In the United States Court of Federal Claims

No. 15-369V
Filed: May 21, 2019
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CARMEN MORENO LOZANO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Vaccine Case; Motion for Review; Tdap Vaccine; *Althen*; Burden of Proof; Causation Analysis

Christina Ciampolillo, Conway Homer, P.C., Boston, MA, for petitioner.

Robert Coleman, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

***SMITH*, Senior Judge:**

Respondent seeks review of an entitlement decision issued by Special Master Brian H. Corcoran, granting petitioner, Carmen Lozano's, petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10–34 (2012) ("Vaccine Act"), alleging that she developed acute disseminated encephalomyelitis ("ADEM") due to receipt of the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine on June 15, 2012. The Special Master awarded compensation, finding that petitioner carried her burden establishing causation. *Lozano v. Sec'y of Health & Human Servs.*, 2017 SW 3811124 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (*Lozano*). Respondent now moves for review of this decision. For the reasons that follow, the Court denies its motion.

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[1] An unredacted version of this opinion was issued under seal on May 21, 2019. The parties were given an opportunity to propose redactions, but no such proposals were made. Nevertheless, the court has incorporated some minor changes into this opinion.

I. BACKGROUND

A brief recitation of the facts provides necessary context.[2]

Petitioner's medical history prior to vaccination shows that she was largely healthy, but that she was pregnant just before she received the vaccine at issue. Prior to and during her pregnancy, Mrs. Lozano exhibited some symptoms that were relevant to those at issue post-vaccination. In February of 2012, during her pregnancy, petitioner reported some bilateral numbness in her fingers and arms. Her family further reported that Mrs. Lozano experienced an episode of eye drooping and, on one occasion, experienced difficulty opening a jar prior to her pregnancy. Neither of these instances were addressed in contemporary medical records.

On July 14, 2012, Mrs. Lozano gave birth at Community Memorial Hospital ("CMH") in Ventura, California. On July 15, 2012, while she was still in the hospital, petitioner received a Tdap vaccine.[3] Two weeks later, on July 30, 2012, petitioner reported to Ventura County Obstetrics and Gynecology ("VCOG"), complaining of low-grade fever, body aches, and breast tenderness, which she reported had persisted since leaving the hospital. The nurse practitioner suspected early mastitis[4] and prescribed medication. Petitioner continued to experience the same persistent symptoms and grew fatigued.

On August 9, 2012, twenty-five days after vaccination, Mrs. Lozano went to the emergency room at CMH, complaining of abdominal pain and difficulty urinating. The lab results showed no sign of infection, so petitioner was discharged, and her symptoms were assumed to be related to her mastitis. Her symptoms continued to worsen, and she returned to CMH later that day, reporting increased weakness, fever, feeling off balance, vision changes, neck pain, headache, vomiting, and dizziness. A brain MRI[5] was performed and showed "numerous focal and patchy high signal intensity lesions[6] involving the brainstem,[7]

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[2] As the basic facts here have not changed significantly, the Court's recitation of the background facts here draws from the Special Master's earlier opinion in *Lozano*.

[3] Tdap is defined as "tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine." *Dorland's Illustrated Medical Dictionary* 1874 (32nd ed. 2012) ("*Dorland's*").

[4] Mastitis is defined as "inflammation of the mammary gland, or breast." *Dorland's* 1111.

[5] An MRI is a "magnetic resonance imaging" exam. *Dorland's* 1184.

[6] A lesion is defined as "any pathological or traumatic discontinuity of tissue or loss of function of a part." *Dorland's* 1025.

[7] The brainstem is "the stalklike portion of the brain connecting the cerebral hemispheres with the spinal cord and comprising the mesencephalon, pons, and medulla oblongata." *Dorland's* 248.

cerebellopontine[8] angles, right cerebellum,[9] basal ganglia,[10] corpus callosum[11] and subcortical white matter,"[12] which suggested to the radiologist that petitioner potentially had multiple sclerosis ("MS"),[13] ADEM,[14] or vasculitis.[15]

Petitioner was admitted to CMH for further evaluation, including a consultation with neurologist, Dr. Francisco Torres. Upon review of her records, Dr. Torres opined that petitioner

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[8] Cerebellopontine is defined as "conducting or proceeding from the cerebellum to the pons." *Dorland's* 332.

[9] The cerebellum is "the part of the metencephalon that occupies the posterior cranial fossa behind the brainstem and is concerned in the coordination of movements." *Dorland's* 332.

