In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 05-1063V
(To be Published)

JOHN A. MURPHY *and* BARBARA E. MURPHY, *parents of* M.M., *a minor*,	*	Special Master Corcoran
	*	Filed: April 25, 2016
Petitioners,	*	
	*	Entitlement Decision; Influenza ("Flu") Vaccine; Autism Spectrum Disorder ("ASD"); Autoimmune Encephalopathy Following Fever or Vaccine; Post-trial Expert Report.
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Patricia A. Finn, Patricia Finn, P.C., Piermont, NY, for Petitioners.

Ryan D. Pyles, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION[1]

On October 5, 2005, John and Barbara Murphy filed a petition on behalf of their minor child, M.M., seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program" or "Program").[2] The Murphys sought to establish that the diphtheria-tetanus-acellular pertussis ("DTaP"), and measles, mumps, and rubella ("MMR") vaccines that M.M. received on October 14, 2002, when he was approximately 17 months old, caused an

[1] Because this decision contains a reasoned explanation for my actions in this case, I will post it on the United States Court of Federal Claims website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole decision will be available to the public. *Id.*

[2] The Vaccine 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 through 34 (2012) (the "Vaccine Act" or "Act"). Individual section references hereafter will be to § 300aa of the Act.

encephalopathy, resulting in M.M.'s purported developmental regression (which Petitioners maintain is not an autism spectrum disorder ("ASD")).

An entitlement hearing was held on May 18-19, 2015, and in the following months the parties submitted post-hearing briefs. Having completed my review of the evidentiary record and the parties' filings, I hereby deny Petitioners' request for compensation for the reasons stated below.

I. FACTUAL BACKGROUND

The record in this case consists of the following: M.M.'s medical records; affidavits from M.M.'s mother (Barbara E. Murphy) and father (John A. Murphy), as well as their testimony; the written reports and testimony of two experts (one for each side) plus a treating physician; and medical or scientific literature submitted by the parties in support of their respective positions. I have reviewed the entire record as required by the Vaccine Act. Section 13(a)(1).[3]

A. M.M.'s Early Medical History.

M.M. was born on May 16, 2001, and shortly thereafter, on May 21, 2001, was assessed as a well child with jaundice. Pet'rs' Ex. 6 at 2; Pet'rs' Ex. 2 at 32. In the months that followed M.M. was seen on several occasions by his pediatrician, Thomas Hickey, MD at Kenneth M. Klebanow, MD and Associates, P.A. in Columbia, Maryland regarding various parental concerns, including a foot issue that resulted in referral to an orthopedist.[4] *See, e.g.*, Pet'rs' Ex. 2 at 27-28,

[3] The medical records in this case are particularly voluminous, and include many records pertaining to the post-vaccination treatment of M.M.'s developmental problems that only bear tangentially on the issues to be resolved in this entitlement proceeding, since they do not relate to the causal effect of the relevant vaccines. Accordingly, I do not discuss all such medical records in detail, but instead focus on what both sides have identified as the most significant records relevant to the causation issues presented herein. *See Paterek v. Sec'y of Health & Human Servs*., 527 Fed. App'x 875, 884 (Fed. Cir. 2013). The same goes for the extensive medical literature submitted by both sides – I have reviewed all such literature filed in preparing my decision, even if each individual piece of literature is not discussed in this decision. *Moriarty v. Sec'y of Health & Human Servs.,* No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted).

[4] On May 24, 2001, M.M. was seen by his pediatrician for a one-week check-up, and parental concerns regarding jaundice and M.M. "sleep[ing] all the time" were noted. Pet'rs' Ex. 2 at 31. M.M. was assessed as having jaundice, and his feeding and sleep schedule were discussed with the parent(s). *Id*. Shortly thereafter, on May 31, 2001, M.M. was again seen by his pediatrician this time for a weight check, and it was noted that he had excellent weight gain. *Id.* at 30. When M.M. was seen by his pediatrician for his one-month well child visit on June 18, 2011, the musculoskeletal examination was abnormal. *Id.* at 28. Thereafter, M.M. was seen by Robert W. Bright, MD at Chesapeake Orthopedic and Sports Medicine Center (in Glen Burnie, MD) on July 5, 2001, regarding concerns of some foot deformities and diagnosed with metatarsus adductus (although he was generally a healthy baby). Pet'rs' Ex. 3 at 14-15. On July 10, 2001, M.M. returned to Chesapeake Orthopedic and Sports Medicine Center "to begin his bilateral metatarsus adductus treatment with manipulation and serial casting," and he was subsequently seen for follow-up visits on numerous occasions. *Id.* at 13, 16-18, 20; Pet'rs' Ex. 2 at 19, 21.

