

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 09-474V

Filed: May 8, 2012

BRANDON KENNEDY	)	
	)	TO BE PUBLISHED
Petitioner,	)	
v.	)	Entitlement; Acute Disseminating
	)	Encephalomyelitis; Tdap vaccine;
SECRETARY OF	)	Meningococcal vaccine
HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA for Petitioner;  
Michael P. Milmo, United States Dep't of Justice, Washington, D.C., for Respondent.

### RULING ON ENTITLEMENT<sup>1</sup>

**LORD**, Special Master.

#### I. INTRODUCTION AND SUMMARY

Petitioner Brandon Kennedy ("Petitioner") maintains that he suffered Acute Disseminating Encephalomyelitis ("ADEM"), a neurological injury, as a result of receiving the Tetanus-diphtheria-acellular pertussis ("Tdap") and meningococcal vaccinations on April 16, 2007. Petitioner sought compensation under the National Childhood Vaccine Injury Act of 1986 (the "Act"), 42 U.S.C. § 300aa-10 et seq. (2006).<sup>2</sup> The Secretary declined to compensate the claim because Petitioner was unable to rule out an infectious process as the cause of Petitioner's affliction. The case was heard in Boston, Massachusetts, on March 22, 2011, and is ready for decision.

Petitioner presented his case-in-chief by submitting expert testimony through Dr. Spencer Weig; medical literature documenting cases of post-vaccination ADEM (albeit

<sup>1</sup> In accordance with Vaccine Rule 18(b), Petitioner has 14 days to file a proper motion seeking redaction of medical or other information that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). Redactions ordered by the Special Master, if any, will appear in the document as posted on the United States Court of Federal Claims' website.

<sup>2</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

following administration of vaccines with different biological properties than those received by Petitioner); evidence that vaccines can cause ADEM by a process known as molecular mimicry; evidence from the medical records that no infectious agent ever was identified in Petitioner's case, despite extensive testing; and evidence that one of Petitioner's treating physicians, an expert neurologist at the Mayo Clinic, stated that this appeared to be a case of ADEM following vaccination.

In response, the Secretary submitted expert testimony through Dr. John T. MacDonald; medical literature showing that, in general, infection is a more likely cause of ADEM than vaccination; and evidence from Petitioner's medical records of a possible infection. Dr. MacDonald did not deny that Petitioner had presented a theory of possible vaccine causation and that, if the theory were applied, it would be logical for his injury to have occurred as it did, and in the time frame that it did. Dr. MacDonald's testimony nearly amounted to a concession that Petitioner had satisfied all three prongs of Althen v. Secretary of Department of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005).

The primary basis for Dr. MacDonald's challenge to vaccine causation was statistical data that infectious or post-infectious ADEM is much more likely than post-vaccination ADEM. It has long been settled that evidence of statistical unlikelihood does not negate causation-in-fact, however. Dr. MacDonald also expounded a standard that would require evidence of epidemiological studies and/or animal models to confirm vaccine causation. This would impose on Petitioner a much higher burden of proof than the law prescribes. It is well established that evidence in a vaccine injury case should be viewed under the preponderance standard as it is understood in civil courts, "not through the lens of the laboratorian." Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1380 (Fed. Cir. 2009).

In sum, the weight of the evidence in this case resulted in Petitioner having established his case-in-chief without the Secretary having presented any effective rebuttal. No significant legal issue was presented – what occurred at hearing was a simple failure to prove that infection was the more likely cause of Petitioner's injury than vaccination. See Lampe v. Sec'y of Dep't of Health & Human Servs., 219 F.3d 1357, 1363 (Fed. Cir. 2000) (affirming decision in which the special master "understood" the petitioners' theory but "simply rejected that theory for failure of proof").

Once Petitioner had established sufficient evidence to carry his burden of persuasion on each of the Althen factors, he had no burden to rule out causation by a biological agent as part of his case-in-chief. See Walther v. Sec'y of Dep't of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007). This is by now well established in the Vaccine Program. See Stone v. Sec'y of Dep't of Health & Human Servs., --- F.3d -- -, 2012 WL 1432525, at \*5 (Fed. Cir. Apr. 26, 2012). When Petitioner established all three of the Althen factors by preponderant evidence, the burden shifted to the Secretary to present preponderant evidence of causation by an alternative factor under

section 13(a)(1)(B). The Secretary expressly did not attempt to carry that burden at hearing and does not argue that it was satisfied.<sup>3</sup>

## **II. FACTUAL BACKGROUND**

### **A. Pertinent Medical History**

The essential facts regarding Petitioner's medical history are not in dispute.

Petitioner was a healthy 16-year-old when he received the Tdap and meningococcal vaccines on April 16, 2007. Pet'r's Ex. 9 at 1. Before that date, Petitioner participated in varsity sports at his high school and had an outstanding academic record. Pet'r's Ex. 14 at 1.

According to his mother, Petitioner experienced a headache 15 days after being vaccinated. Id. at 1.<sup>4</sup> The headache continued over the following days and Petitioner felt fatigued. Id. at 1-2. On May 6, 2007, Petitioner saw Dr. Kurt Landauer at Marshfield Urgent Care Clinic. Pet'r's Ex. 5 at 10. The doctor noted Petitioner's symptoms and that he had recently returned from a vacation in Hawaii, where he had gone scuba diving. Id. Petitioner experienced some dizziness while diving and had a slight bloody nose on the day of the dive. Id. A CT scan of Petitioner's head, without contrast, was normal. Id. He was given a prescription for Tylenol No. 3. Id.

Again according to his mother, Petitioner's headache and fatigue continued, and he began to feel nauseated and weak. He also experienced urinary retention. Pet'r's Ex. 14 at 2. On May 8, 2007, Petitioner saw a physician's assistant ("PA") named Stacy Hammes, who noted his symptoms and assessed "headache, probably sinusitis" and "bilateral otitis media." Pet'r's Ex. 12 at 6-7.

With no alleviation of his symptoms, Petitioner saw PA Hammes again on May 10, 2007. The PA noted that Petitioner continued to feel "week and somewhat shaky with lower abdominal/pelvic discomfort and bladder fullness." Id. at 4. He had been prescribed Ceftin 250 mg twice daily and was advised to increase the dose. Id. He was assessed with suspected urinary retention of unclear etiology, "headache, viral illness; rule out mono" and "mild bilateral otitis media." Id. at 5. The PA consulted a urologist, Dr. Richard Roach. When Dr. Roach saw Petitioner that afternoon, he described Petitioner as having "acute urinary retention" and catheterized him. Pet'r's Ex. 5 at 8.

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<sup>3</sup> If this were an alternative factor case, the question might arise as to whether a specific infectious agent must be identified to prove alternative causation under 42 U.S.C. §13(a)(1)(B). The Vaccine Act states that the term "factors unrelated to the vaccine" "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause . . . ." 42 U.S.C. §13(a)(2)(A). Under the circumstances here, however, where the Secretary expressly declines to rely on causation by an unrelated factor, the question of the proper interpretation of section 13(a) is not before me.

<sup>4</sup> As noted above, the medical record documents the first headache on May 1, 2007. Pet'r's Ex. 5 at 10.

The following morning, May 11, 2007, Petitioner was admitted to the Howard Young Medical Center with headache, weakness, trouble walking, and urinary retention. Pet'r's Ex. 6 at 108. The assessment noted "some type of demyelination syndrome," as well as Petitioner's recent travel to Hawaii and vaccinations. Id. at 126.

Petitioner was taken to St. Joseph's pediatric intensive care unit by helicopter. Pet'r's Ex. 7 at 22. MRIs of Petitioner's brain and spine revealed abnormalities. Id. at 17-20. His recent travel and vaccinations were noted by Dr. Vijay Aswani, id. at 21-23, who stated a probable diagnosis of encephalomyelitis of unclear etiology. "Unsure whether etiology is infectious or postinfectious." Id. at 24. The doctor listed an array of tests that would be performed on Petitioner, including a lumbar puncture, "to look for viral causes," and tests for Lyme's disease, West Nile Virus, and leptospirosis. Id. at 25.<sup>5</sup> Petitioner was started on high dose methylprednisolone to treat "what has characteristics of a transverse myelitis or a postinfective encephalomyelitis." Id. Dr. Aswani noted "diffuse changes in the white and gray matter in a patchy distribution, findings consistent with an encephalomyelitis." Id.