[10] Ganglion is defined as "a knot or knotlike mass[;] anatomical terminology for a group of nerve cell bodies located outside the ventral nervous system; occasionally applied to certain nuclear groups within the brain." *Dorland's* 757.

[11] Corpus callosum is defined as "an arched mass of white matter, found in the depths of the longitudinal fissure, composed of three layers of fibers, the central layer consisting primarily of transverse fibers connecting the cerebral hemispheres." *Dorland's* 417.

[12] White matter, or substantia alba, is defined as "white substance; the white nervous tissue, constituting the conducting portion of the brain and spinal cord; it is composed mostly of myelinated nerve fibers arranged in anterior, posterior, and lateral funiculi in the spinal cord and in a number of named fasciculi in the brain." *Dorland's* 1793.

[13] Multiple sclerosis is

> a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years.

Dorland's 1680.

[14] Acute disseminated encephalomyelitis is

> an acute or subacute encephalomyelitis or myelitis characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination; it occurs most often after an acute viral infection, especially measles, but may occur without a recognizable antecedent. It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Symptoms include fever, headache, and vomiting; sometimes tremor, seizures, and paralysis; and lethargy progressing to coma that can be fatal.

Dorland's 613.

[15] Vasculitis is defined as "inflammation of a blood or lymph vessel." *Dorland's* 2026.

had potentially experienced an attack of MS that should be treated with Solu-Medrol[16] and physical therapy for her ambulatory problems, while petitioner awaited a more comprehensive workup.

Petitioner was discharged on August 13, 2012, after it was determined that steroid treatment was helping with her symptoms. At discharge, her working diagnosis was MS, but lumbar puncture had established that she was negative for oligoclonal bands,[17] and results from the tests that would reveal levels of myelin[18] basic protein antibodies were still pending. On August 17, 2012, Mrs. Lozano had a follow up appointment with Dr. Timothy Sheehy, who determined that a second opinion was necessary to ensure that petitioner's diagnosis was correct.

On August 27, 2012, Mrs. Lozano returned to the CMH 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 that same day, but CMH instructed her to follow up with her primary care physician for a second spinal MRI. That MRI was performed on August 28, 2012, and showed "[p]atchy areas of altered signal intensity within the thoracic spinal cord . . . worrisome for foci of demyelination."[19]

Petitioner sought a second opinion on September 9, 2012, from Dr. Barbara Giesser, a neurologist at the University of California Los Angeles Neurology Outpatient Clinic. At that appointment, Dr. Giesser noted that Mrs. Lozano's current symptoms included the following:

> [N]umbness bilaterally from her chest down to her lower torso, left arm numbness and paresthesias,[20] right arm weakness and paresthesias, right leg weakness, and burning around her left waist. She states that her cognition has declined and that she is thinking slower and forgetting objects, and having short term memory issues.

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16 Solu-Medrol is the "trademark for a preparation of methylprednisolone sodium succinate." *Dorland's* 1731.

17 Oligoclonal bands are defined as "discrete bands of immunoglobulins with decreased electrophoretic mobility; their appearance in electrophoretograms of cerebrospinal fluid when absent in the serum is a sign of possible multiple sclerosis or other diseases of the central nervous system." *Dorland's* 197.

18 Myelin is defined as "the substance of the cell membrane of Schwann cells that coils to form the myelin sheath . . . ; it has a high proportion of lipid to protein and serves as an electrical insulator." *Dorland's* 1218.

19 Demyelination is defined as "destruction, removal, or loss of the myelin sheath of a nerve or nerves." *Dorland's* 486.

20 Paresthesia is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." *Dorland's* 1383.

Dr. Giesser's differential diagnosis included post-viral encephalitis/myelitis,[21] [22] with a working diagnosis of "Clinically Isolated Syndrome," and she prescribed several medications to help improve petitioner's ongoing symptoms.

Throughout the fall of 2012, petitioner continued to experience the burning sensation from her back to her chest with decreased memory, cognition, and depression. On February 13, 2013, a repeat MRI showed dramatic improvement, suggesting that ADEM was a more likely etiology, which was confirmed through later serological[23] findings. Since the winter of 2013, doctors have continued to opine that ADEM is the most likely explanation for petitioner's symptoms. As such, she continues to seek treatment for the same, given that she has persistent lingering neurological and physical impairments that keep her on disability, despite normal MRI results. None of the medical records indicate that any of petitioner's treatment providers doubt her diagnosis. Additionally, Mrs. Lozano never experienced a second set of neurologic symptoms that could reflect a flare-up of symptoms that might suggest that MS was the actual explanation for her condition.

