

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS**

No. 11-03V

Filed: August 8, 2013

MELISSA ALTMAYER *
Legal representation of a minor child, *
MADELYN ALTMAYER, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Autism; Ruling on the Record; Vaccine Act
Entitlement; Insufficient Proof of Causation

Randall G. Knutson, Esq., Farrish Johnson Law Office, Mankato, MN, for petitioner.
Traci R. Patton, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Special Master:

On January 3, 2011, Melissa Altmeyer [“petitioner” or “Ms. Altmeyer”] timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² [“Vaccine Act” or “Program”], on behalf of her minor daughter, Madelyn Altmeyer [“Madelyn”]. The petition alleges that Madelyn suffered from “fever, febrile seizures, and urinary tract and kidney infections,” resulting in a pervasive development disorder caused by the hepatitis A, Haemophilus influenzae

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

type b [“Hib”], and measles, mumps, and rubella [“MMR”] vaccines received on January 4, 2008, and diphtheria, tetanus, and acellular pertussis [“DTaP”], pneumococcal conjugate, and varicella vaccines received on April 1, 2008. Petition at ¶ 9. The petition further alleges that Madelyn’s injuries persisted for more than six months. *Id.* at ¶ 10.

For the reasons stated herein, I find that the petitioner has failed to establish entitlement to an award and thus, the case is dismissed.

I. Procedural History.

The petition was accompanied by fourteen medical exhibits detailing Madelyn’s vaccinations, treatment for illness, and, eventually, her diagnosis of autism.³ See *generally*, Petitioner’s Exhibits [“Pet. Exs.”] 1-14.

Following the initial status conference on February 9, 2011, respondent filed her Rule 4(c) report recommending against compensation. Respondent’s Report [Res. Rpt.], filed Apr. 4, 2011, at 1. In her report, respondent noted that petitioner had failed to provide a reliable medical opinion causally connecting the vaccines and Madelyn’s condition. *Id.* at 3. In response, petitioner filed a letter dated July 6, 2011, from Madelyn’s treating physician, Dr. Norm Schwartz.⁴ Pet. Ex. 15, filed July 8, 2011. In its entirety, the letter reads: “I have been treating Madelyn since May, 2009. Reviewing her medical records prior to my evaluation, I feel vaccinations were a factor in causing her seizures and subsequent developmental delays.” *Id.*

During a status conference, the special master previously assigned to this case⁵ notified petitioner that Dr. Schwartz’s letter was not sufficient to establish a causal relation between Madelyn’s injuries and the vaccines. Petitioner was ordered to submit a supplemental report from him addressing the *Althen* requirements.⁶ Order, issued

³ Autism spectrum disorder (also called “pervasive developmental disorder”) is an umbrella term encompassing several neurological disorders manifesting in early childhood with impairments in communication and social interaction, and the display of restricted, repetitive, or stereotypical patterns of behavior, interests, and activities. A more complete description of the disorder is contained in *White v. Sec’y, HHS*, No. 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011).

⁴ Petitioner did not submit a copy of Dr. Schwartz’s curriculum vitae. According to Dr. Schwartz’s practice webpage, he has over twenty years of experience in integrative medicine and has a background in treating complex chronic health issues. He was the former medical director of Integrative Medicine for Wheaton Franciscan Healthcare in Milwaukee, Wisconsin, and is currently in private practice. He is also a Defeat Autism Now! [“DAN!”] physician, specializing in treating autism spectrum disorders, attention deficit hyperactivity disorder, and neurodevelopmental disorders. <http://www.inwellnesstoday.com/norm-schwartz.php> (last visited Aug. 8, 2013). DAN! physicians subscribe to treatment protocols developed by the Autism Research Institute. These treatments may include chelation and other therapies not vetted as efficacious by controlled clinical studies. *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250, at *20, *178 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁵ This case was reassigned to me on August 17, 2012.

⁶ *Althen* requires a petitioner “to show by preponderant evidence that the vaccination brought about her

July 12, 2011.

On September 20, 2011, petitioner's counsel informed the court that Dr. Schwartz was no longer willing to provide assistance on this case. See Order, issued Sept. 20, 2011. Thereafter, petitioner requested and received several extensions of time to obtain a report from an alternate expert. See, e.g., Order, issued Feb. 27, 2012.

Petitioner filed a statement from Dr. Gregory L. Brown on July 25, 2012.⁷ Pet. Ex. 16. In his statement, Dr. Brown narrated Madelyn's medical history and concluded that there were "strong historical and immunological reason[s] to believe that the vaccines she was given contributed significantly to her developmental delays and subsequent medical course and immunologic issues." *Id.* at 2. However, he did not set forth a theory explaining how her condition was the result of the vaccines.

