United States Court of Federal Claims

No. 12-254V
Filed under seal: December 20, 2018
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MARK MILES, *Legal Representative of a Minor Child J.M.*, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	Vaccine Case; Motion for Review; Influenza Vaccine; *Althen*; *Loving*; Burden of Proof; Causation

OPINION

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SMITH, Senior Judge:

Petitioner, Mark Miles, on behalf of and as the legal representative of a minor child, J.M., seeks review of a decision issued by Special Master Laura D. Millman denying his petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 to -34 (2012), alleging that the influenza ("flu") vaccine administered to his son, J.M. on October 1, 2009, caused J.M. to have a second relapse of his preexisting nephrotic syndrome. The Special Master denied compensation, finding that petitioner failed to provide a persuasive scientific or medical theory proving that the flu vaccine caused J.M.'s second relapse of minimal change nephrotic syndrome. *Miles v. Sec'y of Health & Human Servs.*, 2019 WL 3990987 (Fed. Cl. Spec. Mstr. June 28, 2018) (*Miles*). Petitioner now moves for review of this decision. For the reasons that follow, the Court **DENIES** his motion.

[1] An unredacted version of this opinion was issued under seal on December 20, 2018. The parties were given an opportunity to propose redactions, but no such proposals were made.

I. BACKGROUND

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

A. Pre-Vaccination Records

J.M. was born on February 23, 2001, and he has an extensive medical history. On April 19, 2001, when J.M. was two months old, his mother took him to Willow Bend Pediatrics to be treated for head congestion, sneezing, and loss of appetite. On April 24, 2001, J.M. received his first DTaP, Hib, hepatitis B, and IVP vaccines. On June 12, 2001, J.M. was diagnosed with bronchiolitis[3] by Dr. Michael J. Frank at Willow Bend Pediatrics. On July 2, 2001, J.M. received his second DTaP, Hib, hepatitis B, and IVP vaccines. On February 9, 2002, J.M. was diagnosed with bilateral otitis media[4] and bronchitis[5] by Dr. Frank at Willow Bend Pediatric. On March 26, 2002, J.M. was treated for cough and congestion by Dr. Kimberly F. Mehendale at Willow Bend Pediatrics, at which time he was diagnosed with an upper respiratory infection ("URI"). On April 16, 2002, J.M. received his Varivax[6] and Prevnar[7] vaccinations. On May 24, 2002, J.M. received his third DTaP, Hib, hepatitis B, and IVP vaccines. When J.M. was two years old, he was again diagnosed with a URI at Willow Bend Pediatrics. On December 24, 2004, when J.M. was three years old, he was treated by Dr. Mehendale at Willow Bend Pediatrics for a yellow runny nose, green rhinorrhea,[8] and congestion. On July 12, 2005, when J.M. was four years old, Dr. Frank treated him at Willow Bend Pediatrics for a urinary tract infection and a spastic bladder. On August 8, 2005, J.M. received a DTaP, IPV, MMR, and second hepatitis A vaccine. On November 20, 2006, J.M. received the FluMist[9] vaccine. None of these illnesses or vaccines triggered his minimal change nephrotic syndrome.[10]

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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 *Miles*.

[3] Bronchiolitis is defined as "inflammation of the bronchioles, usually occurring in children less than 2 years old and resulting from a viral infection, particularly with respiratory syncytial virus." *Dorland's Illustrated Medical Dictionary* 252 (32nd ed. 2012) (hereinafter "*Dorland's*").

[4] Otitis media is defined as "inflammation of the middle ear." *Dorland's* at 1351.

[5] Bronchitis is defined as "inflammation of a bronchus or bronchi; there are both acute and chronic varieties. Symptoms usually include fever, coughing, and expectoration." *Dorland's* at 252.

[6] Varivax is the "trademark for a preparation of varicella virus vaccine live." *Dorland's* at 2025.

[7] Prevnar is the "trademark for a preparation of pneumococcal 7-valent conjugate vaccine." *Dorland's* at 1514.

[8] Rhinorrhea is defined as "the free discharge of a thin nasal mucus." *Dorland's* at 1640.

[9] FluMist is the "trademark for a preparation of influenza vaccine for intranasal administration." *Dorland's* at 720.