Petitioner filed her Petition with the Office of Special Masters on April 13, 2014. *See generally* Petition. On November 16, 2015 and June 13, 2016, petitioner filed the expert report of Dr. Norman Latov, M.D., Ph.D.[24] On March 29, 2016, respondent filed the medical report of Dr. Thomas Leist, M.D., Ph.D.[25] An entitlement hearing was held on June 24, 2017, and Special

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[21] Encephalitis is "inflammation of the brain." *Dorland's* 612.

[22] Myelitis is "inflammation of the spinal cord, often part of a more specifically defined disease process." *Dorland's* 1218.

[23] Serology is defined as

> the study of the in vitro reactions of immune sera . . . [t]he term is now used to refer to the use of such reactions to measure serum antibody titers in infectious disease (serologic tests), to the clinical correlations of the antibody titer (the 'serology' of a disease), and to the use of serologic reactions to detect antigens.

Dorland's 1698.

[24] Dr. Latov attended the University of Pennsylvania for both his medical and doctorate degrees. Pet.'s Ex. 22; Transcript of Proceedings (hereinafter "Tr.") at 5. He completed his residency in neurology and immunology at Columbia University before joining their faculty. *Id.* He is now on the faculty at Weill Cornell Medicine, where he directs a peripheral neuropathy center, serves as a professor of neurology and neuroscience, and is an attending neurologist. *Id.* He has previously conducted research in the area of autoimmune neurological diseases. *Id.* at 6. He estimates that about thirty percent of his time is spent seeing patients, while the rest is dedicated to administrative tasks, teaching, and research. *Id.* He commonly treats patients with peripheral neuropathies, but only has occasional experience with ADEM. *Id.* at 7–8.

[25] Dr. Leist attended the University of Zurich, where he obtained his Ph.D. in immunology and biochemistry as well as a post-doctorate degree in experimental pathologies. Tr. at 53; Resp.'s Ex. B. He also completed a post-doctorate at the University of California, Los Angeles

Master Corcoran granted petitioner's claim on August 4, 2017, finding that petitioner carried her burden establishing causation. Decision of the Special Master (hereinafter "Dec.") at 1. Respondent filed its Motion for Review on December 21, 2018. *See generally* Motion for Review (hereinafter "MFR"). Petitioner filed its Response to respondent's Motion for Review on January 22, 2019. *See generally* Response to Respondent's Motion for Review (hereinafter "Resp."). Petitioner's Motion is fully briefed and ripe for review.

II. STANDARD OF REVIEW

Under the Vaccine Act, this Court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). In that instance, the Court may: "(A) uphold the findings of fact and conclusions of law. . . , (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or, (C) remand the petition to the Special Master for further action in accordance with the court's direction." *Id*. at § 300aa-12(e)(2)(A)–(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

This Court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." *Snyder ex rel. Snyder v. Sec'y of Dep't of Health & Human Servs.*, 88 Fed. Cl. 706, 718 (2009). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Id.* Under this standard, a special master's decision "must articulate a rational connection between the facts found and the choice made." *Cucuras v. Sec'y of Dep't of Health & Human Servs.*, 26 Cl. Ct. 537, 541–42 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). This standard is "highly deferential." *Hines v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). "If 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." *Id.*

III. DISCUSSION

Althen v. Secretary of Health & Human Services provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. *See generally Althen*

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and attended medical school at the University of Miami. *Id.* He completed a residency in neurology at Cornell University before becoming a fellow at the National Institute of Health. Tr. at 54. Dr. Leist is board certified in neurology and currently serves as a professor of neurology at Thomas Jefferson University in Philadelphia, Pennsylvania, as well as directing the MS center and guiding the MS or neuro-immunology fellowship program. *Id.* at 53. He sees approximately 2,700 patients diagnosed with MS, as well as seeing patients in tertiary care hospitals affiliated with Thomas Jefferson University Hospital. *Id.* at 57.

v. Sec'y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, a petitioner must

> show by preponderant evidence that the vaccination brought about [petitioner's] 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.

Id. at 1278. In order to succeed, petitioners must provide a "reputable medical or scientific explanation" for their claim. *Id*.

Within this framework, respondent makes two numbered objections to the August 4, 2017 decision. *See* MFR at 10, 13. First, respondent asserts 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. *Id.* at 10. Second, respondent argues that, by finding petitioner entitled to compensation despite her lack of evidence under *Althen* prong two, the Special Master created a de facto Table claim, threatening the integrity of the Vaccine Program. *Id.* at 13.

