienced an MS attack, and began treating her with steroids. Lozano's symptoms improved after three days of treatment and she was discharged with a working diagnosis of MS. Lozano was instructed to follow up with Dr. Timothy Sheehy, who determined that a second opinion was necessary to ensure that her diagnosis was accurate. Before she could obtain that second opinion, however, Lozano returned to the emergency room with burning in her chest, slurred speech, hearing changes, and numbness in her tongue. She was diagnosed with an MS flare and discharged the same day. Lozano was instructed to see her primary care physician for an MRI of the spine. That MRI showed "[p]atchy areas of altered signal intensity within the thoracic spinal cord . . . worrisome for foci of demyelination." *Id.* at \*2.

In September 2012, Lozano sought a second opinion from Dr. Barbara Giesser, a neurologist at the University of California Los Angeles Neurology Outpatient Clinic. Dr. Giesser provided a detailed medical history of Lozano since the onset of her symptoms in July 2012. Dr. Giesser's differential diagnosis included post-viral encephalitis/myelitis, with a working diagnosis of "Clinically Isolated Syndrome," a condition similar to MS. *Id.*

Throughout the fall of 2012, Lozano continued to see Dr. Sheehy, with complaints of a burning sensation from her back to chest and decreased memory, cognition, and depression. In February 2013, however, a repeat MRI "showed dramatic improvement, suggesting that ADEM was a more likely etiology, which was confirmed through later serological findings." *Id.* at \*3. Since that time, Lozano's doctors have continued to opine that ADEM is the likely explanation for her symptoms. *Id.*

In April 2015, Lozano filed a petition for compensation under the Vaccine Act, alleging that she suffered ADEM as a result of the Tdap vaccine. Both parties submitted expert reports from neurologists as well as medical literature and prehearing briefing. In June 2017, the special master held an entitlement hearing, where both sides' experts testified—Dr. Norman Latov on behalf of Lozano and Dr. Thomas Leist for the government.

Dr. Latov opined that Lozano's ADEM was the result of her receipt of the Tdap vaccine. *Id.* He described ADEM "as an autoimmune demyelinating disease of the central nervous system that attacks the white matter of the brain and spinal cord of its patients." *Id.* Dr. Latov noted that ADEM can be confirmed through lesions on an MRI, and that "a hallmark of ADEM is its subsequent resolution—something that can be confirmed by later MRIs." *Id.* He also cited several pieces of medical literature observing an association between tetanus-containing vaccines and ADEM. Dr. Latov proposed that the Tdap vaccine triggered Lozano's autoimmune response, and noted that her treating physicians changed their diagnosis to ADEM after Lozano's "MRIs cleared and she had experienced no subsequent neurological episodes." *Id.* at \*4.

Dr. Latov disputed the government's theory that Lozano was suffering from posterior reversible encephalopathy syndrome ("PRES"), rather than ADEM. In doing so, he explained that "PRES is a condition marked by the presence of edema in the posterior part of the brain as revealed on MRIs," and that the majority of patients with PRES have a "decreased level of consciousness and have seizures." *Id.* at \*5. But Lozano's MRIs "showed lesions throughout the spinal cord and brain—not just in the posterior region—and detected no edema." *Id.* Nor had she experienced seizures or decreased consciousness. Given these factors, and because none of Lozano's treating physicians found that PRES was a reasonable explanation of her

condition, Dr. Latov opined that PRES was an improper diagnosis.

The government's expert—Dr. Leist—testified that Lozano had PRES and that it was not caused by the Tdap vaccine. Given the rapid onset of symptoms after she gave birth, Dr. Leist opined that PRES, a known vascular complication following pregnancy, was likely the correct diagnosis. Although he recognized that none of Lozano's treating physicians considered PRES the proper diagnosis, Dr. Leist "opined that this was because her physicians had not given sufficient weight to the fact that she was postpartum" when the symptoms began. *Id.* at \*6.

Following the hearing, the special master granted Lozano's petition, finding that she was entitled to compensation. At the outset, the special master found that Dr. Latov's testimony and the supporting medical literature demonstrated that the Tdap vaccine can cause autoimmune diseases such as ADEM. *Id.* at \*11. The special master then turned to the government's primary challenges—that ADEM was not the correct diagnosis and that her symptoms began pre-vaccination. As to the first issue, the special master found that, although Lozano's treating physicians initially included MS as part of the differential diagnosis, "her subsequent clinical progression ultimately led them away from MS and toward ADEM." *Id.* at \*12. The special master expressly rejected the government's suggestion that Lozano's proper diagnosis was PRES, on grounds that "the overall record does not support it." *Id.* As to the second issue, the special master found that the government was unsuccessful in establishing that Lozano had symptoms potentially related to her ADEM pre-vaccination. Finally, because Lozano experienced her symptoms roughly 21 days after receiving the vaccine, the special master found that Lozano offered preponderant evidence of a proximate temporal relationship between the vaccine and her injury. Because Lozano carried her burden

to show causation, the special master found that she was entitled to compensation under the Vaccine Act.