[10] Minimal change is defined as

On September 6, 2007, J.M. went to Children's Medical Center in Dallas, Texas, where his medical history indicates he had a new onset of edema,[11] proteinuria,[12] elevated creatinine,[13] and hypoalbuminemia.[14] The findings on J.M.'s renal ultrasound[15] were consistent with those seen in nephrotic syndrome, including large kidneys with increased echogenicity.[16] J.M. had acute renal injury with serum creatinine concentrations of 0.8 to 1.6 mg/dl (normal being 0.3 to 0.7 mg/dl). He was started on prednisone,[17] which he continued to take until February 4, 2008. On October 11, 2007, Dr. Mouin G. Seikaly, J.M.'s first pediatric nephrologist, noted J.M. had new-onset nephrotic syndrome with proteinuria. On November 2, 2007, J.M. continued to show signs of proteinuria, despite his regimen of 40 mg of prednisone every other day. Dr. Seikaly was concerned that J.M. might relapse once his prednisone was reduced. Dr. Seikaly

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> subtle alterations in kidney function demonstrable by clinical albuminuria and the presence of lipid droplets in cells of the proximal tubules; abnormalities of foot processes of the glomerular epithelial cells are present but too subtle to be seen with light microscopy. It is seen primarily in children under age 6 but sometimes in adults with the nephrotic syndrome, and it may or may not progress to glomerulosclerosis or glomerulonephritis.

Dorland's at 539. Nephrotic syndrome is defined as the "general name for any of a large group of diseases involving defective renal glomeruli, characterized by massive proteinuria and lipiduria with varying degrees of edema, hypoalbuminemia, and hyperlipidemia." *Dorland's* at 1840.

[11] Edema is defined as "the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues." *Dorland's* at 593.

[12] Proteinuria is defined as "excessive serum proteins in the urine, such as in renal disease, after strenuous exercise, and with dehydration." *Dorland's* at 1535.

[13] Creatinine is defined as "the cyclic anhydride of creatine, produced as the final product of decomposition of phosphocreatine. It is excreted in the urine; measurements of excretion rates are used as diagnostic indicators of kidney function and muscle mass and can be used to simplify other clinical assays." *Dorland's* at 429.

[14] Hypoalbuminemia is defined as "an abnormally low albumin content of the blood." *Dorland's* at 899.

[15] Ultrasonography is defined as "the visualization of deep structures of the body by recording the reflections of pulses of ultrasonic waves directed into the tissues." *Dorland's* at 1999.

[16] Echogenicity is defined as "in ultrasound, the extent to which a structure gives rise to reflections of ultrasound waves." *Dorland's* at 589.

[17] Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Dorland's* at 1509.

recommended starting J.M. on Tacrolimus[18] and CellCept[19] therapy, as he believed J.M. would benefit from starting CellCept if he did not tolerate tapering of prednisone.

On December 19, 2007, J.M. was in remission and his steroid was slowly tapered. By February 6, 2008, J.M. was in full remission and completely tapered off prednisone. On March 26, 2008, J.M. was still in remission and off prednisone, but he was taking Norvasc,[20] 5 mg twice daily. Around that time, his Norvasc was reduced, and J.M. was started on Cozaar.[21] On July 28, 2008, J.M. received his second Varivax vaccination. On November 19, 2008, J.M. received a flu vaccine. Neither of these vaccines triggered a relapse of his nephrotic syndrome.

On June 15, 2009, Becky Nolde-Hurlbert, Dr. Seikaly's nurse practitioner, noted that J.M. had had proteinuria since June 10, 2009, swelling in his face and abdomen, and elevated blood pressure. J.M. did not report any illness that could have triggered his first relapse of his nephrotic syndrome. On June 22, 2009, J.M.'s parents reported to Willow Bend Pediatrics that J.M. had a relapse of his nephrotic syndrome and was back on high-dose steroids. By June 29, 2009, J.M. was back in remission while taking another course of prednisone. J.M. was weaned off prednisone by September 7, 2009.

B. Post-Vaccination Records

On October 1, 2009, J.M. received a flu vaccine. On October 9, 2009, J.M. saw Dr. Seikaly, who noted J.M. had done well since his last visit in August 2009 until the past two weeks when he had an increase in his urine protein and developed edema. According to the timeline of J.M.'s medical records, the relapse must have occurred prior to his October 1, 2009 flu vaccination. J.M. reported vomiting several times on October 13, 2009. He was hungry but unable to tolerate fluid or food. He did not have fever and had normal stools. On November 4, 2009, J.M.'s urine protein stayed mildly elevated. He was again prescribed prednisone and weaned slowly. When J.M. was weaned to 10 mg of prednisone every 48 hours in December 2009, J.M. had his third relapse.

On February 24, 2010, RN Nolde-Hurlbert noted that "anything that affects the immune system [] could be a contributing factor [to relapse]," but that "no cause and effect relationship [between the flu vaccine and nephrotic syndrome relapse] has been directly documented in the literature[;] there is only speculation." J.M. had a fourth relapse in March of 2010 and his fifth relapse in May of 2010.