The treating neurologist who saw Petitioner on May 11, 2007, Dr. Rahul Kaila, noted that Petitioner's MRI was "suggestive of encephalomyelitis." Id. at 28. He documented Petitioner's symptoms, including "loss of bowel and bladder functions." Id. Dr. Kaila recommended high-dose steroids and additional tests, given the "confusing picture." Id. at 28-29.

The next day, Petitioner was examined by another neurologist, Dr. Rebecca Campbell. She noted that the symptoms "would be suggestive of transverse myelitis and would meet clinical criteria." Pet'r's Ex. 11 at 16. Dr. Campbell added, however, that Petitioner's headache and sleepiness suggested "brain involvement," and that "[t]he associated spinal cord and brain process most likely would be infectious or postinfectious in origin." Id. She recognized the possibility of acute disseminated encephalomyelitis "with both brain and spinal cord involvement." Id.

A repeat MRI on May 14, 2007, suggested that "ADEM would be a possibility." Pet'r's Ex. 7 at 39. There was a concern for immune-mediated vasculitis. Id. The impression following a repeat MRI of Petitioner's spine included idiopathic, acute transverse myelitis, but ADEM was also noted as a possibility, as was multiple sclerosis ("unlikely"). Another possibility was viral encephalomyelitis. Id. at 41.

The results of Petitioner's tests continued to be negative for infection. Id. at 501.

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<sup>5</sup> Leptospirosis is a febrile illness caused by infection with one of the types of *Leptospira interrogans*. Numerous different mammals shed the organisms in their urine, and others become infected through contact with the urine or tissue of such animals or with contaminated water, soil, or vegetations. All types of *L. interrogans* are thought to be able to cause any of the syndromes, which vary from a mild carrier state to a fatal disease. Severe forms, such as Weil syndrome, usually are characterized by jaundice. Different forms of the disease were given different names depending on factors such as clinical features, host animal, geographic distribution, occupation of infected persons, and which serovar of the bacteria was first considered causative. Dorland's Illustrated Medical Dictionary 1024 (32nd ed. 2012).

Petitioner was discharged on May 22, 2007 with a diagnosis of ADEM. Id. at 50. The discharge summary cataloged the extensive testing for infectious agents, all of which was negative. Id. at 51-52. He was sent home on a steroid taper, having suffered an exacerbation of symptoms on May 20, 2007. Id. at 54. At discharge, Petitioner was able to walk and most of his other symptoms had resolved. Id.

On the evening of May 24, 2007, however, Petitioner presented again in the ER at 11:30 p.m., with intermittent incontinence, excessive sleepiness, confusion, and garbled speech. Pet'r's Ex. 6 at 101. He was sent home in the early morning of May 25, 2007, with additional prednisone, but returned to St. Joseph's Hospital later that day with the same complaints, plus inability to walk. Pet'r's Ex. 7 at 60-62.

The neurology consult by Dr. Hema Murali on May 25, 2007, noted Petitioner's worsening symptoms and fever of 101 degrees. Id. at 63-64. He had a lumbar puncture that revealed elevated white blood cells and spinal fluid protein, id. at 74, and an MRI of the brain showing a possible increase in lesions, id. at 58.

Dr. Campbell conducted a follow-up consultation on May 31, 2007. Her assessment was relapsing ADEM "each time Methylprednisolone discontinued." Pet'r's Ex. 7 at 303. Dr. Campbell informed Petitioner's father that "we do not know an association" between vaccination and ADEM. Id.

An MRI on June 8, 2007, was interpreted as "atypical for acute disseminated encephalomyelitis." Id. at 78. It showed "new areas of cortical signal abnormality." Id. at 74. Petitioner was discharged on June 8, 2007, with diagnoses of "1. Acute disseminated encephalomyelitis. Other Diagnosis: 1. Steroids induced hypertension and resolved urinary tract infection." Id. at 76.

On June 15, 2007, Dr. Monica Koehn, a neurologist, agreed with the assessment of atypical ADEM but noted, "The exact diagnosis of Petitioner's inflammatory condition is indeterminate . . . in that there is significant cortical involvement." Pet'r's Ex. 11 at 52. The results of additional testing on that date showed "no evidence of a discrete aneurysm, vascular malformation, or intracranial stenosis of the arteries." Id. at 157.

Petitioner's condition improved during the summer of 2007, but he did not make a complete recovery. See id. at 71-75. On September 15, 2007, Petitioner was taken to the ER with an apparent relapse. Pet'r's Ex. 6 at 5-6.

He was transferred to St. Joseph's on September 17, 2007. A treating physician, Dr. Adrienne Cruz, stated, "This new onset of symptoms may be related to complications of the steroid taper, progression of the ADEM, acute illness . . . trauma with head injury at football on 9/14/2007 . . . vasculitis or metabolic problem." Pet'r's Ex. 11 at 86.

In her notes dated September 16, 2007, Dr. Campbell recorded Petitioner's recurrent symptoms and again assessed his condition as "most consistent with acute

disseminated encephalomyelitis.” Pet’r’s Ex. 7 at 92. He was discharged on September 21, 2007, with a disease process characterized as “multiphasic” ADEM. Id. at 108.<sup>6</sup>

During October and November 2007, Petitioner underwent evaluation by neurologists at the Mayo Clinic. Dr. Nancy Kuntz, a neurologist, noted that Petitioner’s test findings “were compatible with a multifocal diffuse demyelinating process” that could be ADEM or other disorders, including an autoimmune mediated vasculitis or histiocytosis syndrome. Pet’r’s Ex. 4 at 32.<sup>7</sup> She recommended decreasing the steroid dosage to alleviate some of Petitioner’s symptoms. Id.

A neurologist specializing in multiple sclerosis, Dr. Mark Keegan, suspected “central nervous system vasculitis” but not multiple sclerosis. Id. at 29-30. He noted that Petitioner had been vaccinated before his trip to Hawaii, but did not draw any conclusion from that fact. Id. at 28.

On November 30, 2007, Petitioner saw neurologist Dr. E.F. Wijdicks, who also noted the proximity in time (two weeks) of vaccination to the first episode of neurological symptoms. Id. at 24. He agreed with the most likely diagnosis of ADEM and said there was no evidence of vasculitis, although the best test for that condition had not been performed. Id. “In my opinion,” Dr. Wijdicks concluded, “the likely clinical scenario here is ADEM after a vaccination.” Id.

Petitioner continued to experience symptoms in 2008. See Pet’r’s Ex. 11 at 118-75. He suffered an apparent relapse of ADEM in June 2008. Pet’r’s Ex. 6 at 189-90. He was seen by Dr. Koehn, who noted new findings on Petitioner’s MRI. Petitioner continued to have urinary frequency and urgency (every 10 to 15 minutes), and was on chronic steroid therapy (prednisone 10 mg daily). Pet’r’s Ex. 13 at 6-10.

One year later, on July 31, 2009, “acute disseminated encephalomyelitis after meningeal [sic] vaccination” was noted in Petitioner’s past medical history. Pet’r’s Ex. 19 at 9. His urinary symptoms persisted. See Pet’r’s Ex. 17 at 3-4; Pet’r’s Ex. 18 at 16-18, 36-37. In February 2010, Petitioner again presented to the ER. Pet’r’s Ex. 23. During a neurology follow-up visit on January 17, 2011, Dr. Koehn indicated that Petitioner continued to suffer residual neurologic deficits from his chronic ADEM. Pet’r’s Ex. 28 at 14. She ordered additional testing for suspected seizures. Id. at 17-18. Petitioner presented to the ER at Hennepin County Medical Center on February 7, 2011, following a seizure. See Pet’r’s Ex. 27. Dr. Koehn linked the seizure to

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<sup>6</sup> In this context, “multiphasic” ADEM refers to ADEM characterized by “a new clinical event also meeting criteria for ADEM, but involving new anatomic areas of the CNS [central nervous system] as confirmed by history, neurologic examination, and neuroimaging.” Pet’r’s Ex. 21, Tab D at 3.