A. *Althen* Prong Two

In its Motion for Review, respondent argues that the Special Master failed to require evidence of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. MFR at 10. In making this argument, respondent contends that "the Special Master addressed the three prongs of *Althen* before determining which injury petitioner experienced." *Id.* at 11. Specifically, respondent alleges that "[i]t was not until the Special Master turned to prong two of the *Althen* test that he addressed the nature of petitioner's injury." *Id.* (citing Dec. at 16–18).

In support of its proposition that the Special Master misapplied *Althen*, respondent looks to a handful of vaccine cases from the Court of Appeals for the Federal Circuit. Respondent cites to *Lombardi v. Secretary of Health and Human Services*, which states that when "the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." 656 F.3d 1343, 1352 (Fed. Cir. 2011) (citation omitted). *Lombardi* further states that "identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation." *Id.* Respondent also cites to *Moberly v. Secretary of Health and Human Services*, which respondent interprets as standing for the proposition that evidence merely showing a temporal connection between vaccination and injury and absence of another identified cause of the injury is insufficient to demonstrate entitlement to compensation. MFR at 12 (citing *Moberly v. Sec'y of Health and Human Servs.*, 592 F.3d 1315 (Fed. Cir. 2010), *reh'g denied*, (Fed. Cir. Apr. 13, 2010)).

In response, petitioner argues that "there is no strict criteria that must be met, or established factors that must be presented, by petitioner to establish a logical sequence of cause and effect between vaccination and injury." Resp. at 13. In making this argument, petitioner cites to two of the Federal Circuit's more seminal cases: *Althen v. Secretary of Health and Human Services* and *Capizzano v. Secretary of Health and Human Services*. *See generally Althen*, 418 F.3d 1274; *see also generally Capizzano v. Sec'y of Health and Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006). Petitioner first looks to *Althen*, which states that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof [as to] how vaccines affect the human body." 418 F.3d at 1280. Petitioner also highlights the Federal Circuit's holding in *Capizzano*, in which the Court explicitly refused to establish strict criteria requiring petitioners to prove a logical sequence of cause and effect, instead holding that petitioners cannot be required to provide scientific evidence. 440 F.3d at 1325.

In addition to citing Federal Circuit precedent, petitioner also looks to the decision of the Special Master in the case at bar, arguing that the Special Master properly engaged in an *Althen* analysis. As the petitioner points out, Special Master Corcoran "considered lab testing, imaging findings[,] and [the] treating neurologist's records as consistently supportive of a diagnosis of ADEM." Resp. at 15. Specifically, the Special Master found that "[p]etitioner has persuasively established that the record evidence best supports the ADEM diagnosis." Dec. at 16. The Special Master then went on to weigh the evidence that supported a diagnosis other than ADEM against the findings of Mrs. Lozano's treatment providers, ultimately concluding that the evidentiary record supports a finding that petitioner "established a logical sequence of cause and effect from vaccine to injury." *Id.* at 18.

It appears to this Court that, while the Special Master may have employed a nontraditional model in outlining his findings, the simple fact that he did not explicitly identify ADEM as the apparent proper diagnosis until analyzing the second prong of *Althen* is not enough for this Court to overturn his decision. Upon a careful review of the decision and the evidentiary record as a whole, the Court finds that the Special Master's decision did not violate the bounds of his discretion, and, as such, his findings under *Althen* prong two were neither arbitrary nor capricious.

B. De Facto Table Claim

Respondent further argues that because the Special Master misapplied *Althen*, he created a de facto Table claim, thereby threatening the integrity of the Vaccine Program. While this Court agrees that the decision's approach does not follow the traditional prong one, prong two, then prong three *Althen* analysis, the ultimate ruling appears to be correct and the Court does not believe the Special Master erred as a matter of law. The Office of Special Masters is overworked and understaffed, and this Court is consistently impressed with the Special Masters' ability to meet deadlines and issue quality opinions. Furthermore, the Special Masters' resilience in the face of innumerable pressures is remarkable. As the Court remains unpersuaded by respondent's argument regarding the Special Master's causation analysis, the Court does not believe a de facto

Table claim was created or that a single adequate opinion has put the integrity of the Vaccine Program at risk.

IV. CONCLUSION

This Court finds that the Special Master's decision was neither an abuse of discretion nor contrary to law, and his findings were neither arbitrary nor capricious. For the foregoing reasons, the Court **DENIES** respondent's Motion for Review.[26]

IT IS SO ORDERED.

s/ *Loren A. Smith*
Loren A. Smith,
Senior Judge

[26] This opinion shall be unsealed, as issued, after June 5, 2019, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.