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[18] Tacrolimus is defined as "a macrolide immunosuppressant of the calcineurin inhibitor group derived from *Streptomyces tsukubaensis* and having actions similar to those of cyclosporine." *Dorland's* at 1868.

[19] CellCept is the "trademark for preparations of mycophenolate mofetil." *Dorland's* at 325.

[20] Norvasc is the "trademark for a preparation of amlodipine besylate." *Dorland's* at 1291.

[21] Cozaar is the "trademark for a preparation of losartan potassium." *Dorland's* at 427.

J.M. saw his second pediatric nephrologist, Dr. Albert Quan, on May 13, 2010. Shortly thereafter, a renal biopsy was performed, which showed no evidence of focal segmental glomerulosclerosis[22] ("FSGS"). J.M. had one Globally sclerosed glomerulus[23] out of 25 glomeruli. Ultrastructural studies showed thin glomerular basement membranes.

On January 28, 2011, Dr. Quan noted that J.M. had not had a relapse since his last office visit, and J.M. was weaned off Prograf.[24] Dr. Quan prescribed Prograf on June 25, 2011. Dr. Quan also noted that J.M.'s October 2009 flu vaccination "may have triggered the onset of his nephrotic relapse." J.M.'s nephrotic syndrome relapsed by the end of July 2011, but he could not resume prednisone because his nephrotic syndrome was no longer responsive to prednisone.

On August 18, 2011, J.M. had a cardiovascular attack[25] ("CVA"), and he was admitted to Medical City Dallas hospital. He suffered three strokes, which resulted in complete paralysis on his left side. He also had a syncopal episode[26] while he was hospitalized and was treated with anti-epileptic medications. He received inpatient and rehabilitation services until September 23, 2011. Dr. Quan noted that J.M.'s CVA was secondary to his July 2011 nephrotic relapse.

In October 2011, J.M.'s hematologist noted that he had made a remarkable post-stroke recovery, and recommended anticoagulation therapy[27] for six months. At the same time, J.M.'s neurologist noted that he could communicate verbally with normal speech and ambulate

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[22] Focal segmental glomerulosclerosis is defined as

> the occurrence of focal sclerosing lesions of the renal glomeruli, marked by proteinuria, hematuria, hypertension, and the nephrotic syndrome; it may be idiopathic or secondary to another disease, such as heroin-abuse nephropathy, chronic interstitial nephritis, or a malignancy. Exacerbations and remissions may occur, most often in children; progression to renal failure occurs at a variable and unpredictable rate.

Dorland's at 787.

[23] Glomerulus is defined as "a tuft or cluster, used in anatomic nomenclature as a general term to designate such a structure, as one composed of blood vessels or nerve fibers." *Dorland's* at 787. Sclerosis is defined as "an induration or hardening, such as hardening of a part from inflammation, increased formation of connective tissue, or disease of the interstitial substance." *Dorland's* at 1680.

[24] Prograf is the "trademark for preparation of tacrolimus administered orally or intravenously." *Dorland's* at 1523.

[25] Cardiovascular is defined as "pertaining to the heart and blood vessels." *Dorland's* at 295.

[26] Syncope is defined as "a temporary suspension of consciousness due to generalized cerebral ischemia; called also *faint*." *Dorland's* at 1818.

[27] Anticoagulation therapy is defined as "the prevention of coagulation." *Dorland's* at 103. Coagulation is defined as the "formation of a clot." *Dorland's* at 376.

independently, but that he had residual left-sided weakness and concerns about mental processing speed. J.M. also had improving but residual left hemiparesis.[28] J.M. continued on anti-epileptics.

As of March 2012, J.M.'s neurologist recorded that J.M. was off steroids and continued taking anti-epileptic medicine. Dr. Quan noted that J.M. was receiving Prograf, which would help prevent future strokes. Based on a neuropsychological evaluation performed in June 2012, J.M. continued to have cognitive deficits secondary to his CVAs.

On October 20, 2015, J.M. saw Dr. Kazi Majeed, a pediatric neurologist. J.M. had residual spastic hemiparesis. J.M. had a right cerebral infarct[29] in August 2011. Tiny infarcts were also seen in his left hemisphere. Testing for hypercoagulability[30] showed factor V Leiden mutation.[31]

C. Procedural History

Petitioner filed his Petition on behalf of J.M. with the Office of Special Masters on April 18, 2012. *See generally* Petition. On June 30, 2012, petitioner filed the expert report of pediatric nephrologist, Dr. Albert H. Quan.[32] On June 18, 2013, respondent filed the medical report of

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[28] Hemiparesis is defined as "muscular weakness or partial paralysis affecting one side of the body." *Dorland's* at 837.