<sup>7</sup> Vasculitis is inflammation of a blood or lymph vessel. Dorland’s at 2026. Autoimmune means characterized by a specific humoral or cell-mediated immune response against constituents of the body’s own tissues (self antigens or autoantigens). Id. at 181. Histiocytosis is any of a variety of proliferative disorders of macrophages (histiocytes), marked by the abnormal appearance of macrophages in the blood, or by abnormally elevated numbers of macrophages in lymphoid tissue. Id. at 862.

Petitioner's "prior inflammation and necrosis secondary to the encephalitis." Pet'r's Ex. 28 at 19.

Neuroimaging on March 15, 2011, demonstrated "multifocal areas of residual encephalomalacia." Pet'r's Ex. 31 at 7.<sup>8</sup> Dr. Koehn recommended daily anticonvulsant medication. Id. at 9.

In Petitioner's post-hearing medical records, Petitioner reported that on January 3, 2012, he experienced a seizure at work followed by a "major seizure" upon his return home. Pet'r's Ex. 32 at 40. At his January 15, 2012 neurology appointment, Petitioner reported having "partial seizures . . . on average once a month or once every other month" and feeling depressed largely due to his chronic health issues. Id. at 44-45. During Petitioner's March 2, 2012 follow-up with neurologist Dr. Mark Rassier, Petitioner indicated that he had experienced another "partial seizure" in February 2012. Id. at 52. He also reported that his depression had "slightly improved" after discontinuing prednisone. Id. Dr. Rassier recommended anticonvulsant medication, left the remainder of Petitioner's treatment plan intact, and indicated that he would see Petitioner again in August 2012. Id. at 54.

## **B. Evidence at Hearing**

### **1. Dr. Spencer Weig**

Dr. Weig serves as a clinical professor of neurology and pediatrics at the University of North Carolina School of Medicine, an active staff member in the Department of Neurology at North Carolina Memorial Hospital, and a visiting pediatric neurologist at New Hanover Regional Medical Center. Pet'r's Ex. 22 at 2-4. He has worked continuously as a pediatric neurologist since 1987 and is board certified by the American Board of Clinical Neurophysiology, the American Board of Psychiatry and Neurology with special qualifications in child neurology, and the American Board of Pediatrics. Id. at 2-3.

Dr. Weig explained the diagnostic symptoms of ADEM. Tr. at 11-12. He set forth the clinical markers that might be observed in an individual suffering from ADEM, stating that "often, you'll see signs of inflammation with an elevation of the white blood cell count in the spinal fluid. You would also see evidence, often of an increased protein level in the spinal fluid." Tr. at 13.

Dr. Weig described the medical literature that supported his testimony regarding the clinical findings in cases of ADEM. Tr. at 13-14. He described individuals who suffer from recurrent and multiphasic ADEM, Tr. at 15, and explained how the course of Petitioner's illness fit into the criteria described in the medical literature for multiphasic

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<sup>8</sup> Encephalomalacia is the softening of the brain, especially that caused by an infarct. Dorland's at 613. An infarct is an area of coagulation necrosis in a tissue due to local ischemia resulting from obstruction of circulation to the area, most commonly by a thrombus or embolus. Id. at 934.

ADEM, Tr. at 16. Dr. Weig noted the periods of improvement followed by rapid relapse and “new lesions on his MRI.” Id.

Dr. Weig testified that Petitioner’s initial symptom of headache can be typical in cases of ADEM. Tr. at 17.

Dr. Weig reviewed several abnormalities from the test results conducted to determine Petitioner’s illness. His spinal fluid contained elevated white blood cells as well as elevated protein and myelin basic protein. Tr. at 19-20. Dr. Weig noted that the testing was negative for multiple sclerosis. Tr. at 20. “They performed multiple viral cultures on his spinal fluid. And checked in his blood multiple . . . serologies . . . to see if he had had recent infection with a number of bacteria and viruses that were all negative.” Id. The test for Devic syndrome, “which is an autoimmune disorder that affects the spinal cord,” also was negative. Tr. at 20-21. Dr. Weig testified that Petitioner’s MRIs all were consistent with the diagnosis of ADEM. Tr. at 23.

Dr. Weig reviewed Petitioner’s evaluation at the Mayo Clinic, noting that the experts there concluded that neither multiple sclerosis nor vasculitis were likely. Tr. at 26-28. He quoted Dr. Wijdicks, one of the treating physicians at the Mayo Clinic, who stated that “in my opinion, the likely clinical scenario here is ADEM after a vaccination.” Tr. at 28-29.

Dr. Weig noted the additional problems that Petitioner has experienced and the new findings in his later MRIs. Tr. at 30-32. Dr. Weig described the new symptoms as “gliosis and encephalomalacia” resulting in seizures, “from multiple known lesions related” to ADEM. Tr. at 31-32.

Dr. Weig stated that Petitioner’s vaccination caused his multiphasic ADEM. Tr. at 35. He reasoned that “immunizations are a known and recognized cause of ADEM to begin with,” the timing of Petitioner’s initial symptoms “is very appropriate” for vaccine causation, and “essentially, other causes have been ruled out.” Id.

Dr. Weig noted that “there are multiple reports of ADEM following forms of immunization that are no longer employed,” namely, smallpox and rabies immunizations. Tr. at 36. He explained the mechanism of molecular mimicry. Tr. at 36-37. The doctor referenced an article, Pet’r’s Ex. 21, Tab B, in which the concept of molecular mimicry is described as a mechanism by which an inoculation can result in ADEM. Tr. at 37-38.

On cross-examination, Dr. Weig conceded that being hot and weak can be symptomatic of a fever and that Tylenol might be used to treat an infection. Tr. at 44. He agreed that headache, nausea, malaise, and fatigue could be consistent with an infection. Tr. at 45. He also agreed that sinusitis and otitis media can be indicative of an infection. Tr. at 46. Dr. Weig indicated that Petitioner’s elevated white blood count was consistent with an infection, “[a]mong other things”. Id. He agreed that Petitioner was treated with an antibiotic, and antibiotics are used to treat infections. Id.

Dr. Weig recognized that Petitioner, early on in his illness, was noted to have red eardrums, and red eardrums can be associated with an infection. Tr. at 47. He agreed that one of Petitioner's early physician's assistants "was working under the impression of an infection." Id. Additional, similar testimony was elicited in an effort to demonstrate that Petitioner's illness was either infectious or post-infectious. Tr. at 48-50.

Very little evidence of any probative value emerged from this cross-examination. Concededly, Petitioner's treating physicians, especially early on, were working on the assumption that his ailment was infectious. Since infections are very often the cause of the types of symptoms from which Petitioner was suffering, this is merely to be expected. As Dr. Weig explained to counsel for Respondent, "[I]f we're talking about an infection of his nervous system, as opposed to whether he has some infection in his ear cavities . . . he had a very extensive evaluation. They found no evidence of a central nervous system pathogen." Tr. at 49. Dr. Weig explained further that "the fact that he [Petitioner] had multiple . . . relapses . . . in the following 12 months, would make an ongoing infection of the nervous system . . . virtually impossible." Tr. at 49-50.

Dr. Weig was forced to concede that there are "many, many" viruses that have been identified and that testing done on the cerebral spinal fluid does not test "for all thousands or hundreds of thousands or maybe even millions of viruses." Tr. at 50. Instead, Dr. Weig explained, testing is done for "common infections known or agents known to cause central nervous system infection." Id. Such testing, Dr. Weig agreed, "would not be 100 percent" probative of the absence of a viral infection. Id.

Respondent's counsel suggested that testing by an infectious disease specialist for leptospirosis, which Petitioner did not have, proved that the doctor believed Petitioner suffered from an infectious disease. Tr. at 51-52. Dr. Weig responded that "it would be totally irresponsible and improper not to search extensively for infectious agents, especially potentially treatable ones." Tr. at 52.<sup>9</sup> He explained that doctors would continue to search for infectious causes, even for years, because of the severity of Petitioner's MRI findings, and infection would "very appropriately" be in the differential diagnoses for someone with those findings. Tr. at 54. Dr. Weig agreed that a specialist in multiple sclerosis had been "unable to tell the parents whether there was a relationship between the vaccine and the disease." Id.

