# In the United States Court of Federal Claims

No. 05-01063
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| JOHN A. MURPHY AND BARBARA E. MURPHY, parents of M.M., a minor<br><br>Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | ) | National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa–1 to –34 (2012); Vaccine Rule 23; Diphtheria-Tetanus-Acellular Pertussis Vaccine; Measles, Mumps And Rubella Vaccine. |

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**MEMORANDUM OPINION AND ORDER**

GRIGGSBY, Judge

## I. INTRODUCTION

Petitioners, John A. Murphy and Barbara E. Murphy, parents of M.M., a minor child, seek review of the April 25, 2016, decision of the special master denying their claim for compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa–1 to –34 (2012). Petitioners allege that their minor child suffered an encephalopathy,

[*] This Memorandum Opinion and Order was originally filed under seal on August 15, 2016 (docket entry no. 126). The parties were given an opportunity to advise the Court of their views with respect to what information, if any, should be redacted. The parties filed a joint status report on September 15, 2016, in which petitioners request one redaction and respondent takes no position with regard to the proposed redaction (docket entry no. 128). The Court adopts petitioners' proposed redaction. Accordingly, the Court is reissuing its Memorandum Opinion and Order dated August 15, 2016, with the redaction indicated by three consecutive asterisks within brackets ([***]).

resulting in developmental regression, as the result of the diphtheria-tetanus-acellular pertussis ("DTaP") and measles, mumps and rubella ("MMR") vaccinations that he received on October 14, 2002. For the reasons set forth below, the Court **DENIES** petitioners' motion for review and **SUSTAINS** the decision of the special master.

## II. FACTUAL AND PROCEDURAL BACKGROUND[1]

### A. Factual Background

The medical history of petitioners' son, M.M., is discussed in detail in the special master's April 25, 2016, decision ("Special Master's Decision") and can be briefly summarized here. *Murphy v. Sec'y of Health & Human Servs.*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Apr. 25, 2016). M.M. was born on [***], 2001, and on May 21, 2001, M.M. was assessed as a well child with jaundice. *Id*. at *1. Today, M.M. is developmentally delayed in a number of respects. *Id*. at *3. In this action, petitioners allege that the DTaP and MMR vaccines that M.M. received on October 14, 2002, at approximately 17 months of age, caused an encephalopathy and resulted in M.M.'s developmental regression. *See generally* Pet. Mot.

In the first 16 months of his life, M.M. received several immunizations, including three DTaP vaccinations. Dec. at *1 n.5, 2. During this time, M.M.'s doctors did not note any major health issues.[2] *Id.* On October 14, 2002, at 17 months of age, M.M. returned to the pediatrician, where he received his fourth DTaP vaccination and his first MMR vaccination. *Id*. at *2. M.M.'s medical records from that visit indicate that M.M. was a well child. *Id*.

Four days later, on October 18, 2002, petitioners brought M.M. back to his pediatrician. *Id*. at *3. Mrs. Murphy testified that M.M. had developed a rash on his chest and neck after his vaccinations, as well as a fever. Pet. Memo. at 2-5; Tr. at 54-58. The history section from the

[1] The facts recounted in this Memorandum Opinion and Order are taken from the special master's April 25, 2016, decision in *Murphy v. Sec'y of Health & Human Servs.*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Apr. 25, 2016) ("Dec."); the transcript of the entitlement hearing before the special master held on May 18-19, 2015 ("Tr."); petitioners' motion for review, as amended ("Pet. Mot."); petitioners' memorandum of objections ("Pet. Memo."); the exhibits to petitioners' motion for review ("Pet. Ex."); and respondent's response to petitioners' motion for review ("Resp. Brief"). Except where otherwise noted, the facts recited here are undisputed.

[2] Prior to the October 14, 2002, doctor's visit, M.M. had been seen by the pediatrician for a number of minor health issues, including upper respiratory infections, eczema, ear infections, concerns about food allergies and a head injury. *See* Pet. Ex. 4 at 17-32.

medical record of this visit provides that, after M.M. received the vaccinations on October 14, 2002, he began exhibiting symptoms including high-pitched screaming, intermittent fever, and pulling on his ears. Pet. Ex. 4 at 15; Pet. Memo. at 6. Under the phrase "Reason for Visit," M.M.'s pediatrician wrote "?OM," noting concern about a possible "Otitis Media," or ear infection. Pet. Ex. 4 at 15; *see also* Dec. at *3. The physical examination during this visit found M.M. to be fussy, but did not note any other concerns. Dec. at *3; Pet. Ex. 4 at 15. The parties dispute whether M.M. also presented with a rash during this visit. *See*, *e.g.*, Pet. Mot. at 6, 12-13; Resp. Brief at 7.

