

For the reasons discussed more fully below, the undersigned hereby **DENIES** petitioner’s Third Motion for Decision and **DISMISSES** this case for insufficient proof.

I. BACKGROUND

A. Petitioner’s Claim for Program Compensation

On May 25, 2010, Kay Waddell (“petitioner”) filed a petition on behalf of her minor son, Hayden, seeking compensation under the National Vaccine Injury Compensation Program (“the Program”).²

In the first of two petitions filed in this case, petitioner alleged that Hayden was injured as a result of the vaccines he received during his twelve-month well-child examination on May 29, 2007 – namely, the measles, mumps, and rubella (“MMR”), pneumococcal conjugate (“PCV”) and haemophilus influenza type B (“Hib”) vaccines. Pet. at 1. Petitioner asserted that Hayden experienced a “vaccine[-]induced encephalopathy,” with “features of autism, alternating constipation and diarrhea, weakened immune system, loss of speech, inability to make eye contact, failure to respond to name[,], and loss of muscle tone.” *Id.* Petitioner claimed that Hayden’s vaccine-related injuries were either “caused-in-fact” or significantly aggravated by the vaccines he received. *Id.*

Months before his receipt of the May 2007 vaccines, Hayden received a diagnosis of, and subsequent corrective surgery for, his craniosynostosis – a condition caused by a premature closing of the skull. See Pet’r’s Ex. 1 at 20, 35; see also Dorland’s Illustrated Medical Dictionary 428 (32nd ed. 2012). The condition is characterized by an abnormally shaped head. Robert M. Kliegman et al., Nelson Textbook of Pediatrics 2011 (19th ed. 2011). Hayden’s parents aggressively sought treatment for him, and he reportedly recovered successfully. See Pet’r’s Ex. 3 at 131.

B. Respondent’s Rule 4 Report

On August 19, 2010, respondent filed a Rule 4 report, recommending against a Program award of compensation.

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act”). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

Respondent challenged the evidentiary support for petitioner's claim, pointing out that the assertions in petitioner's affidavit are contradicted by the filed medical records and physicians' notes. Rule 4 Report at 9-10. Respondent added that none of Hayden's treating physicians has linked his sustained injuries to the received vaccines. Id. at 10.

C. The Fact Hearing

To resolve the parties' disagreement about the nature and scope of Hayden's symptoms after his receipt of the May 2007 vaccines, the undersigned conducted a fact hearing in Anchorage, Alaska on November 19, 2010. Hayden's family and friends testified regarding the events leading up to, during, and following Hayden's receipt of the vaccines. See Tr. of Proceedings, Nov. 19, 2010.

The parties did not dispute that after receiving the vaccines, Hayden developed a rash, fever, and diarrhea, as well as constipation that lasted from one to two weeks. Fact Ruling at 12. What the parties did dispute was the suddenness and severity of Hayden's symptom onset. Id. at 13-14.

Petitioner testified that "immediately following" the vaccines, Hayden was fussier than usual, extremely irritable, and did not readily take his bottle. Id. at 10 (citing Tr. at 70-71) (describing Hayden as "[e]xtremely fussy, crying, [and] inconsolable"). Hayden's father related that Hayden was fussy and "lying around" – but not screaming. Id. at 11 (citing Tr. at 119-20).

Petitioner and others described Hayden's loss of verbal, motor, and social skills in the weeks following his vaccinations. Ms. Waddell testified that she noticed, within a week of Hayden's receipt of the May 2007 vaccines, a decrease in his verbal as well as motor skills. Id. at 10 (citing Tr. at 76-77). Hayden spoke some words before his receipt of the vaccines, but after his vaccinations, his language consisted mostly of gibberish.³ See id. at 9, 11. Ms. Waddell related

³ Hayden's older brother, Jaycen, testified that before his vaccinations, Hayden could say approximately fifty to sixty words, but after the vaccines, he could only speak a few words that mostly consisted of gibberish. Fact Ruling at 9 (citing Tr. at 42).

Hayden's father agreed that Hayden communicated using babble and gibberish after his receipt of the vaccines, but he estimated that Hayden only spoke fifteen to twenty words before his vaccinations. Id. at 11 (citing Tr. at 124-26).

that Hayden did not recover his motor skills until a few months later, at fifteen to eighteen months of age. *Id.* at 10 (citing Tr. at 101-02).

A number of witnesses also testified about Hayden's loss of social skills following his vaccinations, giving accounts of Hayden's unresponsive and withdrawn nature, as well as his failure to make eye contact. *See, e.g., id.* at 7 (citing Tr. at 12) ("[H]e was 'a lot less interactive' . . . and not 'as willing to smile or make eye contact' as he had been . . . prior to May 29, 2007."); *id.* (citing Tr. at 19) ("[H]e seemed 'very withdrawn and very quiet,' 'did not communicate or look at . . . [anyone],' and 'seemed sort of oblivious.'"); *id.* at 8 (citing Tr. at 30) ("He was less interactive and less playful."); *id.* at 10 (citing Tr. at 83) ("He became unresponsive and did not want to play with his toys.").

Considering the record as a whole, the undersigned found "the testimony regarding the rapid progression of [Hayden's] alleged loss of language, the abrupt change in [his] social interaction, and the sudden loss of [his] gross motor skills [during] the two weeks following the May 29, 2007 vaccinations . . . difficult to credit." *Id.* at 17 (emphasis added).