Dr. Weig agreed that bacteria called mycoplasma can cause ADEM. Tr. at 55.<sup>10</sup> Based on Petitioner's test results, however, he had no acute mycoplasma infection. Petitioner's results were consistent with a remote exposure to mycoplasma, which is "a relatively common" acquired infection. Tr. at 56.

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<sup>9</sup> Dr. Weig stated later in his testimony that untreated leptospirosis would be fatal. Tr. at 63-64.

<sup>10</sup> "Mycoplasma" is a genus of bacteria of the family Mycoplasmataceae made up of round, highly pleomorphic, gram-negative cells that are bounded by a single triple-layered membrane and lack a true cell wall. Dorland's at 1216.

Dr. Weig agreed that a post-infectious process can cause ADEM about two weeks past exposure. Tr. at 56-57. The same would be true of ADEM caused by immunization. Tr. at 57-58. “[T]he one thing I see from his record is that, on April 16<sup>th</sup>, he did receive immunizations. I don’t see anything in his record to state that he was ill in the weeks leading up to May 1<sup>st</sup> when he first developed symptoms.” Tr. at 58. The symptoms of nausea, malaise “and those types of things” that developed after May 1<sup>st</sup> “could be part of an infection, but, they’re also the classic presenting symptoms for ADEM.” Id.; Tr. at 67-68.

Counsel then explored with Dr. Weig various reports of ADEM in children, which indicated that a far greater number fell ill following infection than vaccination. Tr. at 59-61. Dr. Weig noted that the studies on post-vaccination ADEM were “after smallpox vaccination and after the use of a now defunct rabies virus vaccine that was grown in neural tissue.” Tr. at 62.

Dr. Weig stated that the theory of molecular mimicry could apply both to tetanus and meningococcal infection or immunization. Tr. at 65.<sup>11</sup>

On re-direct, Dr. Weig testified that “adverse effects of immunization, luckily, are very rare. . . . But, on rare occasions, there can be injury from the immunization.” Tr. at 69.

On questioning by the Court, Dr. Weig stated that science has not discovered a specific mechanism by which ADEM has been caused by a process of molecular mimicry. There is perhaps only “one possible example where we have identified a homologous epitope and a bacteria that is known to also cause a very specific neurologic disease. And it’s not ADEM.” Tr. at 71. He was comfortable opining on the molecular mimicry theory in this case nevertheless because there is at least one instance where a “very likely” association has been discovered between an unusual form of Guillain-Barre syndrome (“GBS”)<sup>12</sup> and proteins found on a particular bacterium, “where similar molecules are also found in human nervous system tissue in the brain and cerebellum.” Tr. at 71. “[T]his is a realistic way to explain the auto immunity behind ADEM.” Tr. at 71-72.

He opined that the symptoms of ADEM were recorded five or six days before Petitioner’s possible ear infection was noted in the medical records relied upon by the Secretary. Tr. at 75.

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<sup>11</sup> Dr. Weig testified that he “couldn’t make an opinion either way” when asked which of the two vaccines was implicated in Petitioner’s case. Tr. at 66.

<sup>12</sup> GBS is an autoimmune syndrome of rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. Dorland’s at 862.

## **2. Dr. John T. MacDonald**

To rebut the evidence produced by Petitioner through Dr. Weig on the three Althen prongs, the Secretary relied on the testimony of Dr. MacDonald, a pediatric neurologist at the University of Minnesota Medical School. Tr. at 77. Dr. MacDonald has been Board Certified in Psychiatry and Neurology, with special competence in child neurology, since 1980 and has authored numerous articles on pediatric neurology. Resp't's Ex. B at 3-8.

Dr. MacDonald stated that he was "uncomfortable" with the diagnosis of ADEM but testified, "I agree, with most of the treating doctors, that ADEM fits this quite well." Tr. at 79-80. He proposed small vessel vasculitis as an alternative cause, but "I think ADEM does fit this," Dr. MacDonald testified. Tr. at 81.

He conceded that Petitioner's clinical course was consistent with "either" a "preceding infectious illness, particularly viral," or immunization. Tr. at 82-83. The information that determined Dr. MacDonald's opinion of infection causation was "the overall picture," especially his questioning of the scientific studies linking vaccination to ADEM. Tr. at 83-84. "[I]n all these studies, [the] only association is temporal association." Tr. at 84. He noted that the studies relied upon by Petitioner were marred by "ascertainment bias." Id.

Dr. MacDonald was willing to accept that "you can demyelinate after a vaccine," but he rejected that idea that such an association was logical. Tr. at 85. The reason for this conclusion was that "there is no doubt that an infectious process trumps the immunization . . . at least 10 to 1 if not higher." Id. As Dr. MacDonald explained it, "So, just logically, for me to look at these two processes and look at what I know has been reported in my own experience, infection becomes so much more of a possibility than immunization." Id. He concluded, "Why would I pick the least likely and hold that to a reasonable degree of medical certainty being the cause, assuming they are both possible." Id.; Tr. at 92-93.

Dr. MacDonald noted several indications in Petitioner's medical record of a possible infectious cause: sinusitis indicating a chronic viral illness; scuba diving in Hawaii that could have exacerbated that illness; mycoplasma; "just the whole treating doctor issue that they also were considering infection as the most likely cause." Tr. at 87-88. In Dr. MacDonald's view, the fact that the treating doctors explored possible infectious causes of Petitioner's illness indicated that they did not believe vaccination was the cause. Tr. at 88-89.

He opined that the negative results of Petitioner's testing did not indicate the absence of an infectious cause, "It just means we can't identify the agent." Tr. at 89.

Dr. MacDonald testified that chronic serous otitis media is very common, and that "it could be a marker [of] an ongoing low grade infectious process, for quite some time." Tr. at 89-90 (noting that an "untold number of kids end up with ear tubes because of

their chronic disease and most of it is brought on by viruses.”). This was evidence in Petitioner’s case that “something was going on preceding this May 1<sup>st</sup> headache.” Tr. at 90.

Dr. MacDonald stated that recent evidence of epileptic activity in Petitioner’s case might indicate that “they have the wrong diagnosis.” Id. He was interested to see the results of Petitioner’s most recent test results. Id. Respondent has not offered a supplemental report from Dr. MacDonald however, from which I infer that the new evidence did not negate the diagnosis of ADEM. See Tr. at 108 (indicating if the latest MRI does not show “newer lesions,” the possibility of pediatric small vessel vasculitis “falls off the chart to a large degree”).<sup>13</sup> Dr. MacDonald affirmed later in his testimony that Petitioner’s history was not consistent with small vessel vasculitis and that “ADEM is still the number one diagnosis here.” Tr. at 110; see Tr. at 116 (admitting no diagnosis of either multiple sclerosis or vasculitis in Petitioner’s record).

The testing on Petitioner’s spinal fluid “doesn’t help us decide whether this could be a virus or an immunization . . . [either] equally could do that.” Tr. at 91.

On cross examination, Dr. MacDonald agreed with the diagnosis of “multi phasic ADEM,” Tr. at 94; with the timing of onset of injury (“if you accept” the “two week interval,” “it fits with some of the theories of molecular mimicry, auto immune disease”), Tr. at 99; with the fact that “Petitioner’s treating physicians never specifically identified or implicated a viral pathogen as the cause of his ADEM,” Tr. at 100; that Petitioner’s alleged chronic sinusitis did not show up on the MRI of his brain, notwithstanding that “they should look at them [the sinus cavities],” Tr. at 102; that “molecular mimicry is a plausible mechanism to explain how an autoimmune disorder such as ADEM can occur,” Tr. at 104;<sup>14</sup> that the fact that vaccination is less frequently reported as a cause of injury does not mean it could not be a cause in this case. Tr. at 105.

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<sup>13</sup> Dr. MacDonald was willing to ascribe Petitioner’s condition to “vasculitis or some other rare metabolic cause of demyelination,” but was unwilling to believe that it was caused by a rare instance of vaccine injury. Tr. at 90. There is no evidence in the record that rare vaccine causation is less likely than rare vasculitis or “some other rare metabolic cause.” Id. Moreover, as noted above, the statistical rarity of vaccine injuries does not negate causation in a particular case.