M.M. visited the pediatrician again in December 2002 and May 2003, but the pediatrician did not note any major changes in M.M.'s behavior during these visits. Dec. at *3; Pet. Ex. 4 at 13-14. During a regular well child checkup on June 6, 2003, M.M.'s pediatrician noted concern about a language delay for the first time. Dec. at *3.

On October 20, 2005, Dr. Mary Megson, a developmental pediatrician, examined M.M. to evaluate his language delay. *Id*. at *5. In her notes from this visit, Dr. Megson observed that since M.M.'s October 14, 2002, vaccinations, he "gradually lost language" and his "fine motor skills decreased." Pet. Expert Report, Ex. 10.1 at 3, Dec. 17, 2014. She also noted that M.M. had been diagnosed with developmental delay, dyspraxia, apraxia and displayed "features of autism." Dec. at *5. Dr. Megson saw M.M. on several more occasions and eventually diagnosed M.M. with vaccine-related encephalopathy." *Id.* at *11.

On June 8, 2009, M.M. was seen by Dr. Andrew Zimmerman at the Kennedy Krieger Institute for a magnetic resonance imaging consultation. Dec. at *5. Dr. Zimmerman's medical report from that day provides that M.M. was "an 8-year-old male who was previously healthy and developing well until October 2002, when 4 hours after receiving multiple vaccines he developed dilated pupils, drooling, high pitched squeals, facial droop, decreased pain sensitivity, and stereotyped movements thought secondary to vaccine-related encephalopathy versus autism spectrum disorder." *Id.* at *6; Pet. Ex. 3 at 5. During the entitlement hearing, Dr. Zimmerman admitted that his diagnosis of "vaccine related encephalopathy with apraxia and features of autism" was based upon M.M.'s medical history as reported to him by Dr. Scott Schultz, an attending physician at the Kennedy Krieger Institute who obtained this medical history from M.M.'s parents. Dec. at *16; Tr. 259. Dr. Zimmerman's medical report from this visit

recommends "chromosome and microarray testing, DNA fragile X and checking for mitochondrial disorders, in view of [M.M.'s] history." Pet. Ex. 3 at 5. Dr. Zimmerman also suggested that the Murphys bring in prior laboratory work during future visits or fax the laboratory work to the neurology clinic office during this visit. *Id.*; *see also* Pet. Memo. at 10; *see* Tr. at 265. No tests were ordered for M.M. at the time of M.M.'s first visit. Dec. at *6; Pet. Memo. at 10. In addition, although Dr. Zimmerman subsequently treated M.M. on two more occasions–September 21, 2009 and June 24, 2010, he did not revisit the possibility of genetic and metabolic testing. Dec. at *6.

**B. The Special Master's Decision**

On April 25, 2016, the special master issued a decision denying petitioners' claim for compensation under the Vaccine Act. *See generally* Dec. In the decision, the special master determined that petitioners' on-Table and causation-in-fact claims should be denied, because petitioners did not establish that the vaccines M.M. received had a causal connection to his developmental regression, or that the DTaP and MMR vaccines could produce the kind of developmental regression and symptoms that M.M. has experienced. *Id.* at *39.

First, the special master determined that the evidentiary record before the Court did not show that M.M. experienced an on-Table encephalopathy. *Id.* at *31. In this regard, the special master found that M.M.'s reaction and symptoms after receiving the DTaP and MMR vaccines in October 2002 did not constitute an encephalopathy as defined by the Vaccine Injury Table's qualifications and aids to interpretation ("QAI"). *Id.* Specifically, the special master found that the DTaP and MMR vaccinations M.M. received in October 2002 were not followed by any "identifiable, measurable, severe reaction of the kind that would constitute an acute encephalopathy." *Id.* The special master also determined that, at best, petitioners established M.M. had experienced some "transient symptoms" post-vaccination that were not severe enough to require hospitalization. *Id.* In this regard, the special master observed that the QAI "specifically indicates that symptoms such as those now alleged by the Murphys, including '[s]leepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle' are insufficient, standing alone or in combination, to demonstrate an acute encephalopathy." *Id.* at *32.

The special master also found that the contemporaneous medical records from this time did not demonstrate that M.M. experienced symptoms "suggesting any immediate encephalopathic reaction." *Id.* (citation omitted). The special master further found that, even if he accepted petitioners argument that M.M.'s medical records from the time period following the vaccination are sparse due to the fact that petitioners were dissuaded by M.M.'s pediatrician from seeking medical treatment, there was no evidence in the evidentiary record from the time period after the October 14, 2002, vaccinations to show that M.M. was experiencing "a persistent 'change in mental or neurologic status'" that would constitute a chronic encephalopathy. *Id*. at *32 (quoting 42 C.F.R. § 100.3(b)(2)(ii)).