During a status conference on August 16, 2012, petitioner's counsel was informed that Dr. Brown's report did not comply with the court's order as he had failed to address the *Althen* factors. See Order, issued Aug. 16, 2012. Petitioner was directed to file a supplemental report in which Dr. Brown identified the conditions he believed the vaccine caused and indicated whether Madelyn suffered from autism or any disorder on the autism spectrum. *Id.*

Shortly thereafter, this case was reassigned to me. On September 27, 2012, I granted petitioner's motion for an extension of time to secure a supplemental report from Dr. Brown. Order, issued Sept. 27, 2012.

On October 25, 2012, petitioner filed Dr. Brown's supplemental expert report in which he opined that "a chain of events was started by the vaccines given at [Madelyn's] twelve month visit amplified by those given at her fifteen month visit leading to minimized language development, fevers, and other persistent developmental delays." Pet. Ex. 17 at 1. In support of his theory, Dr. Brown stated that Madelyn suffered from an increase in T-helper cells and that "vaccinations can cause broad T-cell responses."⁸ *Id.* at 2. He also added that her activated T-helper cells caused a

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 proximate temporal relationship between vaccination and injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

⁷ Petitioner did not file a copy of Dr. Brown's curriculum vitae. According to Dr. Brown's practice webpage, he has over eighteen years of experience in emergency medicine and is the founder of ARCH Medical Center. He is certified in medical chelation and hyperbaric medicine, and his practice is devoted to helping children with autism spectrum disorders, allergies and other chronic problems. Doctor Brown is currently the medical director of ARCH Medical Center and A&M Hyperbaric, and is also a DAN! practitioner. ARCH Medical Center, <http://www.serenityhealthcarecenter.com/WaukeshaHolisticPractitioners/DrGregBrownMD> (last visited Aug. 8, 2013).

⁸ Doctor Brown cited a single study in support of his theory: S. De Rosa, et al., *Vaccination in humans generates broad T cell cytokine responses*, 173 J. IMMUNOL, 5372, 5380 (2004). Petitioner did not file a copy of this study with the court. Nevertheless, I was able to locate and examine a web copy at:

vaccine “over-response”⁹ which impaired her immune system. *Id.* Notably absent from Dr. Brown’s report was any evidence, other than his opinion, relating the infections to Madelyn’s developmental problems. Although Dr. Brown concluded that Madelyn had a developmental disorder that fell on the autism spectrum, he conceded that he was not qualified to make an autism diagnosis. *Id.*

I convened a status conference on November 7, 2012, during which I informed petitioner’s counsel that Dr. Brown’s supplemental report was not sufficient to prove causation, noting that Dr. Brown had failed to address the *Althen* factors. Petitioner’s counsel indicated that he did not believe Dr. Brown would be able to expand on his report and was unsure whether he could obtain a report from another expert. On November 8, 2012, I ordered petitioner to file an expert report that satisfied the *Althen* factors, a motion to dismiss, or a motion for ruling on the record.

On December 4, 2012, petitioner requested a ruling on the record based on the documents and exhibits already submitted to the court.

II. Relevant Medical History.

A. Madelyn’s Early Health and Development.

Madelyn was born at 38 weeks of gestation on January 1, 2007. Pet. Ex. 6, p. 1. She had no hearing or vision concerns at birth and her Apgar scores¹⁰ were 8 and 9, reflective of a healthy newborn. Pet. Ex. 6, p. 1. She received a hepatitis B vaccine prior to her discharge from the hospital. *Id.*, p. 8.

At her four month well child visit in early May 2007, petitioner reported that Madelyn had suffered fevers “every one to two weeks” the previous month. Pet. Ex. 6, p. 14. Petitioner related similar concerns of low grade fevers on May 2, 2007, and again on November 25, 2007. *Id.*, pp. 16, 24. Otherwise, Madelyn exhibited healthy growth and normal development in her first year, and continued to receive the usual vaccines

<http://www.jimmunol.org/content/173/9/5372.full.pdf>.

⁹ Doctor Brown did not define what he meant by a vaccine “over-response,” but it appears he was referring to an abnormally intense reaction to the stimulus generated by a vaccine. He did not, however, identify any test results that suggested such a response in Madelyn. None of the vaccine titers performed in 2009 were characterized by the laboratories as reflecting an “over-response.” See Pet. Ex. 13, pp. 24 (hepatitis B surface antigen titer “inconclusive”); 23-24 (Hib titer “protective”); 23 (polio titer reflective of vaccination); 21-22 (tetanus titer in “protective” range); 21 (diphtheria titer in “protective” range); 20 (mumps titer low); 19-20 (rubella results reflecting immunity); 19 (varicella titer low). Although her percentage of CD4 T helper cells was slightly high, her total T cell and CD4 T helper cells were both within the reference ranges. *Id.*, p. 19. The other tests performed to assess Madelyn’s immune system were generally in the normal range.