D. The Undersigned's Fact Ruling

The undersigned issued, on July 29, 2011, and re-issued with redaction, on August 5, 2011, a Ruling Regarding Factual Findings ("Ruling").

The undersigned was not persuaded, in the absence of corroborating medical records, that Hayden exhibited symptoms following his vaccinations that were either as severe or as abrupt in appearance as the witnesses described at hearing. *Id.* at 17-18. In addition, the Waddells acknowledged that Hayden's symptoms did not appear to be grave enough to warrant emergent medical attention in the weeks following his vaccinations. *See, e.g., id.* at 11 (citing Tr. at 121) (deciding that "there was no reason to go to the doctor"); *id.* at 14 (citing Tr. at 108) (explaining that "those were [the] reactions [petitioner] was told [Hayden] might get").

Moreover, both the medical records and the testifying witnesses established that when the Waddells did seek care for Hayden, seven months later at his nineteen-month well-child examination, they did not report any concerns regarding significant changes in Hayden's appearance or behavior. *See* Pet'r's Ex. 1 at 10; *see also* Fact Ruling at 20, Findings of Fact 19. Nor do the records from that pediatric office visit include any mention of a lingering rash or fever, or the sudden loss of either Hayden's language or social skills during the preceding months. Pet'r's Ex. 1 at 10.

Petitioner explained that her decision not to seek medical treatment for Hayden in the seven months after vaccination was influenced by her prior experience caring for her older children and the complexity of insurance coverage for emergency room admissions. Fact Ruling at 14 (citing Tr. at 73-74). However, because Hayden’s medical records show that his parents promptly sought treatment for those medical issues of genuine concern, the undersigned found it difficult to reconcile Ms. Waddell’s willingness to wait seven months to seek medical care for Hayden with her account of Hayden’s severe and sudden onset of symptoms after his vaccinations.⁴ Id. at 17-18.

Based on the record as a whole, the undersigned found that Hayden was described as a “happy and responsive child prior to his May 29, 2007 vaccination,” id. at 19, Finding of Fact 10, but that shortly after receiving the vaccines, he became “fussy, crabby, and would not smile,” id. at 20, Finding of Fact 13. Hayden also experienced diarrhea and would not take his bottle readily. Id., Finding of Fact 14. Four to five days after his vaccinations, Hayden developed a fever that “measured between 104 to 104.5 degrees Fahrenheit,” as well as a rash that was “light red in coloration.” Id., Finding of Fact 16.

Although petitioner had not alleged an injury on the Vaccine Injury Table (“Table”) prior to the issuance of the Ruling, the undersigned noted that the record, as it stood, did not appear to support either petitioner’s allegation that Hayden “experienced an encephalopathy within the requisite time period provided on the Table,” or “the requirements [for] an encephalopathy as set forth in the Qualifications and Aids to [Interpretation of the Table].” Id. at 2. See also Vaccine Injury Table, § 14, as amended by 42 C.F.R. § 100.3.

E. Opportunities Afforded to Petitioner for the Identification of Other Theories of Causation

On August 3, 2011, the undersigned conducted a status conference to discuss further proceedings in light of the issued Ruling.

The undersigned again observed that the “factual record evince[d] no evidence that a Vaccine Table Injury ha[d] occurred.” Order, Aug. 8, 2011, at 1. The undersigned also questioned the “reasonableness of proceeding with an [off-

⁴ Specifically, the undersigned found it difficult to reconcile Ms. Waddell’s “willingness to seek medical treatment [for Hayden’s cold symptoms] within the month that he received his vaccines” with her subsequent “unwillingness to seek treatment for the alleged striking changes that occurred two weeks after [Hayden’s] vaccinations.” Id. at 18.

Table] encephalopathy claim” because Hayden’s symptom presentation after vaccination, as documented, comported more closely with the onset of autism than with a vaccine-related encephalopathy. Id.

During the status conference, the undersigned afforded petitioner “the option of proceeding . . . as if the [claim] were formerly part of the [Omnibus Autism Proceedings] (OAP).” Id. The undersigned explained that as part of the coordinated proceeding known as the OAP, six “test cases” were tried under two theories that alleged causation between the administration of certain vaccines and the subsequent development of an autistic spectrum disorder (“ASD”), or autism.⁵ Id. at 1-2. At the conclusion of the proceeding, the three special masters assigned to hear the test cases ruled that there was no reliable evidence demonstrating that vaccines caused ASDs on the theories presented. Id. at 2.

The undersigned advised that if petitioner elected to proceed with her claim, she would have to present previously unconsidered evidence or a theory of causation distinguishable from those which were considered and rejected in the OAP test cases.⁶ Id.

After the status conference, petitioner requested and received two enlargements of time for the filing of an amended petition. See NON-PDF Order, Sept. 7, 2011; NON-PDF Order, Nov. 7, 2011. On petitioner’s third request for

⁵ The term “autism” is used broadly to refer to ASDs. Hazlehurst v. Sec’y of Health & Human Servs., No. 3-654V, 2009 WL 332306, at *19 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (citing Cedillo v. Sec’y of Health & Human Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009)).