The government filed a motion for review of the special master's decision with the Court of Federal Claims. In relevant part, the government argued that the special master erred "by failing to require evidence of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Lozano*, 143 Fed. Cl. at 768. The Court of Federal Claims denied the motion, finding that the special master's decision was neither an abuse of discretion nor contrary to law, and that his fact findings were neither arbitrary nor capricious. *Id.* at 770. The Court of Federal Claims subsequently entered judgment, awarding damages to Lozano in the form of a lump sum payment of \$1,199,216.86.

The government timely appealed the Court of Federal Claims' final judgment to this court. We have jurisdiction under 42 U.S.C. § 300aa-12(f).

#### DISCUSSION

In Vaccine Act cases, we review the Court of Federal Claims' decision de novo, "applying the same standard of review as the Court of Federal Claims applied to its review of the special master's decision." *Griglock v. Sec'y of Health & Human Servs.*, 687 F.3d 1371, 1374 (Fed. Cir. 2012) (citation omitted); see also *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1378 (Fed. Cir. 2015). We owe no deference to the trial court or the special master on questions of law, but we uphold the special master's findings of fact unless they are arbitrary or capricious. *Griglock*, 687 F.3d at 1374 (citation omitted). "We 'do not sit to reweigh the evidence. [If] the Special Master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.'" *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357,

1363 (Fed. Cir. 2000)). Our role is not to “second guess the Special Master[']s fact-intensive conclusions,” particularly in cases where “the medical evidence of causation is in dispute.” *Id.* (quoting *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)).

The Vaccine Act distinguishes between two types of injuries: “Table” and “off-Table.” 42 U.S.C. §§ 300aa–11(c)(1)(C)(i), 300aa–11(c)(1)(C)(ii). “Causation is presumed for Table injuries when a specified condition follows the administration of a specified vaccine within a specified period of time.” *Moriarty v. Sec’y of Health & Human Servs.*, 844 F.3d 1322, 1327 (Fed. Cir. 2016) (citation omitted). All other injuries alleged to be caused by a vaccine are “off-Table injuries,” where the petitioner has to prove causation by a preponderance of the evidence. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). It is undisputed that Lozano’s injury is in the off-Table category, meaning that she must prove “actual causation” or “causation in fact” by preponderant evidence.

To prove causation, a petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In doing so, 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.

*Althen*, 418 F.3d at 1278. Because the special master found, and the parties do not dispute, that Lozano satisfied the first and third prongs of the *Althen* test, only the second prong of *Althen* is at issue in this appeal.

The government's primary argument is that the special master and the Court of Federal Claims erred in finding that proof of a diagnosis, standing alone, suffices to prove causation in a non-Table case. According to the government, the special master ignored "the government's arguments regarding causation, and reliev[ed] petitioner of her burden to demonstrate not only that she suffers from ADEM, but also that the vaccine actually caused her ADEM." Appellant Br. 15. We disagree. As explained below, the special master fully addressed the parties' arguments and considered all of the record evidence in finding that Lozano established causation by preponderant evidence.

At the outset, although the government submits that the special master ignored its arguments, review of the record reveals that the special master specifically addressed the arguments the government raised in connection with *Althen* prong two. In its prehearing briefing to the special master, the government argued that Lozano failed to satisfy the second prong of *Althen* for two reasons: "the timing of petitioner's symptoms pre-date[d] the vaccine administration; and the alternative diagnoses of petitioner's condition provide[d] an alternative explanation for why [she] experienced so many symptoms after vaccination." J.A. 111.

The special master began by addressing the government's arguments regarding diagnosis, finding that the medical evidence supported a diagnosis of ADEM and that none of Lozano's treating physicians had questioned that diagnosis since the winter of 2013. *Lozano*, 2017 WL 3811124, at \*12. The special master next turned to the government's arguments regarding pre-vaccination symptoms, finding that the government was "unsuccessful in establishing that Mrs. Lozano had symptoms potentially related to her ADEM that began pre-vaccination." *Id.* Finally, the special master considered and rejected the

government's argument that Lozano's proper diagnosis was PRES. *Id.*

In reaching these conclusions, the special master noted that he was addressing the government's PRES argument within his *Althen* prong two discussion "since it relates directly to the accuracy of the ADEM diagnosis, and was in fact offered to contradict it," but that he would reach the same conclusion if he had "more rigidly determined that [Lozano] had carried her initial burden, and then considered (under the burden-shifting test applied) whether [the government] had carried [its] burden of establishing an alternative, unrelated cause for Mrs. Lozano's condition." *Id.* at \*12, n.11. Accordingly, although he recognized that he was addressing issues in an unconventional order, the special master focused his analysis on the issues as the government framed them, and expressly noted that his conclusion would have been the same had he structured his analysis differently.

In any event, the government's argument that the special master relied solely on Lozano's diagnosis to satisfy *Althen* prong two is unfounded. Indeed, review of the special master's decision reveals that he considered the record as a whole in finding that Lozano "established a logical sequence of cause and effect from vaccine to injury that is supported by the evidentiary record." *Id.* at \*12-\*13.