[29] Cerebral infarction is defined as "an ischemic condition of the brain, producing local tissue death and usually a persistent focal neurological deficit in the area of the distribution of one of the cerebral arteries." *Dorland's* at 934.

[30] Hypercoagulability is defined as "the state of being more readily coagulated than normal." *Dorland's* at 888.

[31] Factor V is defined as

> proaccelerin: a heat- and storage-labile material, present in plasma but not in serum, functioning in both the intrinsic and extrinsic pathways of coagulation, catalyzing the cleavage of prothrombin to the active thrombin. Deficiency of this factor, an autosomal recessive trait, leads to a rare hemorrhagic tendency called parahemophilia, with varying degrees of severity.

Dorland's at 674.

[32] Dr. Quan has been board-certified in pediatric nephrology since 1993. Pl.'s Ex. 7, at 1. He is licensed to practice in Texas. He was an Associate Professor of Pediatrics at the University of Texas Southwestern Medical Center from 1993–2006. At the time of the expert report submission, he was the Medical Director of Pediatric Nephrology and Pediatric Renal Transplantation at Medical City Children's Hospital and the Medical Director of Pediatric Dialysis at Home Kidney Care. He became J.M.'s treating nephrologist in May 2010. He reviewed J.M.'s medical records and medical literature regarding nephrotic syndrome and vaccinations.

pediatric nephrologist, Dr. Barnard S. Kaplan.[33] Respondent filed the expert report of immunologist, Dr. Arnold I. Levinson, on October 28, 2013.[34] On June 3, 2014, petitioner filed the expert report of immunologist, Dr. Joseph A. Bellanti.[35] Dr. Kaplan submitted supplemental expert reports on July 17, 2014 and September 21, 2015. On August 12, 2014, Dr. Levinson submitted a supplemental expert report. Dr. Bellanti submitted a supplemental expert report on October 10, 2014. Dr. Quan's expert report was filed on January 2, 2015. An entitlement hearing was held on October 17 and 18, 2017, and Special Master Millman denied petitioner's claim on June 28, 2018, finding that petitioner failed to provide a persuasive scientific or medical theory proving that the flu vaccine caused J.M.'s second relapse of minimal change nephrotic syndrome. Decision of the Special Master (hereinafter "Dec.") at 62. Petitioner filed his Motion for Review on July 30, 2018. *See generally* Motion for Review (hereinafter "MFR"). Respondent filed its Response to petitioner's Motion for Review on August 28, 2018. *See generally* Response to Motion for Review (hereinafter "Resp. to MFR"). Petitioner's Motion is fully briefed and ripe for review.

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[33] Dr. Kaplan was the chief of Pediatric Nephrology at the Children's Hospital of Philadelphia ("CHOP") until he resigned in 2010. Resp't's Ex. A. He continues to work in the Division of Nephrology three days a week, seeing old and new patients. He is also Professor of Pediatrics and Medicine at the University of Pennsylvania, Perelman School of Medicine. He is board-certified in pediatrics and pediatric nephrology. He has been practicing pediatric nephrology for 35 years. He has studied and published papers and chapters on nephrotic syndrome and co-edited a textbook in which nephrotic syndrome and immunization of children with renal disease is discussed extensively. He has taught these subjects to medical students, interns, residents, and renal fellows at CHOP.

[34] Dr. Levinson is board-certified in internal medicine and allergy and clinical immunology. Resp't's Ex. D, at 1. He is Emeritus Professor of Medicine and Neurology at the University of Pennsylvania, Perelman School of Medicine. Resp't's Ex. E, at 2. He used to be Chief of the Allergy and Immunology Section, Director of the Fellowship Training Program in Allergy and Immunology, and Director of the Center or Clinical Immunology. He currently serves as Associate Dean for Research. He was author or co-author of 11 articles and 42 editorials, chapters, and invited journal reviews.

[35] Dr. Bellanti is Director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University School of Medicine and Professor of Pediatrics and Microbiology-Immunology at the same institution. Pl.'s Ex. 23, at 1. He lists 269 articles dating from 1961–2013, 200 abstracts dating from 1962–2008, and 59 books or chapters in books dating from 1971–2012. Of his 269 articles, Dr. Bellanti was co-author on just four articles having to do with the kidney; only one of those four concerned minimal change nephrotic syndrome, and it was published in 1981. Of his 200 abstracts, only one concerned the kidney. None of his books or chapters concerned the kidneys.