Unless otherwise specified in this decision, the undersigned uses the terms “autism” and “ASD” interchangeably.

⁶ The first group of three test cases were tried under a theory that a combination of MMR and thimerosal-containing vaccines cause ASDs. See Hazlehurst, 2009 WL 332306; Cedillo, 2009 WL 331968; Snyder v. Sec’y of Health & Human Servs., No. 1-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

The second group of three test cases presented the theory that thimerosal-containing vaccines alone can cause ASDs. See Dwyer v. Sec’y of Health & Human Servs., No. 3-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); King v. Sec’y of Health & Human Servs., No. 3-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); Mead v. Sec’y of Health & Human Servs., No. 3-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

additional time to identify the theory of vaccine causation on which she intended to proceed, see Pet'r's Status Report and Mot. for Enlargement of Time, Jan. 26, 2012, the undersigned directed petitioner's counsel to file not only an amended petition, but also a supportive expert report, see Order, Jan. 27, 2012, at 2.

On March 27, 2012, petitioner filed an amended petition, effectively re-asserting her earlier claim that Hayden suffered a "vaccine[-]induced encephalopathy."⁷ Am. Pet. at 1. Petitioner maintained that Hayden's vaccine-related injuries were either "caused-in-fact" or significantly aggravated by the vaccines he received. Id. Noting that Hayden was being evaluated for an underlying metabolic disorder, petitioner claimed that metabolic disorders are "known to increase inflammatory response[s]" and thereby "increase the risk of an adverse reaction to vaccinations, including MMR." Id. at 2.

Once petitioner filed the amended petition, the undersigned issued an order reiterating that the deadline of May 29, 2012, previously established for the filing of the expert report, remained in place. NON-PDF Order, Mar. 27, 2012.

F. Petitioner's Motions for Decision on the Record

On May 7, 2012, petitioner filed a Motion for a Decision on the Record, advising that she did not plan "to provide additional evidence in support of her claim." First Mot. for Decision at 1.

The undersigned directed petitioner to provide specific record citations, including exhibit and page numbers, as well as any statements, diagnoses, and conclusions made by Hayden's various medical providers, that were supportive of petitioner's claim. Order, May 8, 2012, at 1. The undersigned further directed petitioner to explain in her motion how the administered vaccines could, and did, cause Hayden's alleged vaccine-related injuries. Id.

Two days later, petitioner re-filed the motion. The motion was filed improperly using Hayden's initials, rather than his full name, in the caption of filing.⁸ See Second Mot. for Decision; see also Order, May 14, 2012 (noting the

⁷ Compare Pet. at 1 (alleging a number of injuries, to include that of a "vaccine[-]induced encephalopathy"), with Am. Pet. at 1 (alleging as the only injury a "vaccine[-]induced encephalopathy").

⁸ Although a petitioner is able to request that a child's initials – rather than the minor's full name – appear in the case caption, petitioner did not make such a request. See Vaccine Rule 16(b) (providing that captions for filings made on behalf of a minor may be amended to include only the minor's initials).

improper filing).

On May 14, 2012, petitioner filed a corrected copy of the motion. This third motion supersedes the first two.

In her Third Motion for Decision, petitioner alleges that she has “satisfie[d] the criteria for a ‘Table’ encephalopathy after [a] MMR vaccine” and respectfully requests a ruling on the record in her favor.⁹ Third Mot. for Decision at 10.

Petitioner identifies a number of facts as supportive of her claim. In particular, petitioner points to Hayden’s “normal” development prior to his receipt of the May 2007 vaccines,¹⁰ *id.* at 9, Fact 3, his “significant illness” after his receipt of the MMR vaccine,¹¹ *id.* at 2, 9, Fact 4, the decrease in Hayden’s social and verbal skills during the seven-month period between the vaccinations and his nineteen-month well-child examination,¹² *id.* at 9-10, Facts 3, 5-6, and the “differential diagnosis” of encephalopathy documented in Hayden’s medical records,¹³ *id.* at 10, Fact 7.

G. Response to Petitioner’s Motion for Decision

⁹ Without further explanation, petitioner appears to have abandoned any theory of causation involving metabolic disorders. *See, e.g.*, Am. Pet. at 2.

¹⁰ Petitioner contends that Hayden neither experienced side effects from his prior surgery nor had any issues socializing prior to his receipt of the vaccines. Third Mot. for Decision at 9, Facts 1-2.

¹¹ Petitioner indicates that Hayden suffered diarrhea, exhibited fussiness, and developed a high fever approximately four to five days after he received his MMR vaccine. *See id.*, Fact 4.

¹² Petitioner compared Hayden’s ability to speak seven words as of the date of his receipt of the May 2007 vaccines, to his ability to speak only two words at the time of his next well-child examination in January of 2008. *Id.* at 9-10, Facts 5-6.

¹³ Hayden received a pediatric neurodevelopmental evaluation in May of 2008. At that time, he was assessed with a “static encephalopathy” based on evidence of a “chronic, non-progressive [neuromotor] dysfunction” that manifested as developmental and behavioral disorders. Pet’r’s Ex. 8 at 393. Another evaluator, who examined Hayden two months later in July of 2008, similarly concluded that Hayden’s “pattern of development [was] consistent with [a] static encephalopathy or autism.” Pet’r’s Ex. 12 at 545.