30; Pet'rs' Ex. 3 at 14-15. In the first sixteen months of his life, he received several routine childhood immunizations generally in accordance with the vaccination schedule set forth by his doctor.[5]

On November 20, 2001, M.M. had a six-month well child visit, at which time his parents expressed their concern that he might have a wheat allergy, and also noted that he had recently experienced a rash. Pet'rs' Ex. 2 at 24. However, his physical examination noted no problems, and M.M. subsequently received his third DTaP and Prevnar vaccinations. *Id*. M.M. was later seen by Lynne M. Zheutlin, MD, a Diplomate of American Board of Allergy and Immunology (at her office in Columbia, MD) on February 6, 2002, for an allergy evaluation. Pet'rs' Ex. 3 at 5-6. Dr. Zheutlin diagnosed M.M. as having eczema; the remainder of the examination was unremarkable, and skin allergy tests performed during that visit were negative.[6] *Id*.

M.M. received a nine-month well child checkup on February 22, 2002. Pet'rs' Ex. 2 at 23. At the time, he was febrile (101.8 degrees) with a history of a cough. *Id*. He was assessed as having an upper respiratory tract infection ("URI") with fever, and scheduled immunizations were post-postponed. *Id*. Shortly thereafter, on March 1, 2002, M.M. visited his pediatrician to address a fever that had persisted for five days, accompanied by a decreased appetite, sleeplessness, and a lack of playfulness (among other things). *Id.* at 22. M.M. had a follow-up examination on March 20, 2002, at which time it was noted that he had been experiencing diarrhea, as well as a URI and a runny nose that had been ongoing for three weeks. *Id.* at 21. At this time, M.M. received his third IPV vaccination.[7] *Id*.

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[5] Thus, on July 18, 2001, M.M. was seen for a two-month well child check-up, and he received his first DTaP, inactivated poliovirus ("IPV"), pneumococcal ("Prevnar"), haemophilus influenza B ("Hib"), and Hepatitis B ("Hep B") vaccinations. Pet'rs' Ex. 2 at 27. Thereafter, on August 11, 2001, M.M. was seen by his pediatrician due to parental concerns about a potential breathing problem, but was assessed as a well child. *Id.* at 29. On September 20, 2001, M.M. was seen for his four-month examination; Mrs. Murphy went through a list of concerns with the pediatrician, but upon examination no problems were identified. *Id.* at 26. M.M. received his second DTaP, IPV, Prevnar, Hib, and Hep B vaccinations at that time. *Id*. On October 15, 2001, M.M. was seen by a pediatrician because he was "making [a] funny noise" (which was hoarse-sounding and only occurred when he was laughing), and parental concerns regarding asthma were noted. *Id.* at 25. Upon assessment, M.M. had "possibly mild tracheolaryngitis" and his treatment included reassurance of M.M.'s mother and observation. *Id.*

[6] Mrs. Murphy had difficulty believing that the skin test were negative, so Dr. Zheutlin sent M.M. for a radioallergosorbent ("RAST") test for confirmation. Pet'rs' Ex. 3 at 5-6. It is unclear whether such testing was ever conducted or any results obtained. However, a Pediatric Food Sensitivity Assay ordered by Dr. Layton in December 2004 revealed that M.M. was reactive to certain foods. Pet'rs' Ex. 4 at 48.

[7] On May 17, 2002, M.M. was seen by his pediatrician after a car accident (and the examination was normal). Pet'rs' Ex. 3 at 20.

M.M. was next seen by Dr. Hickey for a one-year well child check on May 20, 2002. Pet'rs' Ex. 2 at 19. Although his physical examination revealed no problems, Mrs. Murphy provided the treater with a history of concerns and questions reflected in the contemporaneous record. *Id*. At this time, vaccinations were withheld for an unspecified reason. *Id*.

One month later, on June 25, 2002, M.M. was seen by Dr. Hickey again because he was "not his normal self." Pet'rs' Ex. 2 at 18. It was noted that M.M. had been rubbing both ears for the past several days, and that he had a fever, cough, and runny nose, and Dr. Hickey diagnosed him with right-side otitis media and prescribed antibiotics. *Id*. On August 31, 2002, M.M. returned to the doctor for follow-up on the ear infection, and also for evaluation of a head injury that had occurred earlier that month. [8] *Id.* at 17. It was noted that M.M. was very wobbly when walking, and that the problem got worse when he was tired. *Id*. M.M. had also been experienced a runny nose for the last four days, resulting in an assessment that he had another URI. *Id*. During this visit, M.M. received his third Hib and Hep B vaccinations, as well as his first varicella vaccination. *Id*.