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 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*. *Loving v. Secretary of Health and Human Services* provides the

"correct framework for evaluating off-table significant aggravation claims." *W.C. v. Sec'y of Health and Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec'y of Health and Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009)). The *Loving* test is comprised of the following six parts:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to the vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

Within this framework, petitioner makes five numbered objections to the June 28, 2018 decision. *See* MFR at 3–5. First, petitioner asserts that the Special Master rejected the well-supported and generally-recognized theory that nephrotic syndrome is caused by an adverse immune reaction, significantly raising petitioner's burden of proof in violation of limitations set by *Althen*. *Id.* at 3. Second, petitioner argues that the Special Master further rejected the petitioner's plausible theory of causation by adopting an idiopathic or unknown cause for the injury in violation of 42 U.S.C. § 300aa-13(a)(2)(A). *Id.* at 3–4. Third, petitioner argues that the Special Master rejected the well-accepted theory of causation based upon the credibility of the treating physician which was arbitrary and capricious, as well as in violation of the instructions in *Andreu ex rel. Andreu v. Sec'y of Health and Human Servs*. *Id.* at 4 (citing *Andreu*, 569 F.3d 1367, 1375 (Fed Cir. 2009)). Fourth, petitioner contends that the Special Master arbitrarily and capriciously misconstrued petitioner's claim to be that the vaccine injury took place on the first through the second of October 2009, when petitioner actually claimed that the injury was the exacerbation of the syndrome from steroid-sensitive to steroid-dependent following the vaccine, an aggravation that was not discovered until December of 2009, well within the three-day to eight-week period consistent with an immune reaction. *Id.* at 4. Finally, petitioner alleges that the Special Master arbitrarily and capriciously ignored the testimony of all the experts in finding that the vaccine did not cause J.M.'s strokes. *Id.* at 5.

A. Burden of Proof

In his Motion for Review, petitioner alleges that "by rejecting a well[-]accepted theory of causation based upon inconclusive new research, the Special Master impermissibly increased the petitioner's burden of proof." MFR at 34. In making this assertion, petitioner posits that he has satisfied the three-prong test set forth in *Althen*, and is, therefore, "entitled to recover unless the respondent shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Id*. at 35 (quoting *Knudsen v. Sec'y of Health and Human*

Servs., 35 F.3d 543, 547 (Fed. Cir. 1994)). Petitioner goes on to argue that "those factors cannot include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." *Id.* (citing 42 U.S.C. § 300aa-13(a)(2)(a)).

In her decision, Special Master Millman accurately articulates petitioner's burden of proof in vaccine compensation cases. A petitioner must provide a persuasive medical theory. "A persuasive medical theory is demonstrated by 'proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" Dec. at 57 (citing *Althen*, 418 F.3d at 1278 (quoting *Grant v. Sec'y of Health and Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992))). The Special Master then goes on to point out that "[w]ithout more, 'evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation.'" *Id.* (citing *Grant*, 956 F.2d at 1149). Finally, a "[m]ere temporal association is not sufficient to prove causation in fact." *Id.* (citing *Grant*, 956 F.2d at 1148).

Petitioner clearly misapplies the law in his Motion for Review. Petitioner argues that "[t]he respondent has not proven by a preponderance of any evidence that there is an alternate cause of nephrotic syndrome or how an alternate cause, if discovered, can lead to the aggravation of the nephrotic state." MFR at 37. Petitioner alone bears the burden of proving his theory of causation. "[T]he statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde v. Sec'y of Health and Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014). If the petitioner is unsuccessful in meeting this burden, that burden does not then shift to the respondent to prove an alternative persuasive medical theory for the petitioner's injury. *Bradley v. Sec'y of Health and Human Servs.*, 991 F.2d 1507, 1575 (Fed. Cir. 1993); *see also Doe 11 v. Sec'y of Health and Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010); *Deribeaux v. Sec'y of Health and Human Servs.*, 105 Fed. Cl. 583, 587 (2012), *aff'd*, 717 F.3d 1363 (Fed. Cir. 2013). Respondent need only "offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case in chief." *De Bazan v. Sec'y of Health and Human Servs.*, 593 F.3d 1347, 1353 (Fed. Cir. 2008).