By response dated May 22, 2012 (“Response”), respondent urged the undersigned to dismiss petitioner’s claim.

Respondent asserts that petitioner has not met her burden of proof that Hayden suffered a MMR-induced encephalopathy, as defined by the Table, see Resp. at 6-9, and observes that petitioner could not, and did not, submit an expert opinion supporting an off-Table claim, see id. at 9-10. Respondent adds that none of Hayden’s treating physicians attributed his condition to the May 2007 vaccines he received. Id.

H. Petitioner’s Reply in Support of her Motion for Decision

On June 1, 2012, petitioner filed a reply (“Reply”), insisting that sufficient evidence exists “to find that Hayden Waddell suffers from a vaccine-induced encephalopathy.” Reply at 1. Petitioner contends that “[a]utistic children usually do not have neurological abnormalities consistent with [a] differential diagnosis of static encephalopathy.” Id. at 2.

II. LEGAL STANDARD

To receive compensation under the Vaccine Act, petitioner must demonstrate that either: (1) Hayden suffered a “Table injury” by receiving a covered vaccine and developing, within the appropriate time period, an injury listed on the Vaccine Injury Table; or (2) Hayden suffered an “off-Table injury” caused by the covered vaccine. Compare § 14(a), as amended by 42 C.F.R. § 100.3, with § 11(c)(1)(C)(ii)(I); see also Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).

If petitioner can establish that Hayden suffered a Table injury, she benefits from a statutorily-prescribed, rebuttable presumption of causation. See § 14(a). Otherwise, petitioner must show that the received vaccines were not only a substantial factor in causing his alleged injury, but also that such injury would not have occurred but for the received vaccines. See Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999)).

To prove an off-Table claim, petitioner must establish: (1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a proximate temporal relationship between the vaccination and the injury. Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

III. DISCUSSION

A. A MMR-Induced Encephalopathy, as Defined by the Table

A vaccine recipient is deemed to have suffered a Table injury if the criteria set forth in the Table and the accompanying Qualifications and Aids to Interpretation (“QAI”) are satisfied. See § 14.

To establish a MMR-induced encephalopathy as defined by the Table, the vaccine recipient must have manifested, within five to fifteen days after receiving a MMR vaccine, an injury that meets the definition of an acute encephalopathy. 42 C.F.R. § 100.3(b)(2). The vaccine recipient also must have manifested an injury that meets the definition of a chronic encephalopathy for more than six months after the vaccination. *Id.* The QAI set forth criteria for an encephalopathy in children less than 18 months of age that differ from the criteria for older children or adults. Because Hayden was less than 18 months old during the period of time in question, the undersigned looks to the criteria that pertain to his age group.

1. The Severity of the Symptoms Associated with an Acute Encephalopathy

The symptoms associated with an acute encephalopathy are neither subtle nor insidious.¹⁴ As informed by the guidance in the Table and the accompanying QAI, an acute encephalopathy is characterized by certain severe symptoms that persist for a prescribed period of time after vaccination.

As amended by 42 C.F.R. § 100.3(b), the QAI provide:

¹⁴ Cases within the Program have described the symptoms associated with a Table encephalopathy as “dramatic.” See Jay v. Sec’y of Health & Human Servs., 998 F.2d 979, 981 (Fed. Cir. 1993) (citing the special master’s observation that “[w]ith [a Table] encephalopathy we have typically seen at least one dramatic aspect [, which] is what separates the events from a normal range [of vaccine] reactions”) (emphasis added). But see Spangler v. Sec’y of Health & Human Servs., No. 90-1526V, 1992 WL 59181, at *9 (Cl. Ct. Spec. Mstr. Feb. 28, 1992) (allowing that the injured vaccinee had a congenitally “disordered brain” that was described in her medical records as an encephalopathy, and that “she did not manifest any of the dramatic symptoms listed in the statutory aids to diagnosing [a Table] encephalopathy,” but finding entitlement based on the vaccinee’s expert’s testimony, her altered state of consciousness, and her seizures – which at that time were recognized as a table injury) (emphasis added).

- (i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
 - (A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. . . .
 -
 - (D) A “significantly decreased level of consciousness” is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . :
 - (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
 - (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
 - (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).
 - (E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle

42 C.F.R. § 100.3(b)(2).

The factors for consideration in determining whether petitioner has established a Table encephalopathy are addressed in turn.

(a) The Hospitalization Requirement

The associated symptoms must be “sufficiently severe” to require hospitalization regardless of whether hospitalization actually occurs. Id. at § 100.3(b)(2). The hospitalization requirement underscores how serious the symptom presentation must be after vaccination to merit classification as a Table

encephalopathy. See Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,685, 7,687 (Feb. 20, 1997) (preamble to final rule) (“[W]e did not intend that hospitalization be viewed as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event.”).

The hospitalization requirement reserves the presumption of entitlement for those circumstances that are serious enough to warrant emergent medical intervention. See Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,678, 7,681 (Feb. 8, 1995) (preamble to final rule) (stating that the definition of encephalopathy contained within the original statute specifically excludes “minor symptoms” such as excessive crying and sleepiness).