In addition, the special master determined that petitioners did not satisfy the *Althen* prongs in bringing their causation-in-fact claim. *Id*. at *33; *see Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). With respect to the first prong under *Althen*, the special master determined that the medical theories put forth by petitioners–that the pertussis toxin could interact with proteins in the body, causing oxidative stress and leading to an encephalopathy or that the tetanus toxin's interaction with M.M.'s G proteins led to an encephalopathy that caused developmental regression–were "facially and structurally weak." Dec. at *33. With regard to the pertussis toxin theory, the special master determined that "[s]ignificant links in the theory chain were missing or proved unreliable, given the disconnect between the theoretical proposition stated and the evidence offered to support it." *Id*. With regard to the tetanus toxin theory, the special master observed that petitioners did not offer direct evidentiary support to establish that the MMR or DTaP vaccines could interact in a harmful manner with the G protein, or to establish that either of these vaccines could play a role in developmental regression. *Id*.

The special master also found that petitioners' theory that a brain injury could occur as a result of the passage of vaccine components through the blood-brain barrier to be without reliable evidentiary support. *Id*. The special master also observed that Dr. Megson "does not specialize in the study of degenerative encephalopathies precipitated by oxidative stress or other genetic causes." *Id.* And so, the special master concluded that Dr. Megson lacked the qualifications necessary to offer persuasive expert testimony in support of petitioners' causation theories. *Id*. at *33-34.

The special master also found that petitioners did not satisfy the second prong of *Althen*, because they failed to show that the vaccines at issue can cause developmental regression. *Id*. at *34. In this regard, the special master determined that petitioners did not established, by preponderant evidence, that the MMR and DTaP vaccines caused M.M.'s developmental problems, either directly or indirectly. *Id*. Rather, the special master determined that the evidence suggested that any loss of skills or language that M.M. suffered "began long after, and independent of, the October 2002 vaccinations." *Id*. The special master also noted that the evidence of a decline in M.M.'s developmental or physiologic state after the October 2002 vaccinations was minimal, and that there was no evidence suggesting that M.M. had a developmental problem before June 2003–approximately eight months after the October 2002 vaccinations. *Id*. at *32, 34-35. And so, the special master concluded that the onset of M.M.'s developmental regression was "too distant in time from the vaccination date to constitute a dramatic or sudden change produced by encephalopathy." *Id*.

The special master similarly found that petitioners did not satisfy *Althen*'s third prong, which requires that petitioners demonstrate a medically reasonable time frame for the onset of symptoms after the vaccinations. *Id*. at *35. Specifically, the special master determined that M.M.'s medical records show that M.M. displayed no symptoms of developmental regression until June 2003−eight months after the subject vaccinations. *Id*. The special master also found that petitioners' claims that M.M. experienced an immediate behavioral or developmental change in October 2002 were rebutted by contemporaneous medical records, including the records of M.M.'s December 2002 pediatric visit. *Id*. In addition, the special master determined that Dr. Megson did not offer any testimony or medical literature to suggest a medically plausible timeframe for her causation theory. *Id*. Given this, the special master concluded that there was no evidentiary support to demonstrate that the vaccines had the temporal effect on M.M. that is alleged by petitioners in this action. *Id*. And so, the special master determined petitioners had failed to meet their burden to prove a Table encephalopathy, or to prove causation-in-fact under *Althen*.

Petitioners, alleging error, seek review of the Special Master's Decision.

### C. Procedural Background

The relevant procedural history is set forth in the Special Master's Decision. In short, on October 4, 2005, petitioners filed a petition for vaccine compensation on behalf of M.M. under the Vaccine Act. Dec. at *1. On May 18-19, 2015, following the submission of medical records and expert reports, the special master convened an entitlement hearing. *Id*. at *2. During the hearing, John and Barbara Murphy, Dr. Andrew W. Zimmerman and petitioners' medical expert, Dr. Mary Megson, testified on behalf of the petitioners, and the government's medical expert, Dr. Max Wiznitzer, testified on behalf of the respondent. S*ee generally* Tr. On April 25, 2016, the special master issued a decision denying petitioners' request for compensation. *See generally* Dec.

On May 25, 2016, petitioners filed a motion for review of the Special Master's Decision. *See generally* Pet. Mot. On May 31, 2016, the Court issued an Order directing petitioners to file an amended motion for review that complies with Rule 24 of the Rules of the United States Court of Federal Claims. *See generally* Scheduling Order, May 31, 2016. On June 2, 2016, petitioners filed an amended motion for review. *See generally* Pet. Mot. The government filed a response to petitioners' motion for review on July 5, 2016. *See generally* Resp. Brief. Petitioners' motion for review having been fully briefed, the Court resolves the pending motion.