Petitioner undercuts his argument by pointing out that his theory of causation is not well documented among medical literature and remains unproven. MFR at 36. Undeterred, petitioner then attempts to shift the burden of proof to respondent by stating that "[t]he respondent has not proven by a preponderance of any evidence that there is an alternate cause of nephrotic syndrome or how an alternate cause, if discovered, can lead to the aggravation of the nephrotic state." *Id.* at 37. Here, it is again important to note that "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." *Grant*, 956 F.2d at 1149. As the burden rests solely on the petitioner to prove his medical theory, and as the Special Master reasonably determined that petitioner did not meet that burden, the Court finds that petitioner's burden was not unreasonably elevated.

B. Theory of Causation

Petitioner's second numbered objection alleges that the Special Master rejected the petitioner's plausible theory of causation by adopting an idiopathic or unknown cause for the injury in violation of 42 U.S.C. § 300aa-13(a)(2)(A). MFR at 3–4. In making this assertion, petitioner once again misapplies the law. *Althen* requires that petitioners must provide a "reputable medical or scientific explanation" for their claim." *Althen*, 418 F.3d at 1278. "The determination of whether a proffered theory of causation is 'reputable' may 'involve an assessment of the relevant scientific data.'" *Hazlehurst ex rel. Hazlehurst v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 473, 479 (2009) (quoting *Andreu*, 569 F.3d at 1379). The Special Master clearly engaged in such an analysis.

In her decision, Special Master Millman narrows down petitioner's case to the following two main issues:

> (1) is minimal change nephrotic syndrome an immune-mediated illness as the medical profession once believed or is it a podoctyopathy as the medical profession currently believes; and (2) do prior flu vaccinations create an anamnestic response so that a flu vaccination can cause a relapse of minimal change nephrotic syndrome within one day without any systemic symptoms such as fever, malaise, lethargy, arthralgia, etc.

Dec. at 58. After careful review of the record, Special Master Millman determined that "minimal change nephrotic syndrome is not immune-mediated, contrary to [petitioner's expert,] Dr. Bellanti's[,] entire presentation." *Id.* She goes on to point out that:

> Once the medical theory that flu vaccine caused an innate immune reaction followed by an adaptive immune response becomes irrelevant to the current understanding of minimal change nephrotic syndrome, the linchpin of petitioner's allegations disappears and we are left with no persuasive medical theory linking the 2009 flu vaccination to J.M.'s second relapse of minimal change nephrotic syndrome, subsequent relapses, and three cerebral arterial strokes.

Id. at 58–59. Having deemed the petitioner's medical theory unpersuasive, the Special Master need go no further. The Special Master determined that "Greenbaum's article supports Dr. Kaplan's thesis that viewing minimal change nephrotic syndrome as immune-mediated is no longer the current medical view." *Id.* at 61. It seems clear to the Court that Special Master Millman determined that the flu vaccine was not the cause of J.M.'s nephrotic syndrome relapse because the petitioner's theory of causation was unpersuasive and insufficient.

In his second numbered objection, petitioner clearly misconstrues the law. Section 300aa-13(a)(1)(B) of United States Code Title 42 requires that the *petitioner* has demonstrated by a preponderance of the evidence that it has met the requirements of 42 U.S.C. § 300aa-11(c)(1). Only once the petitioner has met that burden, does the Special Master need to

analyze whether "there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." *Id.* Section 300aa-13(a)(2)(a) of United States Code Title 42 requires that those "factors unrelated to the administration of the vaccine" not include any "idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." *Id.* However, those rules, when read together, clearly place the burden on the *petitioner* to establish his case, before the respondent is required to refute it. Once the Special Master determines that petitioner fails to meet the standard set forth in 42 U.S.C. § 300aa-11(c)(1), the analysis need go no further. Respondent is not required to disprove a theory of causation that the Special Master has already determined to be insufficient. Therefore, the Special Master did not err in finding that petitioner failed to demonstrate his theory of causation by a preponderance of the evidence.

C. Expert Credibility

In his third numbered objection, petitioner argues that the Special Master was arbitrary and capricious in finding that Dr. Quan was less credible than respondent's expert, thereby rejecting a well-founded theory of causation in favor of new research. MFR at 39. In making this argument, petitioner contends that "[r]ejection of a generally accepted theory of causation based upon credibility raises the petitioners burden of proof and is an error of law," which, petitioner believes violates the standard set forth in *Andreu*. MFR at 42.

In her decision, Special Master Millman acknowledged the following:

> The Federal Circuit in *Capizzano v. Secretary of Health and Human Services*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury."

Dec. at 59 (citing *Capizzano*, 440 F.3d at 1326; *Broekelschen v. Sec'y of Health and Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010); *Andreu*, 569 F.3d at 1375). She then goes on to state that "[t]he undersigned considers seriously the opinion of Dr. Quan, J.M.'s second pediatric nephrologist." *Id*.