(b) A “Significantly Decreased Level of Consciousness”

For children less than eighteen months of age who do not present with an associated seizure event, the QAI state that clinical signs of a “significantly decreased level of consciousness,” lasting for at least twenty-four hours, are indicative of an acute encephalopathy. 42 C.F.R. § 100.3(b)(2)(i)(A).

A “significantly decreased level of consciousness” refers to a state of diminished alertness that is much more than mere sleepiness or inattentiveness. Instead, this reduced level of consciousness requires markedly impaired – or strikingly absent – responsiveness to environmental or external stimuli for a sustained period of at least twenty-four hours.¹⁵

According to the QAI, a vaccine recipient must exhibit a level of unresponsiveness so grave that he “responds, if at all, only to [a] loud voice or painful stimuli” and “does not recognize familiar people or things.” Id. at § 100.3(b)(2)(i)(D)(1), -(3). Moreover, his eye contact must be so diminished or lacking that he “does not fix gaze upon family members or other individuals.” Id. at §100.3(b)(2)(i)(D)(2). See also Robert Ball, et al., Development of Case Definitions for Acute Encephalopathy, Encephalitis, and Multiple Sclerosis Reports to the Vaccine Adverse Event Reporting System, 55 J. Clin.

¹⁵ A measurement of electrical activity in the brain by electroencephalography (“EEG”) can inform whether an acute encephalopathy has occurred. See, e.g., § 14(b)(3)(A) (“Encephalopathy usually can be documented by slow wave activity on an encephalogram.”); Bruesewitz v. Sec’y of Health & Human Servs., No. 95-266V, 2002 WL 31965744, at *12 (Fed. Cl. Spec. Mstr. Dec. 20, 2002) (“If [the vaccine recipient] had an acute encephalopathy, one would see other changes on her EEG: sleep patterns would be grossly distorted, voltages would be remarkably low, the slowing would be diffuse.”).

Epidemiology 819, 824 (2002) (defining an encephalopathy using the same indicia that define a “significantly decreased level of consciousness” under the Table).

The Table’s indicia of an encephalopathy are consistent with the clinical signs used to diagnose an encephalopathy. Among the altered states of consciousness associated with an encephalopathy are states of: (1) increased consciousness, which can present as delirium; and (2) decreased consciousness, which can present as lethargy, obtundation, stupor, or coma.¹⁶ Romano v. Sec’y of Health & Human Servs., No. 90-1423V, 1993 WL 472879, at *6 (Fed. Cl. Spec. Mstr. Nov. 1, 1993) (citing Gerald M. Fenichel, Clinical Pediatric Neurology 42 (1st ed. 1988)). “Regardless of whether the altered consciousness of [an] encephalopathy begins with excitability or lethargy, it ends with stupor or coma.” Id.

Consistent with her authority to promulgate regulations that modify the Vaccine Injury Table, see 42 U.S.C. § 300aa-14(c), the Secretary of the Health and Human Services incorporated the clinical signs of an encephalopathy into the QAI to “clearly distinguish infants and children with brain dysfunction from those with transient ‘lethargy.’” Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7,687. By focusing on the severity, as well as duration, of the changes in behavior after vaccination, the QAI criteria-- as revised from the initial Table--differentiate between the “diminished alertness and motor activity[] which characterize [a] lethargic infant or child” and the “more serious impairment of consciousness that is the hallmark of encephalopathy (i.e., obtundation, stupor and coma).” Id. See also supra note 16 (outlining the medical definitions of lethargy, obtundation, stupor, and coma).

The QAI, as amended, also identify a number of clinical features that, without more, fail to indicate a significant change in one’s level of consciousness.

¹⁶ The medical definitions of the four states of decreased consciousness speak to the quality of symptoms required to establish an encephalopathy.

According to Dorland’s Illustrated Medical Dictionary, the state of “lethargy” is marked by “listlessness, drowsiness, and apathy.” See Dorland’s at 1025. The state of “obtundation” is characterized by “mental blunting with mild to moderate reduction in alertness and a diminished sense of pain.” Id. at 1310. The state of “stupor” is associated with “greatly reduced responsiveness, inattentiveness to the environment, and inaction” and responsiveness “only to vigorous stimulation.” Id. at 1789. The state of “coma” occurs at a level of “unconsciousness from which the patient cannot be aroused, even by powerful stimulation.” Id. at 390.

These features include sleepiness, irritability (or fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and a bulging fontanelle. 42 C.F.R. § 100.3(b)(2)(i)(E). See Gamache v. Sec’y of Health & Human Servs., 27 Fed. Cl. 639, 642 (1993) (affirming the dismissal of a Table encephalopathy claim and referencing the special master’s conclusion that “[u]nder the statute, screaming and crying in and of themselves are not conclusive evidence of encephalopathy. [The vaccinee’s] high-pitched and unusual screaming and inconsolable crying are explainable as a local, systemic reaction to the DPT vaccine rather than as indicia of encephalopathy”); Watt v. Sec’y of Health & Human Servs., No. 99-25V, 2001 WL 166636, at *8 (Fed. Cl. Spec. Mstr. Jan. 26, 2001) (crediting, as consistent with the Table definition of an acute encephalopathy, expert testimony explaining that “the [V]accine [T]able makes some distinctions about [an] encephalopathy, . . . say[ing] that it cannot merely be . . . inconsolable crying . . . [and] it cannot merely be crankiness”) (emphasis added).