<sup>14</sup> The Secretary evidently objects to the use of the word “plausible” in connection with the theory of molecular mimicry. See Tr. at 106; Resp’t’s Post-Hr’g Br. at 16. Dr. MacDonald’s testimony is factually relevant notwithstanding that, as a legal matter, the correct test is not whether the theory of vaccination is plausible but whether it is reliable. See Moberly ex rel. Moberly v. Sec’y of Dep’t of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2010); Knudsen by Knudsen v. Sec’y of Dep’t of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Whether a theory is plausible is not the ultimate question, but it is a pertinent question. When an expert witness states that a theory is not plausible, it is strong evidence that must be taken into account when assessing whether the theory is reliable. If a theory is not plausible, it cannot be reliable. When an expert witness agrees that a proffered theory is plausible, that is some evidence, although not conclusive, of reliability. See, e.g., Andreu 569 F.3d at 1372. Here, the Secretary’s expert agreed the molecular mimicry theory was plausible. Tr. at 104.

In a significant colloquy with counsel for Petitioner, Dr. MacDonald admitted that vaccines definitely can cause neurological injury but stated that to be persuaded of vaccine causation he would need, ideally, “both the epidemiology prospective study, large groups, which is probably impractical. And then, an animal model that was closer to the human where you try to include this consistently.” Tr. at 105. “We’ll probably never have that level of proof,” he conceded. Id.<sup>15</sup>

### III. DISCUSSION

#### A. Burdens of Persuasion

Petitioners seeking to establish causation-in-fact must show by a preponderance of the evidence that but for vaccination they would not have been injured, and that vaccination was a substantial factor in bringing about the injury. Cedillo v. Sec’y of Dep’t of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Shyface v. Sec’y of Dep’t of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999).<sup>16</sup> Proof of actual causation must be supported by a sound and reliable “medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Moberly ex rel. Moberly v. Sec’y of Dep’t of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen by Knudsen v. Sec’y of Dep’t of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)).

Causation is determined on a case-by-case basis, with “no hard and fast per se scientific or medical rules.” Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and “close calls” regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280.

Petitioner’s burden is to show that the vaccination brought about his 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. Respondent, “like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case in-chief.” Stone, 2012 WL 1432525, at \*5 (quoting de Bazan v. Sec’y of Dep’t of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2009)).<sup>17</sup> In proving

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<sup>15</sup> Congress did not intend petitioners in the Vaccine Program to bear the burden of establishing a level of proof that “probably” will never be available. The opposite intent appears in the statute and legislative history. See 42 U.S.C. § 300aa-10 et seq. (2006). “The purpose of the Vaccine Act was to establish a compensation program under which awards could be made to vaccine-injured persons ‘quickly, easily, and with certainty and generosity.’” Shyface v. Sec’y of Dep’t of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) (quoting H.R. Rep. No. 99-908, at 3 (1986)).

<sup>16</sup> Petitioner has not alleged a “Table” injury. Pet’r’s Post-Hr’g Br. at 1, 24; see 42 C.F.R. § 100.3 (2011).

<sup>17</sup> In the context of the Vaccine Program, “prima facie case” and “case-in-chief” have distinct meanings, although they are sometimes used interchangeably in practice. As used by the Federal Circuit in Doe 11,

a vaccine injury case, a petitioner need not eliminate all possible alternative causes of injury. Stone, 2012 WL 1432525, at \*5; Doe 11 v. Secretary of Department of Health & Human Services, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); see Walther 485 F.3d at 1151.<sup>18</sup>

If Petitioner succeeds in establishing his case-in-chief, the burden then shifts to Respondent to prove alternative causation by a preponderance of the evidence. Althen, 418 F.3d at 1278. If Petitioner fails to establish his case-in-chief, however, the burden does not shift. Doe 11, 601 F.3d at 1357-58; see Cedillo, 617 F.3d at 1335 (citing Walther, 485 F.3d at 1151).<sup>19</sup>

If the shift occurs, the Secretary must prove that the “injury . . . described in the petition is due to factors unrelated to the . . . vaccine . . . .” 42 U.S.C. § 300aa-13(a)(1)(B). In such a case, the Secretary must prove not only the existence of an alternative cause but that the alternative actually caused the injury. Knudsen, 35 F.3d at 549.

## **B. Evidentiary Burdens**

The Secretary’s argument rests on a misunderstanding of the evidentiary burdens in a vaccine injury case, in particular, confusing the burden of production with

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the requirements of a prima facie case are statutory, see 42 U.S.C. § 300aa–11(c)(1), while a petitioner’s case-in-chief also requires a preponderance of evidence on the three Althen factors, see discussion infra.

<sup>18</sup> A special master may take into account alternative causes in deciding whether a petitioner has established the case-in-chief. Stone, 2012 WL 1432525, at \*5; Doe 11, 601 F.3d at 1358. I have considered the Secretary’s allegation of a viral cause for Petitioner’s illness and find that it does not outweigh the evidence supporting Petitioner’s case-in-chief. See discussion infra.

<sup>19</sup> The Federal Circuit discussed the burden of proof in de Bazan:

[T]he petitioner’s case-in-chief concerns the medical evidence relating to the possible role the *vaccine* had in causing her injury. The government’s burden, in contrast, concerns “factors unrelated to the administration of the vaccine described in the petition.” See 42 U.S.C. § 300aa–13(a)(1)(B). While a failure of proof that the vaccine was the cause of the petitioner’s injury suggests that some other cause was responsible, that is not equivalent to having proven by preponderant evidence that a *particular* agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor). This latter showing is the government’s burden once the petitioner has met her burden. In other words, successfully proving the elements of the Althen test establishes that the medical evidence indicating that the vaccine may have caused the petitioner’s injury is strong enough to infer causation-in-fact *absent proof that some other factor was the actual cause*. The government then must provide that proof by identifying a particular such factor (or factors) and presenting sufficient evidence to establish that it was the sole substantial factor in bringing about the injury. Knudsen v. Sec’y of the Dep’t of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994).

de Bazan, 539 F.3d at 1353-54.

the burden of persuasion.<sup>20</sup> Once evidence of vaccine causation has been presented by the petitioner, the burden of production is shared by the parties, each of whom must rebut the evidence presented by the other in order to establish the facts necessary to prove its case. Failure to present rebuttal evidence in response to an opponent's evidentiary showing may result in an adverse finding on that point. Regardless of which party ultimately bears the burden of persuasion, each party must carry its burden of production. The burden of production may shift many times in the course of an effort by the party bearing the burden of persuasion to prevail.

In this case, Petitioner presented evidence of vaccine causation. The Secretary failed to rebut that evidence with sufficient evidence of non-vaccine causation. The Secretary's expert effectively conceded Petitioner's key factual allegations. Dr. MacDonald relied on the fact that infection was statistically a more likely cause of Petitioner's illness, and that there was no epidemiological evidence of a causative link between ADEM and the vaccinations Petitioner received. Neither of those grounds has been deemed sufficient, under the law, to negate vaccine causation. Moreover, Petitioner effectively refuted the Secretary's evidence of viral infection with testimony from Dr. Weig that Petitioner's ongoing and recurring symptoms were unlikely to have an infectious etiology. The Secretary did not respond with evidence overcoming the persuasiveness of this testimony. Weighing all the evidence presented by both parties, I conclude that Petitioner's evidence was more persuasive than the Secretary's on each of the Althen prongs, and, therefore, Petitioner prevails.

Confusion may occur where, as here, the Secretary's main response to a petitioner's case is to suggest an unrelated causative factor. As discussed below in regard to Doe 11, proving alternative causation is only one of the ways the Secretary can defeat a vaccine injury claim. Another way is to challenge the validity of the evidence presented in the petitioner's case-in-chief. The Secretary hardly undertook the effort of challenging Petitioner's factual presentation here. The evidence she did present, including evidence of possible alternative causation, was not sufficient to persuade me that viral causation was more likely than vaccine causation.