## III. STANDARDS FOR DECISION

### A. Standard Of Review

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2).

The special master's determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master's findings of fact are reviewed for clear error. *Id.*; *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious."). In addition, a special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are "supported by substantial evidence." *Doe v. Sec'y of Health & Human Servs*., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citation omitted); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"). This "level of deference is especially apt in a case in which the medical evidence of causation is in dispute." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). And so, the Court will not substitute its judgment for that of the special master "if the special master has considered all relevant factors, and has made no clear error of judgment." *Lonergan v. Sec'y of Health & Human Servs.*, 27 Fed. Cl. 579, 580 (1993).

**B. Vaccine Injury Claims**

Pursuant to the Vaccine Act, the Court shall award compensation if a petitioner proves, by a preponderance of the evidence, all of the elements set forth in 42 U.S.C. § 300aa–11(c)(1), unless there is a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table ("Table"), or by proving causation-in-fact. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C); *Althen*, 418 F.3d at 1278. And so, to receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either that: (1) the petitioner suffered a "Table Injury" that corresponds to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) the petitioner's illnesses were actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa–13(a)(1)(A), 300aa–11(c)(1)(C)(i-ii), 300aa–14(a); *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).

In Table and non-Table cases, a petitioner bears a "preponderance of the evidence" burden of proof. 42 U.S.C. §§ 300aa–13(a)(1)(A); *Althen*, 418 F.3d at 1278 (citing *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). And so, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (holding that mere conjecture or speculation is insufficient under a preponderance standard).

When a Table Injury claim is successfully established, causation is presumed. 42 C.F.R. § 100.3. To prove a Table Injury, petitioners must show that "the first symptom or manifestation of the onset . . . of any such illness, disability, injury, or condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." *Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995) (quoting 42 U.S.C. § 300aa–11(c)(1)(C)(i)).

To establish a *prima facie* case when proceeding on a causation-in-fact theory, as petitioners also seek to do in this matter, a petitioner must "prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface*, 165 F.3d at 1352. "[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show 'a medical theory causally connecting the vaccination and the injury.'" *Id.* at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (*per curiam*)). In other words, "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury,'" *id.* at 1353 (quoting *Grant*, 956 F.2d at 1148), and "[t]his 'logical sequence of cause and effect' must be supported by a sound and reliable medical or scientific explanation." *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994) (quoting *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 984 (Fed. Cir. 1993)); *see also* 42 U.S.C. § 300aa–13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."). However, medical or scientific certainty is not required. *Knudsen*, 35 F.3d at 548-49.

In *Althen*, the Federal Circuit addressed the three elements that a petitioner must provide to prove causation-in-fact:

> (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.

*Althen*, 418 F.3d at 1278. All three prongs "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In addition, if a petitioner establishes a *prima facie* case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa–13(a)(1)(B); *Shalala*, 514 U.S. at 270-71. But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case. *See Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, 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.").

**C. Encephalopathy**

The Vaccine Injury Table identifies an encephalopathy as one of the illnesses, disabilities, injuries, or conditions that may result from the DTaP or MMR vaccinations. 42 C.F.R. § 100.3. The Table defines an encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." 42 U.S.C. § 300aa–14(b)(3)(A). According to the Table's qualifications and aids to interpretation, an individual is considered to have suffered a Table encephalopathy if he or she "manifests, within the applicable period, an injury meeting the description . . . of an acute encephalopathy, and then a chronic

encephalopathy persists in such person for more than 6 months beyond the date of vaccination." [3] 42 C.F.R. § 100.3(b)(2). For a child less than 18 months of age who did not experience an associated seizure event, an acute encephalopathy is "indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). The QAI explains that "sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle," presented either individually or alone, do not demonstrate that an acute encephalopathy has occurred. 42 C.F.R. § 100.3(b)(2)(i)(E).

The QAI also defines a chronic encephalopathy to be "a change in mental or neurologic status, first manifested during the applicable time period, [and that] persists for a period of at least 6 months from the date of vaccination." 42 C.F.R. § 100.3(b)(2)(ii). Individuals who "return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy." *Id*. Moreover, "[i]f a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table." *Id*. Similarly, "[a]n encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known)." 42 C.F.R. § 100.3(b)(2)(iii).