¹⁰ An Apgar score is a numerical assessment of a newborn’s condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant’s heart rate, respiration, muscle ton, reflex irritability, and color, with from zero to two points awarded in each of the five categories. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY [“DORLAND’S”] at 1682 (32th ed. 2012).

without apparent ill effects.¹¹ See *generally*, Pet. Ex. 6. Based on parental report, Madelyn was very interactive and would play and socialize normally with her brother at this age. Pet. Ex. 14, p. 2.

B. Madelyn's Second Year.

This section discusses the evolution of Madelyn's condition in her second year and the evidence regarding the allegedly causal vaccinations received between her first and second birthdays. It further details Madelyn's history of infections, fevers, and, subsequently, her series of febrile seizures.

1. Medical Records and Histories Prior to May 2008 Hospitalization.

a. The January 2008 Vaccinations.

In late December 2007, through January 2008, Madelyn suffered from rhinitis and a cough for about ten days. Pet. Ex. 6, pp. 26-27. At her one year well child visit on January 4, 2008, pediatrician Dr. Frank Baur diagnosed Madelyn with bilateral otitis media and viral upper respiratory infection ["URI"]. *Id.* She was afebrile and the development screen indicated that she was "without significant delays." *Id.* Madelyn received hepatitis A, Hib, and MMR vaccines during this visit.

Three days after receiving the vaccines, Dr. Baur noted that Madelyn continued to suffer from bilateral otitis media and also suffered from either a viral URI or sinusitis. Since her previous visit, she had developed a constant 102° fever, and her rhinitis and cough showed no improvement. Pet. Ex. 6, p. 28. Four days later, on January 11, 2008, Madelyn's bilateral otitis media, sinusitis, cough, and rhinitis had improved, her temperature had returned to normal, and she had developed a non-allergic Amoxicillin rash. *Id.*, p. 30.

On January 13, 2008, petitioner called Dr. Baur, concerned that Madelyn had another fever. Pet. Ex. 6, p. 32. The following day, Madelyn presented to the pediatrician with acute sinusitis and bilateral otitis media. *Id.*, p. 35. Madelyn's rash had worsened and she suffered from rhinitis, cough, and fever as high as 103°. Doctor Baur discontinued Augmentin and began Madelyn on Ceftriaxone treatment.

By January 24, 2008, Dr. Baur noted that Madelyn's otitis media, rash, fever, and cough had improved. Pet. Ex. 6, p. 41. He also noted that Madelyn had developed an allergy to Augmentin, but had "no other problems or concerns." *Id.*, p. 43. As of February 21, 2008, Madelyn had no fever, obvious ear pain, rhinitis, or cough. Her skin rash had resolved. *Id.*, p. 45.

¹¹ Prior to Madelyn's one year well child visit, she had received the following vaccines: Pediarix (which contains DTaP, hepatitis B, and polio vaccines), Hib, Prevnar, and RotaTeq at her two month well child visit on March 1, 2007 (Pet. Ex. 6, p. 13), and again at her four month well child visit on May 1, 2007 (*id.*, p. 15); and Pediarix, Prevnar, and RotaTeq at her six month well child visit on July 5, 2007 (*id.*, p. 19). She received an influenza vaccine at her nine month well child visit on October 1, 2007. Pet. Ex. 6, p. 23.

On February 24, 2008, and again on March 22, 2008, Madelyn presented to the Aurora Sheboygan Memorial Medical Center ["ASMMC"] with a fever and was diagnosed with an acute febrile illness. Pet. Ex. 6, pp. 47-48, 55-56.

b. The April 2008 Vaccinations.

On April 1, 2008, at her fifteen month well child visit, Dr. Baur observed that Madelyn was healthy and appeared well. However, he noted that she "[did] not use mama and dada specifically or say one word besides mama and dada so far." Pet. Ex. 6, p. 59. He also noted that her developmental screen was otherwise without delays and scheduled a more exhaustive assessment of her skills at eighteen months. *Id.* She received DTaP, Pevnar, and varicella vaccines during this visit.

On April 18, 2008, seventeen days after receiving this second set of allegedly causal vaccines, Madelyn was seen for a three day history of fever that reached 104.7°, and was diagnosed with a viral URI. Pet. Ex. 6, p. 65. At a follow up visit on May 8, 2008, petitioner reported that these symptoms eventually resolved. *Id.*, p. 68.