In the absence of a specific indication to the contrary, words used in the statute will be given their common, ordinary and accepted meaning, and the plain language of the statute will be afforded its plain meaning. See 2A Sutherland Statutory Construction § 46:1 (7th ed. 2007); see also Turner v. Sec’y of Health & Human Servs., No. 99-544V, 2007 WL 4410030, at *4 (Fed. Cl. Spec. Mstr. Nov. 30, 2007) (quoting same). Because the terms “significantly,” “decreased,” and “consciousness” are not defined in the pertinent regulations, the undersigned affords each term its ordinary meaning as instructed by the canons of statutory construction. The MacMillan Dictionary defines the term “significantly” to be “easily noticeable” or “relevant;” the term “decreased” to be the state of “becom[ing] less;” and the term “consciousness” to be “the state of being awake and able to hear, see, and think.” Definitions of Significantly, Decreased, Consciousness, MacMillan Dictionary, available at www.macmillandictionary.com (last visited July 10, 2012). Accordingly, as defined, a “significantly decreased level of consciousness” must be a meaningfully diminished state of awareness or alertness.

If petitioner can make the requisite showing to establish that an acute encephalopathy has occurred, petitioner must also show that a chronic encephalopathy ensued, before the presumption of vaccine-related causation afforded by the Table can attach.

2. The Persistence of the Symptoms Associated with a Chronic Encephalopathy

Petitioner must prove that effects from the initial acute event have persisted for a period of six months beyond the date of vaccination. 42 C.F.R.

§ 100.3(b)(2).

The six-month persistence requirement again underscores – like the hospitalization requirement for an acute encephalopathy – how serious the initial presenting symptoms must be. As defined by the Table, a chronic encephalopathy develops when the initial acute event leads to residual neurologic deficits. See Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7,687 (“It is expected that any child or adult with a chronic encephalopathy as a result of a vaccine-related acute encephalopathy would show evidence of abnormalities in mental or neurological status in the days to weeks following the vaccination.”). See also Estep v. Sec’y of Health & Human Servs., 28 Fed. Cl. 664, 667 (1993) (noting the agreement of the parties’ respective experts that “most things that can cause acute encephalopathies can also cause chronic encephalopathies”).

As further explained in the QAI, a chronic encephalopathy occurs “when a change in mental or neurologic status, [that] first manifested during the applicable time period [set forth in the Table], persists for a period of at least six months from the date of vaccination.” Id. at § 100.3(b)(2)(ii). Residual neurologic deficits in infants or children present as “a loss or slowing of developmental milestones during [the] time period following the acute event.” Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7,687-88.

The QAI counsel that if preponderant evidence establishes that the vaccine recipient’s chronic encephalopathy either is “caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma,” or “secondary” to “genetic, prenatal or perinatal factors,” then such “chronic encephalopathy shall not be considered to be a condition set forth in the Table.” 42 C.F.R. § 100.3(b)(2)(ii)-(iii). See also Doe v. Sec’y of Health & Human Servs., 19 Cl. Ct. 439, 451 n.17 (1990) (reasoning that an encephalopathy of unknown origin does not entitle a petitioner to compensation if the vaccine-relatedness of the condition is at issue).

B. Petitioner Has Not Met Her Burden of Proving a Table Injury of MMR-Induced Encephalopathy

Petitioner claims that Hayden suffered a “significantly decreased level of consciousness” within fifteen days of his MMR vaccination. Third Mot. for Decision at 9. Petitioner also claims that Hayden’s symptoms “persisted for over 6 months after the initial presentation.” Id.

In determining whether Hayden suffered a Table encephalopathy, the undersigned must “consider the entire medical record.” 42 C.F.R. § 100.3(b). The record here does not show that Hayden’s symptoms after vaccination rose to the

level of an acute encephalopathy, as defined by the Table and the accompanying QAI.

Petitioner expressed grave concerns at the hearing about Hayden's presentation and change in behavior after he received the May 2007 vaccines. But her described alarm did not prompt her to seek medical treatment for Hayden until seven months later. Petitioner's refusal to seek treatment more urgently strongly suggests that Hayden's symptoms were not as striking – either in severity or duration – as petitioner later recalled. Moreover, when petitioner next saw the pediatrician with Hayden, the purpose of the office visit was a well-child examination and not to address symptoms of concern alleged to have developed in the weeks following Hayden's twelve-month vaccines. The striking inconsistency between petitioner's contemporaneous conduct and her later-recalled testimony significantly diminishes the likelihood that Hayden experienced abrupt and severe symptoms within two weeks of receiving the May 2007 vaccines.

Even if the undersigned were to credit petitioner's hearing testimony over the contemporaneous medical records, a number of the symptoms she described are not characteristic of an acute encephalopathy, as defined by the Table and the accompanying QAI. In particular, Hayden's loss of skills in the verbal, motor, and social domains does not constitute the type of "significantly decreased level of consciousness" contemplated by the Table. Certainly in this case, Hayden's lack of responsiveness did not translate into a lack of consciousness. See Gerald M. Fenichel, Clinical Pediatric Neurology 47 (3rd ed. 1997) (explaining that a lack of responsiveness is not always caused by lack of consciousness); Romano, 1993 WL 472879, at *6 ("[W]ith certain non-encephalopathic conditions, a child may be non-responsive, but fully alert nonetheless.").