## IV. LEGAL ANALYSIS

Petitioners enumerate several objections to the special master's decision. *See generally* Pet. Memo. First, petitioners argue that the special master erred in finding that M.M.'s October 18, 2002, visit to the pediatrician was due to an ear infection. *Id.* at 2, 5. Second, petitioners argue the special master also erred in determining that petitioners failed to file medical literature to support the testimony of their medical expert. *Id.* at 7. Third, petitioners contend that the

[3] The "appropriate time period" varies based upon which vaccine allegedly caused the encephalopathy. The Table specifies that the appropriate time period for an acute encephalopathy to manifest after a DTaP vaccination is within 72 hours after the vaccine is administered, while the appropriate time period with respect to the MMR vaccine is within five to fifteen days after vaccination. 42 C.F.R. § 100.3(a).

special master made several errors with regard to how he considered and weighed the testimony of Dr. Zimmerman. *Id.* at 8, 14-15. Finally, petitioners argue that the special master erred in finding that M.M. did not suffer a chronic encephalopathy. *Id.* at 8.

The government counters that the special master's decision to deny compensation in this case is reasonable, in accordance with law and supported by the record evidence. *See generally* Resp. Brief. For the reasons discussed below, the Court agrees. And so, the Court **SUSTAINS** the decision of the special master.

### A. The Special Master Did Not Err In Finding That M.M.'s October 18, 2002, Doctor's Visit Was Due To An Ear Infection

As an initial matter, the record evidence demonstrates that the special master properly determined that M.M. visited his pediatrician on October 18, 2002, due to an ear infection. The Court reviews the special master's findings of fact on this issue for clear error. *Andreu*, 569 F.3d at 1373.

In his decision, the special master determined that M.M. visited the pediatrician on October 18, 2002, "because of concerns that [M.M.] had an ear infection." Dec. at *3. The special master based this finding upon the medical records for this visit which show that the pediatrician wrote "?OM"–meaning otitis media, or ear infection–under the section of the records designated as "Reason for Visit." *Id*. at *3 (citing Not. Of Filing Medical Records, Ex. 2 at 15, Nov. 10, 2009). The special master also considered Mrs. Murphy's testimony during the entitlement hearing, in which she testified that M.M. presented with a rash during this visit. *Id*. at *3, 7 n.20; Tr. 54-58, 129-30. The special master determined, however, that the medical records for this visit did not support Mrs. Murphy's testimony. *Id*. at *7 n.20; *see also* Pet. Ex. 4 at 15.

This Court has long recognized that when witness testimony conflicts with contemporaneous medical records, the Court may accord such testimony little weight. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)) (explaining that "oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); *see also Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952, 958 (Fed. Cir. 2011) (holding that when medical records and testimony are "inconsistent, a special master may give greater weight to the

medical records"). And so, here, the special master found that the probative value of M.M's contemporaneous medical records outweighed Mrs. Murphy's testimony that the October 18, 2002, visit was due to a rash. Dec. at *3. Given the conflict between the relevant medical records and Mrs. Murphy's testimony, the special master also appropriately acted within his discretion in giving more weight to M.M.'s contemporaneous medical records than to the testimony of Mrs. Murphy. And so, the Court will not disturb the finding of the special master. *See Cucuras*, 993 F.2d at 1528 (holding that the special master's reliance on contemporaneous medical records over conflicting oral testimony given after the fact was not arbitrary or capricious); *see also Burns*, 3 F.3d at 417 (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master").

The Court will also not disturb the special master's factual finding that M.M. did not present with a rash during the October 18, 2002, visit. In their motion for review, petitioners contend that the letter "e," which they allege appears next to the word "rash" in the records for this visit indicates that a rash was present and evaluated by the pediatrician. *Id*.; *see* Pet. Ex. 4 at 15. But, as discussed above, the medical records for this visit show that the reason for the visit was a possible ear infection. Pet. Ex. 4 at 15. In addition, petitioners do not point to any evidence or testimony to support their contention that the medical records also show that a rash was evaluated or observed by the pediatrician during this visit. *See generally* Pet. Mot.; Pet. Memo. And so, the Court cannot draw a reasonable inference from the relevant medical records that M.M. actually presented with a rash during the October 18, 2002, visit.[4]

### B. The Special Master Properly Found That Petitioners Did Not Submit Medical Literature On Glutathione

The special master similarly did not err in finding that the medical literature submitted by petitioners to support the testimony of their medical expert failed to show how children with developmental disabilities possess lower levels of glutathione. In the decision, the special master

[4] It is also important to note that, even if M.M. did present with a rash during the October 18, 2002, doctor's visit, such a symptom is not indicative of an acute encephalopathy. *See Waddell v. Sec'y of Health & Human Servs.*, No. 10-316V, 2012 WL 4829291, at *10 (Fed. Cl. Spec. Mstr. Sept. 19, 2012) (finding that symptoms of a fever, rash, diarrhea and fussiness following the child's vaccinations, without more, were insufficient to support a finding of an acute encephalopathy). And so, petitioners also fail to show how the special master's alleged error would have changed the outcome of this case.

observed that petitioners' medical expert, Dr. Megson, relied upon certain medical studies in her testimony that were not included in the medical literature filed in the case. Dec. at *14 n.41. In particular, the special master noted that medical studies authored by Jill James and Dr. Richard Deth, that purportedly support Dr. Megson's testimony that children with developmental disabilities possess lower levels of glutathione, were not filed with the Court. *Id.*; *see also* Tr. at 200.