It is well established that petitioners need not present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, we have explained that medical records and medical opinion testimony can satisfy *Althen* prong two, and that evidence used to satisfy one of the *Althen* prongs can overlap to satisfy another prong. *Id.* at 1326.

We have also recognized that expert testimony is often very important in off-Table cases like this one, which require proof of actual causation. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000) (“As is often true in Vaccine Act cases based on a theory of actual causation, the expert medical testimony was important in this case.”). Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). As such, the special master’s credibility findings “are virtually unchallengeable on appeal.” *Id.*

Here, the special master examined the medical records, medical literature, and both parties’ expert reports and testimony. The record demonstrates that the special master was persuaded by Lozano’s expert, Dr. Latov, who offered both written and oral testimony opining that Lozano’s “ADEM was the product of her receipt of the Tdap vaccine.” *Lozano*, 2017 WL 3811124, at \*3. Based on the clinical signs and symptoms set forth in Lozano’s medical records, Dr. Latov agreed with Lozano’s treating neurologist, Dr. Sheehy, that she suffered from ADEM. *Id.* Dr. Latov explained that ADEM typically develops days to weeks following a triggering event, such as an infection or vaccination. *See id.* And he testified that it is well accepted in the medical community that tetanus-containing vaccinations, such as Tdap, can cause ADEM. *Id.* at \*4. Given the record evidence that Lozano began to experience symptoms of ADEM roughly three weeks after her vaccination, coupled with the fact that no treating physician identified any alternative cause for her ADEM, Dr. Latov testified at the entitlement hearing that it was “highly likely that [Lozano] had vaccine-induced ADEM.” J.A. 226–28.

The government argues that Dr. Latov’s expert analysis is insufficient to prove causation in light of our decision in *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d

1315 (Fed. Cir. 2010). Specifically, the government maintains that, in both *Moberly* and this case, experts found causation based solely on: (1) evidence that a vaccine can cause an injury; (2) proof that the petitioner developed an injury within the expected onset time after receiving that vaccination; and (3) a conclusion that there was no likely alternative cause. Appellant Br. 21 (citing *Moberly*, 592 F.3d at 1320–21, 1323). According to the government, we rejected this evidence in *Moberly* on grounds that the petitioner failed to demonstrate actual causation, and we should do the same here. But in *Moberly*, the special master found the petitioner’s expert’s testimony “contradictory and confusing,” and thus discredited his testimony on those grounds. 592 F.3d at 1320. Setting aside the expert testimony, the special master found, and we agreed, that the remaining evidence merely showed a temporal association between vaccine and injury, which was insufficient to demonstrate actual causation. *Id.* at 1323.

Here, however, Lozano’s expert neurologist—Dr. Latov—proffered testimony that was supported by peer-reviewed, published medical literature, as well as Lozano’s own medical records. *Lozano*, 2017 WL 3811124, at \*11–12. Unlike *Moberly*, where the expert testimony was discredited, the special master here found Dr. Latov’s testimony reliable and persuasive. *Id.* We see no reason to disturb that credibility determination on appeal. *See Lampe*, 219 F.3d at 1361–62. Because the evidence of record in *Moberly* was significantly different from the record in this case, the result in *Moberly* does not compel the same result here.

To the extent the government suggests that Lozano cannot satisfy *Althen* prong two because no treating physician expressly opined that the Tdap vaccination caused her ADEM, we have made clear that “testimony from treating physicians is not required in Vaccine Act cases.” *Moberly*, 592 F.3d at 1325. Given the testimony from Dr. Latov, coupled with the evidentiary record, the special master found

that Lozano “provided sufficient preponderant evidence to meet her *Althen* Two burden. She established a logical sequence of cause and effect from vaccine to injury that is supported by the evidentiary record.” *Lozano*, 2017 WL 3811124, at \*13. Because it is clear that he considered the record as a whole in reaching this conclusion, we agree with the Court of Federal Claims that the special master did not violate the bounds of his discretion and that his findings were neither arbitrary nor capricious. *See Lozano*, 143 Fed. Cl. at 769.

We likewise agree with the Court of Federal Claims that, despite the government’s suggestion to the contrary, this case neither creates a “new ‘Table’-type presumption for non-Table conditions,” nor compromises “the scientific integrity of the Vaccine Program.” Appellant Br. 22–23; *see Lozano*, 143 Fed. Cl. at 770 (rejecting the government’s arguments that “a de facto Table claim was created” and that the special master’s “opinion has put the integrity of the Vaccine Program at risk”). On this record, there was sufficient evidence to support the special master’s causation analysis, including his conclusion with respect to *Althen* prong two. We therefore decline the government’s request to remand for reapplication of the *Althen* test.

#### CONCLUSION

We have considered the government’s remaining arguments and find them unpersuasive. For the foregoing reasons, we conclude that the special master applied the correct legal standard and considered the entire record in finding that Lozano proved causation by a preponderance of the evidence. Accordingly, we affirm the judgment of the Court of Federal Claims, which affirmed the special master’s decision granting Lozano entitlement to compensation.

**AFFIRMED**