Petitioner called the pediatrician on May 7, 2008, concerned about Madelyn's hearing. Pet. Ex. 6, p. 67. She reported that Madelyn interacted well with her, but not with her dad, her brother, or other children. Doctor Baur referred Madelyn for an audiologic evaluation and reiterated his plan to reevaluate her at eighteen months. The next day, Madelyn presented with a history of fever for the past one and a half days with temperatures reaching 104.5°. *Id.*, p. 68.

2. May 2008 Hospitalization.

On May 9, 2008, more than one month after the April 2008 vaccinations, Madelyn was admitted to ASMMC for a 105° fever and a possible febrile seizure. Pet. Exs. 6, p. 70-71; 5, p. 142-43. Petitioner recalled that Madelyn had stiffed and thrown her head back, but had appeared relatively normal after the episode. She was diagnosed with febrile seizures and a urinary tract infection ["UTI"]. Pet. Ex. 6, p. 71. Madelyn was discharged, but admitted again several hours later after a second febrile seizure. She was assessed with right lower lobe pneumonia and a possible UTI or viral syndrome. Pet. Ex. 5, pp. 117-19.

Madelyn remained at ASMMC until May 12, 2008. While hospitalized, she suffered a third febrile seizure that lasted about five minutes, but within half an hour of receiving antipyretic medication, her "behavior and level of alertness returned to normal." Pet. Ex. 5, p. 121. A urine culture grew *Escherichia coli*, and the treating physician concluded that this infection might explain her prolonged fevers without other symptoms. *Id.*

Although Dr. Baur noted that Madelyn showed no signs of central nervous system infection, he transferred her to the Children's Hospital in Milwaukee for further evaluation. Pet. Ex. 5, p. 121. At Children's Hospital, she underwent a chest x-ray that

revealed mild pneumonia. Pet. Ex. 8, pp. 14, 18. She was also diagnosed with left vesicoureteral reflux¹² with enlarged kidneys (*id.*, pp. 64-65), UTI, and a kidney infection (Pet. Ex. 6, pp. 103-04). By May 14, 2008, Madelyn's temperature returned to normal, and her UTI and pyelonephritis¹³ had improved. Pet. Ex. 6, p. 96-97.

3. Evaluation and Treatment for Speech & Language Delay.

In early June 2008, Dr. Baur referred Madelyn for early childhood evaluations at the Sheboygan County Birth-to-Three Program to determine whether intervention services were necessary. Pet. Ex. 10, pp. 1-2. The test revealed delays in both her receptive and expressive language skills. In particular, Madelyn's functional weaknesses included "limited interaction with others, decreased participation in joint attention awareness activities" and inconsistency in imitating gestures, actions, sounds, and words. *Id.* After reviewing the results, Dr. Baur referred Madelyn for speech therapy through the Birth-to-Three Program to improve her language skills. *Id.*, p. 3.

Madelyn appeared for her eighteen month well child visit on July 15, 2008. Pet. Ex. 6, 118-19. The purpose of this visit was also to follow up on Madelyn's history of recurrent fevers.¹⁴ Doctor Baur noted that she suffered vesicoureteral reflux, hydronephrosis,¹⁵ and pyelonephritis, but otherwise appeared well. According to his report, Madelyn's scores on the Ages and Stages Questionnaire ["ASQ"] indicated speech delay, but "no behaviors suggested an autism spectrum disorder." *Id.* A routine audiologic evaluation six days later revealed that her hearing was quite good, but petitioner was concerned about Madelyn's limited vocabulary, in that only about four to five words that Madelyn uttered were truly coherent. *Id.*, p. 125.

4. Initial Concerns of Possible Autism.

On September 24, 2008, Dr. Baur reviewed the log from Madelyn's speech therapy, which stated: "Madelyn presents with decreased eye contacts, self-stim[ulating] behaviors, disregard for others in her surroundings, and with difficulties engaging in activity with other people. These behaviors appear to be possible characteristics of an autism spectrum disorder." Pet. Ex. 10, p. 9; *see also* Pet. Ex. 6, p. 132. Noting these concerns, Dr. Baur opted to continue therapy on a regular basis and stated that if "additional findings suggestive of possible autism spectrum disorder" emerged, he would refer Madelyn to a child development clinic. Pet. Ex. 6, p. 132.

¹² Vesicoureteral reflex is "the passage of urine from the bladder back into a ureter." DORLAND'S at 1616.

¹³ Pyelonephritis is the "inflammation of the kidney and renal pelvis because of bacterial infection." DORLAND'S at 1559.