In their motion for review, petitioners incorrectly argue that the special master's finding is partially in error, because petitioners did submit a medical study authored by Jill James. *See* Pet. Memo. at 7; Notice of Filing Medical Literature, April 30, 2015. A careful review of the article submitted by petitioners reveals, however, that this article does not discuss whether children with developmental disabilities possess lower levels of glutathione. Notice of Filing Medical Literature, April 30, 2015; Pet. Ex. 5. Nor does the article even address glutathione at all. Notice of Filing Medical Literature, April 30, 2015; Pet. Ex. 5. Given this, the special master correctly determined that petitioners had failed to file the referenced medical study.

**C. The Special Master Properly Considered The Testimony Of Dr. Zimmerman**

Petitioners' various objections to the special master's evaluation of the testimony of Dr. Zimmerman are similarly without merit. Pet. Memo. at 9-15. In their motion for review, petitioners raise four objections to the special master's findings regarding the testimony of Dr. Zimmerman. First, petitioners argue that the special master erred in determining that Dr. Zimmerman did not order metabolic tests for M.M. *Id.* at 9-13. Second, petitioners argue that the special master erred in finding that Dr. Zimmerman accepted M.M.'s medical history as recounted by M.M.'s parents to Dr. Schultz "without question." *Id.* at 11-13. Third, petitioners argue that the special master also erred by declining to analyze Dr. Zimmerman's testimony under the treating physician standard. *Id.* at 13-14. Lastly, petitioners object to the special master's finding that Dr. Zimmerman was not qualified to testify about mitochondrial disease. *Id.* at 14-15. For the reasons discussed below, the Court finds that petitioners' objections are unsubstantiated by the record evidence.

### 1. The Special Master Did Not Err In Finding That Metabolic Testing Was Not Ordered For M.M.

As an initial matter, the testimony and evidence in the record make clear that the special master reasonably concluded that Dr. Zimmerman did not order metabolic testing in connection with his treatment of M.M. In his decision, the special master found that Dr. Zimmerman suggested, but did not order, metabolic testing for M.M when he treated M.M. at the Kennedy Krieger Institute on June 8, 2009. Dec. at *5, 37. Specifically, the special master found that Dr. Zimmerman's medical report from this visit recommended a review of the results of any metabolic or genetic testing that had been previously performed on M.M. *Id*. at *16; *see also* Pet. Ex. 3 at 5; Pet. Memo. at 10; Tr. at 265. The special master determined, however, that no metabolic or genetic tests were ordered by Dr. Zimmerman at that time, and that the possibility of genetic and metabolic testing was not revisited during M.M.'s subsequent visits to Dr. Zimmerman on September 21, 2009 and June 24, 2010. Dec. at *6.

A review of Dr. Zimmerman's testimony during the entitlement hearing shows that the special master's finding is correct. Dr. Zimmerman testified during the entitlement hearing that he "didn't order [metabolic testing] in the sense of ordering it directly from out clinic, because . . . it was recommended that [M.M.'s parents] either bring the prior lab work that has been performed to future visits or to fax the lab work to the neurology clinic office." Tr. at 265. Dr. Zimmerman also testified that he did not "have any record of results of metabolic testing" for M.M. Tr. at 259. M.M.'s medical records similarly do not indicate that metabolic testing was ever ordered or performed. *See generally* Pet. Exs. 3, 4. And so, the evidentiary record demonstrates that the special master correctly concluded that Dr. Zimmerman did not order metabolic testing in connection with his treatment of M.M.

### 2. The Special Master Reasonably Determined That Dr. Zimmerman Accepted The Medical History Provided By M.M's Parents

The evidentiary record similarly makes clear that the special master correctly concluded that Dr. Zimmerman relied upon a recounting of M.M.'s medical history as provided by M.M.'s parents during a June 8, 2009 visit to the Kennedy Krieger Institute. In his decision, the special master determined that, during this visit, the Murphys relayed M.M.'s medical history to Dr. Scott Schultz−an attending physician at the Institute−and that Dr. Schultz relayed this medical

history to Dr. Zimmerman. Dec. at *16; Tr. at 287. The special master also notes in the decision that Dr. Zimmerman admitted during the entitlement hearing that his diagnosis of "vaccine-related encephalopathy with apraxia and features of autism" was based upon M.M.'s medical history as relayed to him by Dr. Schultz. Dec. at *16; *see also* Tr. at 259.