In its response, respondent correctly points out that "'there is nothing in *Andreu* that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted.'" Respondent's Response to Petitioner's Motion for Review (hereinafter "Resp.") at 16 (citing *Snyder*, 88 Fed. Cl. at 745 n.67; 42 U.S.C. § 300aa-13(b)(1) (statements of treating physicians are not binding on special masters)). Respondent goes on to argue that "[a] treating physician's opinion on vaccine causation is only as strong as its underlying basis." *Id.* (citing *Perreira v. Sec'y of Health and Human Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994); *See also Dobrydnev v. Sec'y of Health and Human Servs.*, 566 Fed. Appx.

976, 982–983 (Fed. Cir. 2014) (holding that the Special Master was correct in noting that "when an expert assumes facts that are not supported by preponderance of the evidence, a finder of fact may properly reject the expert's opinion").

Special Master Millman repeatedly cited to both the expert reports and testimony of Dr. Quan, but ultimately determined that petitioner's theory of relapse was inadequate. The Special Master found that "[Dr. Quan] succinctly described the problem with understanding minimal change nephrotic syndrome in his expert report." Dec. at 59. She further found that "Dr. Quan also made some other important admissions," including that "it was impossible to say if a flu shot would make a relapse already in progress worse," and that "one does not really know if there is a natural course of minimal change nephrotic syndrome." *Id*. at 61 (citing Transcript of Proceedings (hereinafter "Tr.") at 66, 225). Ultimately, Special Master Millman found that these admissions, as well as respondent's evidence disputing the petitioner's theory of causation, tipped the scale firmly in respondent's direction.

Petitioner may not like the outcome of Special Master Millman's analysis, but "it is important to recognize that Special Masters may use their discretion in weighing expert testimony." *Cunningham v. Sec'y of Health and Human Servs.*, 2017 WL 1174448 at 5(Fed. Cl. Jan. 25, 2017). "'[R]eversible error will be extremely difficult to demonstrate' where the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" *Porter*, 663 F.3d at 1253–54 (quoting *Hines*, 940 F.2d at 1528); *see also Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d at 1343, 1353 (Fed. Cir. 2010). The Court does not believe the Special Master's decision runs afoul of this deferential standard, and, as such, her findings as to Dr. Quan's expert opinions are neither arbitrary nor capricious.

D. *Althen* and *Loving* Standards

In his fourth numbered objection, petitioner argues that the Special Master was arbitrary and capricious in finding that the onset of J.M.'s nephrotic syndrome relapse occurred too soon after administration of the flu vaccine. MFR at 4. In order to prevail under both *Althen* and *Loving*, petitioner must show by a preponderance of the evidence a proximate temporal relationship between vaccination and injury or significant aggravation. *Althen*, 418 F.3d at 1278; *see also Loving*, 86 Fed. Cl. at 144. The Court does not believe that the Special Master erred in determining that petitioner has not met the requisite burden.

Medical literature seems to support the Special Master's findings that vaccination could not trigger a relapse that began less that twenty-four hours after administration of the vaccine. The Special Master cites to a number of case studies with a causal connection between vaccine administration and nephrotic syndrome, but those case studies document relapses occurring, five

days,[36] eight days,[37] three weeks,[38] and four weeks[39] after vaccination. Moreover, Special Master Millman points to the relationship between nephrotic syndrome and proteinuria and edema. For example, the Special Master highlights the Fluss article, which posits that "nephrotic syndrome is a common renal disorder in children characterized by severe proteinuria, hypoalbuminemia, and edema." Dec. at 23 (citing Pl.'s Ex. 27[40]). She also notes the testimony of Dr. Bellanti, who stated that "[n]ephrotic syndrome refers to a group of kidney disorders involving loss of protein through the kidneys, called proteinuria, leading to low protein levels in the blood, predominantly called hypoalbuminemia, causing water to be drawn into soft tissues, called edema." *Id.* at 42 (citing Tr. at 154). J.M. had a five-pound weight gain between September 30, 2009 and October 1, 2009, and he had three plus proteins in his urine on October 2, 2009.

In determining whether a special master's finding of fact is arbitrary and capricious, this Court must look to plausibility, not to whether it is supported by a preponderance of the evidence. As long as the finding of fact is "based on evidence in the record that [is] not wholly implausible, [this Court is] compelled to uphold the finding as not being arbitrary or capricious." *Porter v. Sec'y of Health & Human Servs.*, 663F.3d 1242, 1249 (Fed. Cir. 2012) (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)). Ultimately, Special Master Millman determined the following:

> J.M.'s second relapse of minimal change nephrotic syndrome either began before he received his flu vaccination on October 1, 2009, simultaneously with the vaccination, or within 16 hours of the vaccination when petitioner measured the protein in J.M.'s urine on October 2, 2009 and it was plus 3, meaning proteinuria. Any of those three onsets is problematic for petitioner prevailing in this case.