¹⁴ Prior to this visit, Madelyn presented to her pediatrician on July 3, 2008, with fever and was diagnosed with likely viremia. Pet. Ex. 6, p. 108. The following week, she suffered from a series of intermittent low-grade fevers of unclear origin. *Id.*, pp. 110, 112, 114. Her temperature returned to normal by July 14, 2008. *Id.*, p. 116.

¹⁵ Hydronephrosis is the "distention of the pelvis and calices of the kidney with urine, as a result of obstruction of the ureter." DORLAND'S at 879.

About two months later on November 21, 2008,¹⁶ the speech therapist called Dr. Baur with concerns about Madelyn's behavior. Pet. Ex. 6, p. 157. The message reads: "Behavior concerns – fleeting eye contact – stares a lot – poor body awareness – rather play by self – overall disengaged – flat affect – delayed speech – imitates words off of toys and T.V., but slow to imitate people's speech – family concerned about possible autism." *Id.* The therapist also later noted that Madelyn continued to suffer either an ear infection or fever each week and that "[t]his may be affecting her speech and language skills." Pet. Ex. 10, p. 11.

B. Madelyn's Third Year.

This section reviews the progression of Madelyn's condition in her third year and the events leading up to her treatment for autism. Between her second and third birthdays, Madelyn suffered from recurrent infections and continued to exhibit developmental difficulties. During this period, she was diagnosed with autism and began undergoing treatment by DAN! physicians.

1. Events Leading to Autism Diagnosis.

At her two year well child visit on January 5, 2009, Dr. Baur noted that Madelyn had a known history of expressive language delay: she did not use two word combinations, consistently respond to her name or make eye contact, and only sometimes followed simple instructions. Pet. Ex. 6, pp. 164-65. He also noted that her results on the personal/social section of the ASQ were "between normal and concerning behaviors." *Id.* Based on his observation and tests, Dr. Baur referred Madelyn to the Child Development Clinic at Children's Hospital. *Id.*

On January 12, 2009, Madelyn was evaluated at Children's Hospital and diagnosed with a speech and language disorder or delay. Pet. Ex. 8, pp. 86-88. Clinical psychologist Robert L. Schum, Ph.D., noted that Madelyn "[did] not show the social distancing of an autistic-spectrum disorder. Her primary difficulty appears to be a speech-language disorder or delay." *Id.* He also added that she showed "many examples of communicative intent" and would continue to improve through participation in the Birth-to-Three program. *Id.*

On January 22, 2009, Madelyn was evaluated by Dr. Mark Simms, a developmental pediatrician. Pet. Ex. 8, pp. 91-93. Doctor Simms authored a letter on March 26, 2009, indicating that Madelyn had "a disorder of language development, normal non-verbal cognitive ability and a bifid uvula." *Id.*, p. 108. He described Madelyn's condition as the result of "congenital neurological disorder of brain function that likely has a genetic basis (her father was learning disabled as a child)" and concluded that her problems were "not 'developmental' in nature." *Id.* He also believed that there may be physical or structural issues with her uvula affecting her

¹⁶ Prior to this visit, Madelyn presented to Dr. Baur on November 13, 2008, for an influenza vaccine. Pet. Exs. 6, p. 155; 7, p. 2. She was not seen again until December 2, 2008, for a bilateral otitis media. Pet. Ex. 6, p. 158.

developmental problems.

Madelyn was diagnosed with autism on April 20, 2009, by Eric J. Lund, a clinical psychologist at the Wisconsin Early Autism Project, Inc. ["WEAP"]. Pet. Ex. 11, pp. 1-2. She scored between moderately and severely autistic; he recommended immediate intensive behavioral treatment. Petitioner notified Dr. Schum of the assessment and, while Dr. Schum encouraged therapy, he informed her that did not agree with the diagnosis. Pet. Ex. 8, p. 122.

Between January and May 2009, Madelyn presented to the pediatrician on four separate occasions for a number of illnesses, including bilateral otitis media, intermittent fevers, coughing, and vomiting.¹⁷ Pet. Ex. 6, pp. 170, 172, 174, 176.

2. Treatment by DAN! Physicians.

Doctor Schwartz began treating Madelyn for autism in May 2009. She underwent multiple laboratory studies, and was prescribed supplemental vitamins and probiotic therapy. Pet. Exs. 5, p. 165; 12 at 1. On July 1, 2009, Madelyn began seeing Dr. Gregory Brown at the Autism Recovery and Comprehensive Health Center. Doctor Brown performed a physical exam and ordered additional blood work. Pet. Exs. 5, p. 171; 16, at 1. Under his care, Madelyn received a number of dietary and nutritional therapies, as well as allergy immunotherapy. Pet. Ex. 16 at 2.