In addition, Hayden's undisputed symptoms of fever, rash, diarrhea and fussiness in the weeks after his vaccines are insufficient, without more, to support a finding that an acute encephalopathy occurred. The mere presence of these symptoms – within the five to fifteen day period after vaccination – does not demonstrate the type of markedly diminished change in mental status required to establish a Table encephalopathic injury. As the QAI inform, symptoms of sleepiness and irritability – whether they occur alone or in combination – are not conclusive proof of an acute encephalopathy in the absence of a meaningfully diminished state of awareness and alertness. See 42 C.F.R. § 100.3(b)(2)(i)(E).

The contemporaneous medical records provide no evidence that Hayden suffered an acute encephalopathy in the days after his MMR vaccination. Because petitioner has not shown that Hayden experienced an acute encephalopathy, as defined by the Table and the accompanying QAI, her Table claim must fail, and without evidence of an acute encephalopathy, the undersigned need not reach the

question of whether a chronic encephalopathy developed.

C. Hayden's Symptoms Following Vaccination Are Consistent with the Onset of Autism

Evidence that Hayden suffered a MMR-induced Table encephalopathy is lacking. The presentation of Hayden's symptoms was, however, characteristic of the onset of autism.

In her Reply, petitioner asserted that “[a]utistic children usually do not have neurological abnormalities [that are] consistent with [a] differential diagnosis of static encephalopathy.” Reply at 2. But petitioner fails to make the proper distinction between a Table encephalopathy, which is presumed to be vaccine-related if it timely presents with the requisite symptom severity, and the neurodevelopmental condition of autism, a medical encephalopathy known to have a strong genetic underpinning but not causally linked by scientifically reliable evidence to the MMR vaccine. See Hazlehurst, 2009 WL 332306, at *31.

1. The Hallmarks of Autism

The hallmarks of autism include impairments in the three domains of: (1) social interaction; (2) communication; and (3) developmentally appropriate behavior, interests, or activities. See Kliegman et al., supra, at 100-01 (citing to the DSM-IV-TR Diagnostic Criteria used to identify an autistic disorder).

Impairments in the development of social skills and ability to engage in reciprocal social interaction are characteristic symptoms of an ASD. See id. at 100. Early social deficits can include, among other things, marked impairments in the use of nonverbal behaviors such as eye contact, a failure to develop peer relationships appropriate to developmental level, and an impaired ability to engage in reciprocal social or emotional interaction. Id. at 101 (citing to the DSM-IV-TR Diagnostic Criteria used to identify an autistic disorder).

The manifestation of the verbal impairment associated with an ASD varies. Id. at 100. Early abnormal language concerns can include, among other things, a delay in the development of social language, as well as any loss of language or social skills at any time. Id. at 100-01 (citing to the DSM-IV-TR Diagnostic Criteria used to identify an autistic disorder).

Impairments in the domain of behavior are generally characterized by ritualistic behavior and rigidity, restrictive or repetitive interests and activities, and preoccupation with parts of objects. Id.

The symptoms associated with autism often present gradually. Typically, for children with ASDs, the symptoms have been present for weeks or months before parents report them to healthcare providers. Cook v. Sec’y of Health & Human Servs., No. 3-2355V, 2012 WL 664766, at *5 (Fed. Cl. Spec. Mstr. Feb. 18, 2012) (citing Cedillo, 2009 WL 331968). Because the symptom development of an ASD occurs very gradually, it is not uncommon for parents to be unable to pinpoint the date of onset very precisely. Id.

Petitioner’s decision to wait seven months to seek medical care for Hayden, and Hayden’s father’s testimony that his problems became more apparent after a period of time, provide strong, preponderant evidence that Hayden began to manifest the symptoms of autism gradually, rather than precipitously. See Fact Ruling at 12 (citing Tr. at 127) (“Mr. Waddell testified that . . . as time went on, the couple began to realize ‘there’s something wrong here.’”) (emphasis added). Moreover, the medical treatment sought for Hayden after his May 2007 vaccines was not for emergency purposes, but rather for a regularly scheduled well-child examination.

2. Autism is, by Medical Definition, an Encephalopathy, but Its Most Typical Presenting Symptoms Do Not Meet the Statutorily Defined Characteristics of a Table Encephalopathy

The medical term “encephalopathy” is defined very generally as “any disorder of the brain.” Stedman’s Medical Dictionary 636 (28th ed. 2006). The term characterizes a “constellation of signs and symptoms reflecting a generalized disturbance in brain function.” Kathleen Stratton et al., Inst. of Med., Adverse Events Associated with Childhood Vaccines 48 (1994).

An encephalopathy may be either “acute or chronic.” See Kliegman et al., supra, at 2061. In its “acute” form, the encephalopathy is marked by “a short and relatively severe course.” Dorland’s at 24. Contrastingly, in its “chronic” form, the encephalopathy is recognized to have “persist[ed] over a long period of time.” See id. at 358.

An encephalopathy may also be “progressive or static.” See Kliegman et al., supra, at 2061. When “progressive,” the condition is “advancing” and “increasing in scope or severity.” See id. at 1523. But when “static,” the condition is “at rest” or “not dynamic.” See id. at 1767. By definition, an encephalopathy is static if its “manifestations do not worsen over time.” Dorland’s at 615.