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[36] B.D. Humphreys, et al., *Minimal-change nephrotic syndrome in a hematopoietic stem-cell transplant recipient*, 2 NATURE CLIN PRACTICE NEPHROL 9:535-39 (2006).

[37] I. Islek, et al., *Nephrotic syndrome following hepatitis B vaccination*, 14 PEDIATR NEPHROL 89–90 (2004); describing a four-year-old boy whose eyelids swelled eight days after his third hepatitis B vaccination.

[38] C-D Kao, et al., *Guillain-Barré syndrome coexisting with pericarditis or nephrotic syndrome after influenza vaccination*, 106 CLIN NEUROL NEUROSURG 136–38 (2004); describing the three-week onset of nephrotic syndrome after flu vaccination as creating suspicion of a causal relationship.

[39] C. Clajus, et al., *Minimal change nephrotic syndrome in an 82 year old patient following a tetanus-diphtheria-poliomyelitis-vaccination*, 10 BMC NEPHROL 21–25 (2009); describing an 82-year-old woman with edema occurring four weeks after the TD/Polio vaccine, typical for nephrotic syndrome.

[40] J. Fluss, et al., Cerebral sinovenous thrombosis and idiopathic nephrotic syndrome in childhood: report of four new cases and review of the literature, 165 EUR J PEDIATR 709–16 (2006).

Dec. at 60. It seems wholly plausible to this Court that the weight gain, which signaled edema, and the proteinuria began prior to and unrelated to the vaccination. As such, the Court must uphold Special Master Millman's findings as neither arbitrary nor capricious.

E. Expert Testimony

In his final numbered objection, petitioner argues that the Special Master arbitrarily and capriciously ignored the testimony of all the experts in finding that the vaccine did not cause J.M.'s strokes. MFR at 5. In making this assertion, petitioner points to "Dr. Quan's conclusion that J.M.'s strokes were caused by thrombosis resulting from his prolonged poorly controlled nephrotic state." *Id.* at 47. That conclusion alone is not enough to link J.M.'s second relapse of minimal change nephrotic syndrome to the flu vaccine.

Petitioner's argument is a bit of a misnomer. He asks the Court to determine that the Special Master erred in not finding that J.M.'s strokes were a direct result of his October 2009 flu vaccine, despite the fact that none of the experts ever attempted to find such a direct causal link. In his testimony, Dr. Quan testified that he believed that "flu vaccine led to J.M.'s new onset of his latest relapse that finally led to his stroke." Tr. at 64. Yet, petitioner's argument omits the important intermediate step between the vaccine and the strokes—nephrotic syndrome.

Special Master Millman noted Dr. Quan's testimony that "[a] poorly controlled nephrotic syndrome has a higher risk of stroke or any other type of clotting complication." Dec. at 37 (citing Tr. at 64). She also highlights the testimony of Dr. Kaplan, who could not "ascribe J.M.'s strokes to the flu vaccine or to his nephrotic syndrome." Dec. at 52 (citing Tr. at 370). Ultimately, Special Master Millman found that "the issue of J.M.'s strokes is an enigma that neither Dr. Quan nor Dr. Kaplan could explain in terms of sequelae." *Id.* at 59.

Even if the Special Master had accepted Dr. Quan's testimony and found that J.M.'s nephrotic syndrome caused his strokes, petitioner's theory still fails. The important causal link remains absent. Special Master Millman determined that "petitioner has failed to provide a persuasive scientific or medical theory proving that flu vaccine caused J.M.'s second relapse of minimal change nephrotic syndrome." Dec. at 62. Having arrived at that conclusion, it logically follows that the strokes resulting from the nephrotic syndrome relapse cannot be causally linked to that same vaccination. As such, Special Master Millman did not err in her determination that flu vaccine did not cause J.M.'s strokes.

III. CONCLUSION

The Court finds that petitioner has not met his burden of proof in alleging that his October 2009 influenza vaccine resulted in J.M.'s nephrotic syndrome relapse or significantly

worsened his nephrotic syndrome. For the foregoing reasons, the Court **DENIES** petitioner's Motion for Review.[41]

IT IS SO ORDERED.

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

[41] This opinion shall be unsealed, as issued, after January 3, 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.