On August 17, 2009, Madelyn was evaluated at the University of Wisconsin American Family Children's Hospital and was assessed with "autistic features, substantial delay in her speech development," and questionable subclinical seizures.¹⁸ Pet. Ex. 14, p. 3. These records reflect that Madelyn had developed allergies to Augmentin, Amoxicillin, soy, casein, and gluten. *Id.*, p. 11.

Later in 2009, Madelyn was re-evaluated by Sheboygan County Birth-to-Three Program. According to the report, Madelyn had made impressive gains over the past year in her expressive and receptive language skills. Pet. Ex. 9, pp. 6-7. She occasionally responded to her name or a greeting, had about twenty words she used daily, and was beginning to imitate words. However, Madelyn continued to have difficulty interacting with others and was unable to follow novel directions. *Id.*

¹⁷ Madelyn received her second Hep A vaccine at her two year well child visit on January 5, 2009. Pet. Ex. 7, p. 2. She was not seen again until about a month later on February 2, 2009, for a two day history of rhinitis, cough, and fever. Pet. Ex. 6, p. 170. Doctor Baur diagnosed her with a viral URI.

¹⁸ According to the August 2009 records from Children's Hospital, petitioner was concerned that Madelyn had occasional starring episodes that lasted for a few seconds in which she would be non-responsive. Pet. Ex. 14, p. 2. A review of Madelyn's medical history did not reveal any prior history of starring episodes. Children's Hospital performed an electroencephalography ["EEG"] on Madelyn in early September 2009 to assess for possible subclinical epileptic seizures. The results of the EEG indicated no concerns. *Id.*, p. 8.

III. Evaluating Petitioner's Claim.

Under the Vaccine Act, petitioner may prevail on her claim by proving a "Table" injury, in which causation is presumed or, alternatively, by proving an "off-Table" injury, in which she identifies a causal link between the vaccine and the injury alleged. Because fever, febrile seizures, infections, or autism spectrum disorders are not Table injuries for any vaccine appearing on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2009), petitioner in this case must produce preponderant of evidence that a covered vaccine is responsible for Madelyn's injuries.

A. Legal Standard.

An "off-table" claim requires that petitioner establish by preponderant of evidence that a covered vaccine caused or significantly aggravated the injury claimed. § 11(c)(1)(C)(ii)(II). Petitioner need not show that the vaccinations were the sole cause, or even the predominant cause, of Madelyn's condition; showing that the vaccinations were a "substantial factor" and a "but for" cause of her injury are sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); see also *Pafford v. Sec'y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of the vaccination).

Although a petitioner cannot be 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," when petitioner files medical literature, a special master may weigh and evaluate that medical literature. When the filed literature fails to support the medical theory alleged, it can be an important factor in determining whether petitioner has met her burden to show vaccine causation. Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y, HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280; but see *Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

The Federal Circuit has set forth three factors petitioner must satisfy to prove causation in off-Table cases. *Althen* requires that petitioners provide: "(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." 418 F.3d 1274, 1278 (Fed. Cir. 2005). All three *Althen* factors must be satisfied to prevail on an off-Table claim.

The medical theory must be a reputable one, although it need only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. The Supreme Court's opinion in *Daubert v. Merrel Dow Pharmaceuticals, Inc.*, likewise

requires that courts determine expert opinions to be reliable before they may be considered as evidence. “In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Daubert*, 509 U.S. 579, 590 (1993) (citation omitted). The Federal Circuit has stated that a “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly v. Sec’y, HHS*, 592 F.3d 1315, 1324 (Fed. Cir. 2010).

B. Summary of Petitioner’s Theory of Causation.

Petitioner alleges that the hepatitis A, Hib, and MMR vaccines received on January 4, 2008, and the DTaP, Prevnar, and varicella vaccines administered on April 1, 2008, caused Madelyn to suffer from fever, febrile seizures, and urinary and kidney infections, the sequela of which was a pervasive development disorder. Petitioner’s treating expert, Dr. Brown, contends that because Madelyn had infections and febrile seizures after receiving the vaccines, these “immunological abnormalities” (see Pet. Ex. 16 at 2) and her developmental delays are vaccine related.

To explain Madelyn’s injuries, Dr. Brown opined that the January 2008 vaccines exacerbated her existing illness and increased her susceptibility to other infections. He also added that the April 2008 vaccines further compromised her immune system, resulting in fevers, febrile seizures, developmental problems in addition to food sensitivities and allergies. In support of his theory, Dr. Brown reasoned that the vaccines caused a decrease in Madelyn’s natural killer cells and an increase in her T-helper cells, producing a vaccine-over response. He believes that this condition impaired her immune system and left her vulnerable to further infection.