If the Secretary had identified a specific virus that she alleged caused Petitioner's ADEM, it might have increased the weight of the evidence in rebuttal of Petitioner's showing. That would have been a different case. But it was not necessary for the Secretary to present evidence of a specific infectious agent in order to rebut Petitioner's case. If Petitioner had presented weaker evidence of vaccine causation, or the Secretary had presented stronger evidence of non-vaccine causation, the Secretary

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<sup>20</sup> Numerous authoritative sources explain the difference between the burden of production and the burden of persuasion, and the consequences of failure to carry these respective burdens. See, e.g., Schaffer ex rel. Schaffer v. Weast, 546 U.S. 49, 56 (2005) (explaining that the burden of persuasion indicates "which party loses if the evidence is closely balanced" while the burden of production indicates "which bears the obligation to come forward with the evidence at different points in the proceeding.").

might well have prevailed without identifying any alternative causative factor, and certainly without needing to specify the suspected viral agent.<sup>21</sup>

## C. Analysis

### 1. Althen Prong 1

Under Althen prong 1, a petitioner must set forth a medical theory explaining how the vaccine could cause the injury complained of. This requirement has been interpreted as “can the vaccine(s) at issue cause the type of injury alleged?” Pafford v. Sec’y of Dep’t of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (quoting Pafford v. Sec’y of Dep’t of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at \*4 (Fed. Cl. Spec. Mstr. July 16, 2004)). Although the theory of causation need not be corroborated by medical literature or epidemiological evidence, the theory must be sound, reliable, and reputable – in other words, the theory need not be scientifically certain, but it must have a scientific basis. See Knudsen, 35 F.3d at 548 (finding actual causation “must be supported by a sound and reliable medical or scientific explanation”).

In evaluating whether a petitioner has presented a legally probable medical theory, “the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” Cedillo, 617 F.3d at 1339 n.3 (quoting Moberly, 592 F.3d at 1324). A special master is not required to rely on a speculative opinion that “is connected to existing data only by the ipse dixit of the expert.” Snyder v. Sec’y of Dep’t of Health & Human Servs., 88 Fed. Cl. 706, 743 (2009) (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)); accord Perreira v. Sec’y of Dep’t of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir.1994) (“An expert opinion is no better than the soundness of the reasons supporting it.”).

Assessing the reliability of an expert opinion in Vaccine Act cases can be challenging because often there is little supporting evidence. See Althen, 418 F.3d at 1280 (noting that the “field [is] bereft of complete and direct proof of how vaccines affect the human body”). Most expert opinions extrapolate from existing data and knowledge. The weight to be given to an expert’s opinion is based in part on the size of the gap between the science and the opinion proffered. Cedillo, 617 F.3d at 1339 (citing Joiner, 522 U.S. at 146).

Dr. Weig’s testimony and the medical literature submitted by Petitioner are sufficient to establish that the immunizations Petitioner received could have caused his ADEM. Dr. Weig testified that immunizations are a known cause of ADEM. Tr. at 35. He offered medical literature in support of his opinion, including articles by Tenembaum

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<sup>21</sup> In Knudsen, the Federal Circuit rejected the petitioner’s argument that identification of a specific virus was required to establish alternative causation. See Knudsen, 35 F.3d at 549. The Secretary’s argument that, because she need not identify a specific virus, Petitioner is required in his case-in-chief to negate the existence of any virus in the world that could possibly have caused Petitioner’s illness, does not follow logically from the decision in Knudsen.

et al. (Pet'r's Ex. 21, Tab A), Menge et al. (Pet'r's Ex. 21, Tab B), Gupte et al. (Pet'r's Ex. 21, Tab C), and Dale et al. (Pet'r's Ex. 30). As noted in the Tenembaum article, "ADEM is an inflammatory demyelinating disease of the CNS [central nervous system] that often follows a viral illness or vaccination." Pet'r's Ex. 21, Tab. A at 2. Menge and his coauthors report that "[u]p to three-quarters of [ADEM] cases may be regarded as postinfectious or postimmunization . . . ." Pet'r's Ex. 21, Tab. B at 2. The Gupte authors state that ADEM "is thought to be immune mediated [and] often follows an antecedent infection or immunization." Pet'r's Ex. 21, Tab C, at 2. According to the Gupte article, ADEM has been reported after both live and killed vaccines and after meningococcal vaccination. Id. at 6. Dale also reports ADEM after vaccinations in patients who, like Petitioner, experience multiphasic conditions and seizures. Pet'r's Ex. 30 at 5-6.<sup>22</sup>

The theory of molecular mimicry is that "due to certain delicate structural or partial amino-acid sequence homologies" there are similarities between an inoculated pathogen and a host CNS protein. Pet'r's Ex. 21, Tab B at 3. Because of these similarities, "[t]he pathogen is hence not readily recognized as 'foreign' in order to be eliminated, nor 'self', which would result in immune tolerance." Id. In the case of ADEM, the theory is that the inoculated pathogen activates T cells, which cross-activate antigen-specific B cells, both of which are capable of entering the CNS. Id. These cells, by chance, encounter the similar myelin protein, which sets off a "cascade of events." Id. "Following local reactivation by antigen presenting cells, an inflammatory immune reaction against the presumed foreign antigen is elicited, and the initially physiological immune response engenders detrimental autoimmunity distant from the original site of inoculation." Id. Dr. Weig summarized the process stating that, for an unknown reason, the individual reacts abnormally to components of the vaccine, "[s]o that an immune reaction that is started against the foreign antigen then attacks the individual's own nervous system, which is a classic autoimmune disease." Tr. at 37.

Dr. Weig's testimony concerning the theory of molecular mimicry was supported by the medical literature. See Pet'r's Ex. 21, Tab B at 3. In particular, Menge and his coauthors suggested molecular mimicry as a cause of ADEM and noted an animal study with "kinetics . . . strikingly similar to those observed between the preceding infection or vaccination, and the subsequent onset of ADEM-compatible symptoms in human patients." Id.

Dr. MacDonald, Respondent's expert, did not successfully rebut Dr. Weig's testimony. He concurred that Petitioner's diagnosis of ADEM was appropriate. Tr. at

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<sup>22</sup> These reports were at least partially attributable to contaminated vaccines, specifically rabies and Japanese B encephalitis vaccines. See Pet'r's Ex. 21, Tab B at 2-3 (noting contamination from host animal tissue in which the vaccines were propagated). That is true with respect to some but by no means all the reports of post-vaccination ADEM. See Pet'r's Ex. 21, Tab A at 3, Table I (noting measles vaccination in seven reported cases and pertussis in three); Pet'r's Ex. 21, Tab B at 2 ("[T]he incidence of measles vaccination-associated ADEM is about 0.1/100,000."); Pet'r's Ex. 21, Tab C at 6 ("Post-vaccinal cases of ADEM have been reported following immunization with live (measles, rubella, vaccinia) and killed vaccines (influenza, rabies). Recently, ADEM has been reported following meningococcal A and C vaccination."); Pet'r's Ex. 30 at 6 (reporting ADEM after "mumps rubella immunization" and "BCG vaccine").

79, 94. Dr. MacDonald agreed that, although viral infections are more commonly causative of ADEM than vaccinations, it “could be either.” Tr. at 82-83. He also agreed that molecular mimicry is associated with autoimmune disorders, Tr. at 104, and concurred that molecular mimicry is a plausible mechanism to explain how ADEM can occur, Tr. at 104, 107. Dr. MacDonald agreed that there are case reports of ADEM following immunizations, Tr. at 105, and that Petitioner’s treating physicians never identified a viral cause of his ADEM, id. at 100.

In response to Petitioner’s presentation, Dr. MacDonald pointed to statistical data showing that infection causes ADEM far more often than vaccination, and to the lack of epidemiological or animal studies to prove that vaccines can cause ADEM. Tr. at 105. From a scientific standpoint, Dr. MacDonald’s reluctance to endorse vaccine causation under these circumstances is understandable. It is clear, however, that the level of scientific evidence needed to establish a causal association in the opinion of a medical expert is not necessarily required to demonstrate entitlement to compensation under the Vaccine Program. See Moberly, 592 F.3d at 1322 (finding an explanation of vaccine injury need only be “legally probable, not medically or scientifically certain”) (quoting Knudsen, 35 F.3d at 548-49).