Petitioners contend that the special master's finding is in error, because Dr. Zimmerman "not only incorporate[d] the information being orally relayed by M.M.'s parents, but . . . [also] decide[d] if this [medical] history was logically applicable to M.M.'s condition at presentation." Pet. Memo. at 12. Petitioners' argument is, however, belied by Dr. Zimmerman's own testimony during the entitlement hearing. As discussed above, Dr. Zimmerman acknowledged that his diagnosis was based upon the medical history relayed by M.M.'s parents. Tr. at 259. In addition, the medical records reflecting Dr. Zimmerman's subsequent treatment and evaluation of M.M., between June 8, 2009 and June 24, 2010, also do not show that Dr. Zimmerman analyzed or revisited M.M.'s medical history. *See generally* Pet. Exs. 3, 4. And so, Dr. Zimmerman's testimony and the relevant medical records support the special master's determination that Dr. Zimmerman based his diagnosis upon the medical history that M.M.'s parents provided to Dr. Schultz.[5]

### 3. The Special Master Did Not Err In Declining To Consider Dr. Zimmerman's Testimony Under The Treating Physician Standard

The record evidence similarly shows that the special master properly declined to consider the testimony of Dr. Zimmerman under the treating physician standard. In their motion for review, petitioners argue that the special master committed reversible error by declining to treat Dr. Zimmerman as a treating physician. Pet. Memo. 13-14. Petitioners arguments are unsubstantiated by the facts.

In this case, it is undisputed that Dr. Zimmerman was not M.M.'s treating physician at the time that M.M. received the DTaP and MMR vaccinations in October 2002. *See* Pet. Mot. at 10-11 (explaining that M.M.'s pediatrician at Klebanow and Associates vaccinated him on October 14, 2002); *see also* Pet. Mot. at *15-16; Resp. Brief at 9-10. It is also without dispute

[5] Petitioners also argue that the special master improperly discredited Dr. Zimmerman's assessment of MM's injuries, because Dr. Schultz obtained M.M.'s medical history. Pet. Memo. at 15. But, petitioners offer no evidence to demonstrate that the special master discredited Dr. Zimmerman's analysis because of Dr. Schultz's involvement. *See* Pet. Memo. at 15-16.

that Dr. Zimmerman did not begin to treat M.M. until June of 2009−almost seven years after the subject vaccinations, and many years after the onset of M.M.'s symptoms. *See* Dec. at *5; *see generally* Pet. Ex. 3. Given these undisputed facts, it was reasonable for the special master to decline to apply the treating physician standard to Dr. Zimmerman's testimony.

More importantly, the record evidence shows that Dr. Zimmerman's testimony supports the special master's determination that M.M. did not suffer a vaccine-related encephalopathy. During the entitlement hearing, Dr. Zimmerman testified that, based upon his review of M.M.'s December 2002 medical records, M.M. was not "encephalopathic at that time." Tr. at 288; Dec. *16 n.49. And so, Dr. Zimmerman's testimony substantiates the special master's determination that M.M. did not suffer an encephalopathy in the weeks and months immediately following the October 2002 vaccinations. *See* 42 C.F.R. § 100.3(b)(2) (To establish that an encephalopathy occurred, petitioners must prove that M.M. "manifest[ed], within the applicable time period, an injury meeting the description . . . of an acute encephalopathy, and then a 'chronic' encephalopathy persist[ed] . . . [for] more than 6 months beyond the date of vaccination.").

**4. The Special Master Properly Determined That Dr. Zimmerman Was Not Qualified To Testify About Mitochondrial Disease**

The special master also reasonably found that Dr. Zimmerman lacked the qualifications to testify about mitochondrial disease during the entitlement hearing. In his decision, the special master determined that Dr. Zimmerman "admitted that he lacked the direct expertise to opine on the topic [of mitochondrial disease], even though he had read enough to be knowledgeable about it." Dec. at *16. Petitioners contend that the special master erred in this determination, because the special master stated that "Dr. Zimmerman has the qualifications to tell you about [mitochondrial disease]" during the entitlement hearing. Pet. Memo. at 14; Tr. at 261.

Petitioners' contention is simply without merit. The transcript for the entitlement hearing makes clear that, when Dr. Zimmerman was specifically asked about whether he had "any special expertise regarding mitochondrial dysfunction/disorder and vaccines," Dr. Zimmerman testified in response "no." Tr. at 266. Given Dr. Zimmerman's own testimony that he lacks any such expertise, the Court finds no error in the special master's determination.