The scope of the medical term “encephalopathy” is more expansive than the

narrower, statutory definition set forth in the Table.¹⁷ The broader medical term “encephalopathy” properly encompasses the condition of autism as a “generalized disturbance in brain function.”

Petitioner’s assertion that that Hayden received a “differential diagnosis that included encephalopathy,” more than a year after his receipt of the MMR vaccine, Third Mot. for Decision at 10, Fact 7, does not bolster petitioner’s claim. As learned during the Omnibus Autism Proceedings, autistic persons have been found--when examined on autopsy--to have a characteristic pattern of disordered brain architecture. Hazlehurst, 2009 WL 332306, at **26-29. A structurally disordered brain is properly defined as an injured brain and thus, as a medical encephalopathy. But, absent proper proof, the mere existence of a medical encephalopathy is not dispositive of whether a vaccine-induced encephalopathy has occurred.

Hayden presented after his May 2007 vaccines with symptoms that are characteristic of autism. See e.g., Pet’r’s Ex. 12 at 545 (“Hayden’s pattern of development is consistent with [a] static encephalopathy or autism”) (emphasis added). Eventually he was diagnosed with the condition. His diagnosis, described as an encephalopathy, is well-documented. See Pet’r’s Ex. 8 at 392-93; Pet’r’s Ex. 12 at 545 (noting diagnostic impressions of static encephalopathy and

¹⁷ Cases within the Program have drawn a distinction between the broad, medical meaning of the term “encephalopathy” and the more stringent, statutory definition of encephalopathy set forth in the Table. Compare Agarwal v. Sec’y of Health & Human Servs., 33 Fed. Cl. 482, 484, 487-88 (1995) (recognizing the vaccine recipient’s history of mental retardation as a medical, but not a statutory, encephalopathy), and Spangler, 1992 WL 59181, at *7 (both parties’ experts defining an “encephalopathy” as “disordered or abnormal brain function”), with Perez v. Sec’y of Health & Human Servs., No. 00-328V, 2003 WL 431593, at *5 (Fed. Cl. Spec. Mstr. Jan. 14, 2003) (drawing a distinction between the specific, legal definition of encephalopathy and the broader, “medically appropriate definition” of encephalopathy).

“evidence of chronic, non-progressive brain dysfunction”).¹⁸

Hayden’s first pediatric neurodevelopmental evaluation occurred on May 28, 2008. He was noted to have “delayed and somewhat ‘atypical’ communication skills, accompanying social impairments, and a restricted repertoire of solitary, self-directed play, activity and behavior, which is at this time consistent with [a]utism.” Pet’r’s Ex. 8 at 392 (emphasis in original). During a second evaluation two months later, the examiner noted that the therapy for Hayden should focus on “social development and language.” Pet’r’s Ex. 12 at 545.

Although the record is clear that Hayden suffered from the medical encephalopathy of autism, it does not establish that he suffered from a Vaccine Injury Table encephalopathy. On the contrary, the evidence concerning Hayden’s early symptoms of autism does not meet the statutorily defined characteristics of a severe and sudden onset of symptoms that distinguish a Table encephalopathy.

D. Nor Has Petitioner Presented Adequate Support for an Off-Table Claim

Because petitioner has not met her burden of showing that Hayden suffered an alleged Table injury, she is not entitled to a statutorily-prescribed presumption of causation. See § 14(a). To prevail on an off-Table claim, petitioner must prove that Hayden’s receipt of the MMR vaccine caused his autism. See § 11(c)(1)(C)(ii)(I).

In evaluating a claim for Program compensation, the representations of petitioner alone cannot be accepted. Rather, a vaccine claim must be documented by either the medical records or a qualified expert. See § 13(a)(1). Here, the medical records demonstrate that Hayden experienced developmental problems several months after his vaccinations, but Hayden’s treaters do not attribute his autism to his receipt of the MMR vaccine. Nor has petitioner filed an expert

¹⁸ Of note, Hayden’s autism would not be defined as a chronic encephalopathy under the Table because his neurologic deficit is very likely “secondary” to genetic factors. The pertinent section of the QAI provides that if an encephalopathy is brought about by other causes, such as genetic disorders, metabolic disturbances, structural lesions, or trauma, then the condition cannot be appropriately considered a chronic encephalopathy under the Table. See 42 C.F.R. § 100.3(b)(2)(ii)-(iii). As referenced earlier in this Decision and as explained during the OAP, the specific cause for most cases of autism is unknown, but there is a wealth of reliable evidence that the condition is a strongly genetic one. Hazlehurst, 2009 WL 332306, at *31.

opinion supportive of her claim of vaccine-related causation.

Without evidence that the MMR vaccine caused Hayden's autism, petitioner's off-Table claim must also fail.

IV. CONCLUSION

Petitioner has not met her burden of demonstrating that Hayden suffered the Table injury of a MMR-induced encephalopathy. Nor has petitioner shown that the MMR vaccine caused Hayden's autism.

For the foregoing reasons, the undersigned **DENIES** petitioner's Third Motion for Decision and **DISMISSES** the claim for insufficient proof. The clerk shall enter **JUDGMENT** accordingly.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Chief Special Master