I find that Dr. Weig’s testimony and the medical literature on which he relied furnished sufficient reliable evidence that Petitioner’s vaccination could have caused his ADEM. The biological mechanisms by which vaccination could actually cause injury through a process of molecular mimicry are not well understood, but the theory is not to be rejected on that basis alone. See Knudsen, 35 F.3d at 549 (“[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccination compensation program.”).

I note that, in a case with different facts, evidence and testimony, molecular mimicry might not be deemed a likely possible cause of the petitioner’s injury. Because each case must be judged on its own facts, the conclusion in each case reflects not only the weight of the evidence in that case under each of the Althen prongs, but the weight of the evidence in the context of the entire record. Thus, strong evidence on Prong 2 may change the amount of evidence that is required to persuade a special master that Prong 1 has been met. See Capizzano v. Sec’y of Dep’t of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (noting that evidence under one prong of the Althen causation test may increase the probative value of evidence relating to the other prongs). Seemingly inconsistent results may permissibly occur as a result of this case-by-case adjudication process. See Hanlon v. Sec’y of Dep’t of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998) (indicating decisions are not binding on special masters except in the same case), aff’d, 191 F.3d 1344 (Fed. Cir. 1999); see also Stone, 2012 WL 1432525, at \*5 (“[T]he special master is entitled to consider the record as a whole in determining causation.”); Moberly, 592 F.3d at 1322 (requiring “a reputable medical or scientific explanation that pertains specifically to the petitioner’s case”).

## **2. Althen Prong 2**

The second prong of Althen requires a petitioner to prove “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Andreu, 569 F.3d at 1374 (quoting Althen, 418 F.3d at 1278). The sequence of cause and effect must be “logical’ and legally probable, not medically or scientifically certain.” Knudsen, 35 F.3d at 548-49. Along those lines, a petitioner is not required to show “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, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Id. at 1325-26; see Andreu, 569 F.3d at 1375-77. Further, evidence used to satisfy one prong of the Althen test may overlap to satisfy another prong. Capizzano, 440 F.3d at 1326.

### **a. Petitioner Established a Logical Sequence of Cause and Effect, Which Was Not Effectively Rebutted.**

Petitioner contended that his vaccinations triggered ADEM, an autoimmune, demyelinating disorder of the CNS. As described above, Dr. Weig’s testimony established a logical sequence of cause and effect between Petitioner’s vaccinations and his ADEM. There is no question Petitioner received the vaccinations. There is agreement on the record that vaccination can cause ADEM, and agreement on the record that Petitioner likely suffered from ADEM. The question is whether another possible cause, infection, is more likely than vaccination. While the Secretary’s evidence on this point was relevant, see Stone, 2012 WL 1432525, at \*5 (noting that evidence of other possible sources of injury can be relevant to whether a “prima facie showing” has been made that the vaccine was a substantial factor), it was not preponderant.

Here again, Dr. Weig’s testimony was reliable and persuasive. Based on the extensive test results, he opined that Petitioner’s ADEM was not due to a virus or bacterial infection. Tr. at 49. The pertinent testing was conducted over a period of months by a series of experts, none of whom discovered an infectious source of the illness. Dr. Weig opined further that Petitioner’s relapses would make it “virtually impossible” for his condition to be caused by an ongoing infection of the nervous system. Tr. at 50.

Dr. MacDonald relied on the evidence of sinus and ear infection “described early on” as a possible alternative to vaccination as the cause of Petitioner’s ADEM. Tr. at 87. He provided little evidence, however, other than statistics, indicating why those conditions were the cause of Petitioner’s ADEM. The Secretary’s case seemed to consist of the argument that, in the absence of direct evidence of causation, vaccination and infection were equally likely causes; the matter therefore was in equipoise, resulting in a decision for the Secretary, since Petitioner bears the burden of proof. See Resp’t’s Post-Hr’g Br. at 17. I find on examination of the record as a whole that the

evidence is not in equipoise, however, and that vaccination was more likely than not the cause-in-fact of Petitioner's illness.

As noted above, the Secretary did not respond effectively to Dr. Weig's argument that a viral infection of the central nervous system would be unlikely to persist and recur over a period of years. The Secretary's suggestion of mycoplasma infection also was not persuasive. None of Petitioner's treating physicians focused on mycoplasma infection as a possible cause of Petitioner's neurological disorders, and Dr. MacDonald provided no reliable evidence of a link between the remote exposure to mycoplasma in Petitioner's case and his ADEM. See Tr. at 87-88. Dr. Weig's testimony was more persuasive on all of these points.

**b. Treating Physician "Opinions" Are Inconclusive.**

Petitioner asserts that "Petitioner's treating physicians immediately linked his vaccines with the onset of his symptoms of ADEM." Pet'r's Post-Hr'g Br. at 33. This was not the case: the treating physicians recorded the fact that Petitioner had received the vaccinations but did not state that vaccination caused his injury. Therefore, this is not an occasion requiring detailed consideration of the opinions of treating physicians, contrary to Petitioner's assertion. See Pet'r's Post-Hr'g Br. at 34. With the possible exception of Dr. Widjiks, see infra, no treating physicians' opinions are expressed in the notations emphasized by Petitioner. See Pet'r's Post-Hr'g Br. at 33-34. The doctors simply recorded the history of Petitioner's vaccinations in temporal proximity to the onset of his disorder, see, e.g., Pet'r's Ex. 4 at 28, and, in one instance, his father's insistence on blaming the vaccines for Petitioner's ordeal, Pet'r's Ex. 7 at 303.

The evidence that comes closest to a treating physician opinion is that of Dr. Wijdicks, who wrote: "The episode of neurological symptoms occurred about two weeks after he had a meningococcal vaccination. The episode involved decreased strength and balance and eventually a picture of transverse myelitis . . . . In my opinion, the likely clinical scenario here is ADEM after a vaccination." Pet'r's Ex. 4 at 24.

Dr. Wijdick's isolated statement does not present persuasive evidence of vaccine causation. Dr. Wijdicks was one of several specialists who evaluated Petitioner at the Mayo Clinic, primarily to determine his proper diagnosis – ADEM, transverse myelitis, multiple sclerosis, vasculitis, etc. The treating physicians were trying to determine what was wrong with Petitioner so that they could help him. They were not providing formal opinions as to causation. I agree that the notation by Dr. Wijdicks is corroborative of Dr. Weig's opinion, but it is in no way dispositive of the issue. Cf. Andreu, 569 F.3d 1375-76 (involving unequivocal opinions of treating physicians).

The record shows that other doctors assumed Petitioner's difficulties were due to infection rather than vaccination. See, e.g., Pet'r's Ex. 7 at 30, 36; Tr. at 47-52. That is only to be expected, however, since infection is the cause of ADEM most of the time. See Resp't's Ex. G at 1; Tr. at 85-86. Under these circumstances, the notations by treating physicians and other treating professionals, while they must be considered, are

not conclusive as to whether a vaccination caused an injury. See 42 U.S.C. §300aa-13(b)(1)(B) (“Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court.”); Broekelschen v. Sec’y of Dep’t of Health & Human Servs., 618 F.3d 1339, 1346-49 (Fed. Cir. 2010) (affirming special master’s fact finding where correct diagnosis was disputed in the medical record); Cedillo, 617 F.3d at 1348 (finding that the special master “did not err in failing to afford significant weight to the opinions of [Petitioner’s] treating physicians”).

**c. Petitioner Does Not Bear the Burden of Eliminating Viruses as Possible Causes of His ADEM.**

The Secretary argues that the Petitioner cannot demonstrate “a logical sequence of cause and effect” because he “is unable to rule out a much more likely cause for his injury, a viral infection.” Resp’t’s Post-Hr’g Br. at 11. Petitioner does not bear the burden, however, to “rule out” an unidentified virus as a possible cause of his ADEM in order to satisfy Prong 2.