It is not clear from Dr. Brown’s report whether he believes that the vaccines caused Madelyn’s injuries or that Madelyn’s injuries were significantly aggravated by the vaccines.¹⁹ Petitioner did not assert and the record does not support a claim of significant aggravation, but nevertheless a brief analysis is provided below in section D.

C. Analysis of *Althen* Factors.

1. The Medical Theory Advanced is Unreliable.

The first prong of *Althen*’s three part causation test has been characterized as the equivalent of the “Can it cause?” inquiry used in toxic tort litigation. See *Pafford v. Sec’y, HHS*, No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff’d*, 64 Fed. Cl. 19 (2005), *aff’d*, 451 F.3d 1352 (Fed. Cir. 2006). Based on careful consideration of the evidence, I find nothing in Dr. Brown’s report or anything else in Madelyn’s record which provides a reliable medical theory of vaccine causation. Doctor

¹⁹ In his supplemental report, Dr. Brown reasoned that the January 2008 vaccines worsened Madelyn’s existing injuries, while later asserting that the same set of vaccines “started a chain of events.” Pet. Ex. 17 at 1. Additionally, Dr. Brown did not distinguish which injuries he believes the vaccines caused. He appeared to associate all of her resultant fevers and infections after the January 2008 visit with the vaccines.

Brown reached unsupported conclusions. He failed to provide any support for the proposition that vaccines can cause persistent immunological problems or that such persistent immunological problems can lead to developmental delays or autism. Additionally, the medical literature referenced by him provides little to no evidentiary support for petitioner's theory of causation as applied to Madelyn's situation.

Relying on some evidence that vaccines can cause broad T-cell responses, Dr. Brown concluded that Madelyn suffered from immunological abnormalities and that these abnormalities were the result of the vaccines she was administered.²⁰ However, the single study cited in Dr. Brown's supplemental report in no way indicates that the vaccines Madelyn received are causally associated with her infections. Although the paper suggests that there may be differences in cytokine profiles induced by different vaccines, none of the vaccines addressed are ones at issue in this case.²¹ Even presuming certain biochemical similarities between the vaccines discussed and the ones Madelyn received, the sample size examined in the study is too small to draw any statistically significant conclusions. See S. De Rosa, et al., *Vaccination in humans generates broad T cell cytokine responses*, 173 J. IMMUNOL, 5378, 5380 (2004). I also find no support for Dr. Brown's theory that Madelyn's purported "vaccine-over and under-responses"²² symbolize an immune system compromised by vaccine administration. This conclusion has no support in any medical record or scientific literature, nor has Dr. Brown provided any.

Even if I accepted Dr. Brown's theory that the vaccines aggravated Madelyn's infections and caused her fevers and febrile seizures, the evidence is insufficient to show that fevers and brief febrile seizures caused her developmental problems. Doctor Brown did not support his conclusion with any medical theory. He stated that he is not qualified to make a diagnosis of autism and thus, it is unlikely that he is qualified to opine that vaccines can cause it. In summary, petitioner's evidence does not support Dr. Brown's assertion that the vaccines administered on January 2008 and/or April 2008 are causally linked to Madelyn's alleged autism.

2. Lack of Logical Connection.

The second prong of *Althen*, the requirement for a logical sequence of cause and effect between the vaccine and the injury, has been characterized as addressing the "Did it cause?" or specific causation query. See *Pafford v. Sec'y, HHS*, No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19

²⁰ Doctor Brown's opinion largely relies on Madelyn's medical records and the parental history, rather than his own clinical assessment. He was not Madelyn's treating physician at the onset of her injury and had only seen Madelyn on a total of five occasions when he authored his note. See Pet. Ex. 16 at 1.

²¹ The study cited in Dr. Brown's supplemental report examines the immune responses to two vaccines: hepatitis B and tetanus, neither of which is relevant to this case. See 173 J. IMMUNOL, 5372-73.

²² Doctor Brown did not specify what immunological tests showed such responses. Based on the ARCH medical records submitted to the court, Dr. Brown ordered blood tests on July 18, 2009. Pet. Ex. 13, pp. 19-26. The results are discussed, *supra*, n. 9.

(2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). In other words, even if vaccines can cause the injury alleged, petitioner must show that they did so in Madelyn's case.