### D. The Special Master Reasonably Determined That M.M. Did Not Suffer A Chronic Encephalopathy

As a final matter, the special master also reasonably concluded that M.M. did not suffer either an acute or a chronic encephalopathy. Pursuant to the Vaccine Injury Table's qualifications and aids to interpretation, an individual is considered to have suffered a Table encephalopathy if he or she "manifests, within the applicable period, an injury meeting the description . . . of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination." 42 C.F.R. § 100.3(b)(2). For a child like M.M., an acute encephalopathy is "indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A).

The qualifications and aids to interpretation defines a chronic encephalopathy to be "a change in mental or neurologic status, first manifested during the applicable time period, [and that] persists for a period of at least 6 months from the date of vaccination." 42 C.F.R. § 100.3(b)(2)(ii). And so, individuals who "return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy." *Id*.

In his decision, the special master determined M.M. did not suffer an acute encephalopathy, because M.M.'s contemporaneous medical records show that M.M.'s vaccinations in October 2002 "were not followed by any identifiable, measurable, severe reaction of the kind that would constitute an acute encephalopathy." Dec. at *31. In this regard, the special master also determined that, "[a]t most, [p]etitioners have established that M.M. experienced some transient symptoms, such as a high fever that arguably could be attributed to the vaccinations." *Id*. Such symptoms are not sufficient to demonstrate an acute encephalopathy.

The special master further found that there was "no compelling evidence from the days, weeks, or months after the October 14, 2002, pediatric visit establishing that M.M. was experiencing a persistent 'change in mental or neurologic status'" that could constitute a chronic encephalopathy. Dec. at *32 (quoting 42 C.F.R. § 100.3(b)(2)(ii)). Rather, the special master

observed that no pediatric records document any concerns about M.M.'s developmental problems before June 2003−eight months after the subject vaccinations. *Id.*

While petitioners object to the special master's determinations, their specific objection is difficult to discern. It appears that petitioners contend that the special master erred by failing to properly analyze the relevant factors to demonstrate the existence of a chronic encephalopathy under the Vaccine Injury Table's qualifications and aids to interpretation. Pet. Mot. at 10; Pet. Memo. at 8; 42 C.F.R. § 100.3(b)(2)(ii-iii). To the extent that this is the case, petitioners' argument is misguided.

The record evidence demonstrates that the special master reasonably determined that M.M. did not suffer from an acute encephalopathy. As discussed above, the special master reviewed M.M.'s medical records and found that these records provided "no persuasive evidence of a significant change in M.M.'s consciousness" following the vaccinations. Dec. at *31. A careful review of the medical records for M.M.'s October 2002 doctor's visit also demonstrates that there is no indication that M.M. suffered from a significantly decreased level of consciousness during the days and weeks following the vaccinations. *Id.*; Pet. Ex. 4. In fact, the medical records for M.M.'s December 10, 2002 doctor's visit shows that the pediatrician found M.M. to be a well child with no noted neurological concerns. *See* Pet. Ex. 4 at 14. And so, the special master reasonably determined that M.M. did not suffer an acute encephalopathy following the subject vaccinations.

As the government correctly notes in its response to petitioners' motion for review, M.M. simply could not have suffered a chronic encephalopathy, because the record evidence in this case clearly demonstrates that M.M. did not suffer an acute encephalopathy following the subject vaccinations. *See* Resp. Brief at 8-9. Petitioners also fail to identify any evidence or testimony to show that M.M. experienced a change in his neurologic state that lasted at least six months after the subject vaccinations. *See generally* Pet. Mot.; Pet. Memo. Rather, the record evidence shows that it was not until June 2003–eight months after the subject vaccinations−that concerns were first raised about M.M.'s developmental regression. Dec. at *32, 34-35; Pet. Ex. 4 at 10. Given the weight of this evidence, the special master's determination that M.M. did not suffer a vaccine-related encephalopathy−either acute or chronic−is well supported by the record evidence. And so, the Court will not set aside the special master's decision.

## V. CONCLUSION

In sum, the record evidence in this case demonstrates that petitioners have not met their burden to show that the special master erred in denying their vaccine injury claim. To the contrary, the record evidence in this matter demonstrates that the special master's decision was reasonable, supported by the evidence and in accordance with law.

And so, for the foregoing reasons, the Court **DENIES** petitioners' motion for review and **SUSTAINS** the decision of the special master.

The Clerk is directed to enter judgment accordingly.

Each party to bear their own costs.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential, or sensitive personally-identifiable information that should be protected from disclosure. Accordingly, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall also **FILE**, by **September 15, 2016**, a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed

redaction.

**IT IS SO ORDERED.**

s/ Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
Judge