The Federal Circuit has mandated a framework for decision that does not require “ruling out” alternative causes as part of the petitioner’s case-in-chief. Stone, 2012 WL 1432525, at \*5; Doe 11, 601 F.3d at 1357-58; see Walther, 485 F.3d at 1151. The framework consists of the three Althen factors. The special master must determine whether those factors are established by a preponderance of the evidence. If they are, and the Secretary cannot establish alternative causation, the petitioner prevails. The Secretary’s argument that a petitioner bears the additional burden of eliminating alternative factors to establish a case simply is wrong, as a matter of law. The Federal Circuit has held that “the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.” Walther, 485 F.3d at 1150. Instead, Petitioner needs only to meet the Althen requirements and establish by a preponderance of the evidence that the vaccine was “a substantial factor” in causing the claimed injury. de Bazan, 539 F.3d at 1351 (citing Walther, 485 F.3d at 1150).

Doe 11 did not abrogate the principle, established in Walther, that a petitioner need not rule out alternative causes in order to establish the case-in-chief. Stone, 2012 WL 1432525, at \*5. Doe 11 simply held that a special master may consider evidence of factors unrelated to vaccination in deciding whether the petitioner has established the case-in-chief. Doe 11, 601 F.3d at 1351-52; accord Stone, 2012 WL 1432525, at \*5. I have considered the evidence that ADEM is statistically more often caused by infection than by vaccination, see Resp’t’s Post-Hr’g Br. at 14, and that some of Petitioner’s symptoms were consistent with a viral illness, but that evidence fails to persuade me that Petitioner’s ADEM was caused by infection, more likely than not.

The Secretary notes that Petitioner’s expert, Dr. Weig, agreed that many of Petitioner’s symptoms were consistent with infection. Resp’t’s Post-Hr’g Br. at 11-12.<sup>23</sup>

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<sup>23</sup> The Secretary notes that Dr. Weig believed that the first symptom of Petitioner’s ADEM was a headache on May 1, 2007; the medical records describe the headache as having occurred on May 6,

Dr. Weig also testified, however, that no evidence of a CNS pathogen ever was found. Id. at 12. Dr. Weig concluded, logically, that the possibility of an infectious cause was rendered less likely than the possibility that a vaccine caused Petitioner's illness because there was no evidence of a viral or bacterial agent in Petitioner's record that would explain his illness. Tr. at 35. Meanwhile, a known post-vaccination syndrome does explain his illness.<sup>24</sup> The Secretary's assertion that "[t]his is patently insufficient to prove causation in fact," Resp't's Post-Hr'g Br. at 13, is incorrect. Dr. Weig's is precisely the type of analysis by a reliable medical expert that will support vaccine causation. Special masters do not deny vaccine injury claims simply because there are "many, many" viruses in the world that are capable of making people sick. See Resp't's Post-Hr'g Br. at 13. Otherwise, claimants in the Vaccine Program would hardly ever receive compensation – infection by one of "many, many" viruses is always a possibility when etiology cannot be conclusively determined, as it cannot be in most litigated cases under the Act.

### **3. Althen Prong 3**

Dr. Weig testified that the onset of symptoms of Petitioner's ADEM, 14 days after his vaccinations, was an appropriate interval for the symptoms to have resulted from the vaccines. Tr. at 39. Dr. MacDonald agreed. Tr. at 98, 107. Althen Prong 3 is established, and is consistent with a logical sequence of cause and effect. See Resp't's Post-Hr'g Br. at 15 n. 8 (conceding Prong 3).

### **4. The Secretary Misconstrues Applicable Law.**

The Secretary expressly disclaims reliance on section 13(a)(1)(B). "Here, respondent did not assert that a specific viral 'factor unrelated' to the vaccinations Petitioner received caused his injury, nor was she required to do so. Because petitioner failed to prove a prima facie case, respondent had no need to establish a factor unrelated." Resp't's Post-Hr'g Br. at 17. Nevertheless, the Secretary relies on Knudsen for the proposition that "Respondent . . . is not required to identify the exact virus involved . . . . It is enough that a viral cause is more likely than not even if the specific virus is never isolated." Resp't's Post-Hr'g Br. at 13.

The Secretary's reading of Knudsen is erroneous if the decision is cited for the proposition that mere statistical likelihood of viral causation is sufficient to rebut a case of vaccine causation. The Federal Circuit specifically rejected a similar line of reasoning

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2007. Resp't's Post-Hr'g Br. at 11. The Secretary does not argue that this minor discrepancy has any significance, and I find that it has none. See Resp't's Post-Hr'g Br. at 14 (discussing Dr. Weig's theory that immunization or infection would take "approximately two weeks to cause ADEM so the timing is appropriate for both possible causes of petitioner's injury.").

<sup>24</sup> The Secretary essentially admits as much, stating, "Dr. Weig's opinion is based almost strictly on the fact that Petitioner received an immunization which certain case series have indicated are [sic] rarely associated with ADEM." Resp't's Post-Hr'g Br. at 13. Short of direct evidence or controlled studies, which do not appear in this record, reliable case reports may be accepted as the best evidence available of vaccine injury causation.

and found that “[t]he bare statistical fact that there are more reported cases of viral encephalopathies than . . . of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection . . . and not caused by the DTP vaccine.” Knudsen, 35 F.3d at 550.

It is the Secretary who failed to present sufficient evidence to rebut Petitioner’s showing of vaccine causation. The Secretary maintained that there are many thousands of viruses for which Petitioner was not tested, Tr. at 50, without presenting persuasive evidence that any virus, whether or not it could be identified, more likely than not caused Petitioner’s ADEM. In fact, Petitioner effectively rebutted the Secretary’s suggestion of viral causation with evidence that Petitioner was tested for the known biological agents that are believed to cause ADEM, and all such tests were negative. See Tr. at 20.

The Secretary’s case fails because Petitioner presented more and better evidence on each Althen Prong, not because the Secretary was assigned the burden to prove an alternative factor under section 13(a)(1)(B) – she was not. While the Secretary did not need to identify a specific virus as causative, the Secretary did need to present persuasive evidence that some virus was causative, or that there was some other flaw in Petitioner’s case. The Secretary needed some persuasive evidence, in addition to statistics and the mere possibility of a viral etiology, to rebut Dr. Weig’s testimony. “A special master may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence.” Stone, 2012 WL 1432525, at \*5 (citing Walther, 485 F.3d at 1151).

Comparing Doe 11 to the circumstances in this case provides a useful contrast. The respondent in Doe 11 alleged that the cause of the vaccinee’s death was sudden infant death syndrome (SIDS). The Doe 11 evidentiary record contained literature describing the pathological findings in a typical SIDS autopsy, in studies of both explained and unexplained SIDS deaths. Doe 11 v. Sec’y of Dep’t of Health & Human Servs., No. 99-212V, 2008 WL 4899356, at \*20-21 (Fed. Cl. Spec. Mstr. Oct. 29, 2008). The special master found that many of those classic findings of SIDS were present in a post-mortem examination of the vaccinee in Doe 11. Id. at \*21. This conclusion, which rebutted the petitioner’s case-in-chief, was based on medical evidence in the record pertaining to the individual vaccinee – not on hypothetical causes supported by nothing more than general statistical probabilities.

The Federal Circuit stated in Doe 11: “A petitioner’s failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternative cause.” Doe 11, 601 F.3d at 1358 (citing de Bazan, 539 F.3d at 1353-54). The Federal Circuit in Doe 11 held that a special master could consider alternative causes in evaluating a petitioner’s case-in-chief. Doe 11, 601 F.3d at 1356-57. The Federal Circuit did not hold that merely raising the possibility of other causes, without any factual support, defeats a showing of vaccine injury, unless refuted by the petitioner. Only if the Secretary produces effective rebuttal evidence may a

petitioner be required in turn to produce evidence in refutation. A petitioner cannot be required to knock down shadows.

As noted herein, the Secretary was permitted to adduce evidence to refute Petitioner's case-in-chief. That evidence was considered carefully and found to be of insufficient probative value in light of the entire record and under applicable law.

#### **IV. CONCLUSION**

Petitioner has satisfied the requirements for proving that Petitioner's April 16, 2007, Tdap and/or meningococcal vaccinations were the cause of his ADEM and related health problems. Therefore, Petitioner has established entitlement to compensation under the Vaccine Act. This case shall proceed to the damages phase.

**IT IS SO ORDERED.**

s/ Dee Lord  
Dee Lord  
Special Master