I am not persuaded by petitioner's claim that the vaccines led to fever, febrile seizures, and urinary tract and kidney infections. Madelyn's medical records suggest that her seizures were induced instead by fevers associated with previously diagnosed URI or viral infections. See, e.g., Pet. Exs. 5, pp. 114-16; 6, pp. 96-97; 8, p. 73. Moreover, the physicians who diagnosed and treated Madelyn's febrile seizures and urinary and kidney infections did not attribute them to vaccines. See Pet. Exs. 5, pp. 142-44; 6, pp. 70-82. Instead, Dr. Simms, a development pediatrician, ascribed her language problems to a congenital neurological disorder of brain function. The only mention in the medical records of a possible causal connection between Madelyn's injuries and the vaccines originated with petitioner. See, e.g., Pet. Ex. 6, pp. 16, 61.

Additionally, the theory advanced by Dr. Brown is not supported by the facts of this case. While his opinion suggests that Madelyn was not symptomatic prior to her one year, her records indicate that she began exhibiting medical issues, including fevers, months prior to receiving the January 2008 vaccines. Petitioner described fevers every one to two weeks in April 2007, and reported similar concerns in May 2007 and again in November 2007. Pet. Ex. 6, pp. 14, 16, 24. Because Madelyn had recurrent fevers prior to the allegedly causal vaccines, I find it unlikely that the vaccines caused the fevers that followed weeks or months later.

Assuming, *arguendo*, that the vaccines could have caused Madelyn's fevers, febrile seizures, and infections, there is little in the record except for Dr. Brown's unsupported opinion to connect those injuries to Madelyn's subsequent developmental problems. In fact, Dr. Simms asserts that Madelyn's condition was the result of a "congenital neurological disorder of brain function that likely has a genetic basis (her father was learning disabled as a child)." Pet. Ex. 8, p. 108.

Although "the Vaccine Act does not require [a] petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case," a petitioner "may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient." *Walther v. Sec'y of HHS*, 485 F.3d 1146, 1149-50 (Fed. Cir. 2007) (citing *Pafford*, 451 F.3d at 1359). As reflected in her medical record, Madelyn began exhibiting recurrent infections and fevers prior to receiving the alleged causal vaccines and there is a likely genetic basis for her developmental delay. Thus, I find that it is improbable that the vaccines caused Madelyn's injuries.

3. Proximate Temporal Relationship.

The third *Althen* factor requires that petitioner establish that Madelyn's injury occurred within a time frame that is medically appropriate for the alleged mechanism of harm. See *Pafford*, 451 F.3d at 1358. However, merely showing a proximate temporal connection between a vaccination and an injury is insufficient, standing alone, to

establish causation. *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A proximate temporal relationship, even when coupled with the absence of any other identified cause for the injury, is not enough to demonstrate probable cause under the Vaccine Act's preponderance standard. *Moberly*, 592 F.3d at 1323 (citing *Althen*, 418 F.3d at 1278). Doctor Brown did not identify any specific medically appropriate timeframe between the January 2008 and/or April 2008 vaccines and the onset of Madelyn's developmental delay, which occurred during the time in a child's development in which autism's early symptoms often manifest. See *White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011).

D. Significant Aggravation.

To establish a claim for significant aggravation, petitioner must establish the combined causation factors identified in *Whitecotton v. Sec'y, HHS*, 81 F.3d 1099 (Fed. Cir. 1996) and *Althen. Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053 at *40 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd*, 91 Fed. Cl. 126 (2010). Therefore, to prevail on a significant aggravation claim, petitioner must establish by preponderant evidence that: (1) the vaccinee's condition prior to administration of the vaccine; (2) the vaccinee's current condition or condition following the vaccine; (3) whether the comparison of the two conditions constitutes a significant aggravation of the person's condition; (4) a medical theory causally connecting a significantly worsened condition to the vaccine; (5) a logical sequence of cause and effect demonstrating that the vaccine was the reason for the significant aggravation; and (6) a proximate temporal relationship between the vaccine and the significant aggravation. *Loving v. Sec'y, HHS*, 86 Fed. Cl. 135, 144 (2009).

In most off-Table significant aggravation cases, it may be more logical to consider the last three *Althen* factors first. *Hennessey*, No. 01-190V, 2009 WL 1709053 at *1. If the evidence does not establish that a vaccine can significantly aggravate a condition, it does not matter whether Madelyn was worse after the vaccine than she was before, because petitioner has failed to show that the vaccine could or did cause the worsening. In this case, petitioner's claim for significant aggravation has the same deficiencies as her current petition for vaccine-related causation. No reliable medical theory was advanced to explain how the vaccines could have significantly aggravated Madelyn's condition.

IV. Conclusion.

Petitioner has failed to produce preponderant evidence that vaccines are responsible for Madelyn's condition, and has thus failed to demonstrate entitlement to compensation. **Her petition is therefore dismissed. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/Denise K. Vowell

Denise K. Vowell

Special Master