B. October 2002 Vaccinations and Purported Reactions.

M.M. returned to the pediatrician for his 16-month well child checkup on October 14, 2002. Pet'rs' Ex. 2 at 16; Tr. at 9-10, 13, 23-24. At this time, he received his fourth DTaP vaccination and his first MMR vaccination. Pet'rs' Ex. 1 at 1 (vaccination record); Pet'rs' Ex. 2 at 16 (record from visit). Records from this visit indicated that M.M. was a well child who was now receiving diluted whole and soy milk. Pet'rs' Ex. 2 at 16.

Four days later, on October 18, 2002, the Murphys brought M.M. back to their pediatrician because of concerns that he had an ear infection. Pet'rs' Ex. 2 at 15. In the history section from the record of this visit, it was noted that in the day following M.M's October 14, 2002, receipt of vaccination he began exhibiting a number of symptoms, including (1) high pitched screaming when lying down on October 15, 2002; (2) increased sleep time starting on that date; (3) intermittent fever; and (4) was pulling on his ears. *Id*. Upon physical examination, however, M.M. was afebrile, and was merely noted to be "fussy." *Id*. The pediatrician attempted to reassure the Murphys about M.M.'s condition, but instructed them to return if his symptoms persisted or worsened. *Id*. There are no other medical records for the interval between the October 14th well child visit and the October 18th return.[9]

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[8] On August 15, 2002, M.M. was seen in the emergency room at Howard County General Hospital, Inc. after falling into the corner of the coffee table. Pet'rs' Ex. 7 at 11-19. He had swelling and a hematoma around his eye, but the examination was otherwise normal. *Id*.

[9] Despite the lack of records from this time period (an interval highly relevant to the Petitioners' claim), the Murphys allege (as discussed below) that they repeatedly phoned Dr. Hickey's office to report concerns about M.M.'s behavior but were rebuffed. In an effort to substantiate their claims, prior to the hearing in this matter, Petitioners filed a motion

There is a subsequent approximate two-month gap in the medical records. On December 10, 2002, M.M. returned to Dr. Hickey for his 18-month well child check-up. Pet'rs' Ex. 2 at 14. Other than mild eczema, the examination was normal. *Id*. This record contains no mention of any problems, issues, or distress M.M. is alleged to have experienced in October 2002, nor does it mention the vaccines he received at that time.

In the months that followed, M.M. was seen by his pediatrician periodically for a number of minor issues. *See, e.g.*, Pet'rs' Ex. 2 at 9-13. For instance, on May 3, 2003, M.M. visited his treater because he had been pulling both ears for the prior four days while afebrile, but no other changes in M.M.'s behavior were noted. *Id.* at 13. A few days later, on May 9, 2003, M.M. had another pediatric visit for evaluation of a laceration to his left toe (reportedly caused by a pot falling on it), but again no behavioral changes were noted. *Id.* at 12. M.M. was brought to the pediatrician a third time that month on May 20, 2003, because he had a fever (of 105.8 degrees), coughing, a URI (for two days), and pharyngitis, as well as a failure to have a bowel movement for two days. *Id.* at 11. At this time, M.M. was prescribed antibiotics and ibuprofen, with the direction to call the pediatric office if the illness persisted in two days or did not improve. *Id*.

C. Concerns about M.M.'s Development and Resulting Treatment Efforts.

M.M. returned to the pediatrician for his two-year well child checkup on June 6, 2003. Pet'rs' Ex. 2 at 10. His physical examination was unremarkable, but – for the first time in the medical records – concerns about language delay were noted. *Id.* The medical records subsequent to this visit that were filed in this case reflect that M.M. was now recognized to be developmentally delayed in a number of respects. *See, e.g.*, Pet'rs' Ex. 4 at 1; Pet'rs' Ex. 8 at 2-6. Petitioners do not, however, accept that M.M. has an ASD, despite the fact that such a diagnosis has been made for him by certain of his treaters.[10]

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requesting authorization to issue a subpoena for phone messages or records allegedly documenting M.M.'s adverse vaccine reactions reported to Dr. Hickey (including any records related to emergency phone calls from M.M.'s parents to Dr. Hickey at Klebanow and Associates on October 14, 2002), which I granted. ECF No. 91. Such records, filed after the hearing (ECF No. 102) do in fact document numerous occasions on which M.M.'s parents called the pediatrician's office to express concerns regarding M.M., but include no documented calls from the period of time in question (October 14th through October 18th 2002). ECF No. 102-2 at 13-45 (call records).

[10] For example, on May 9, 2007, M.M. was assessed at The County Diagnostic Center in Columbia, Maryland based on a referral from the Individualized Education Plan ("IEP") team at Bushy Park Elementary School. Pet'rs' Ex. 13 at 1-19. M.M. "was found to qualify for special educational services with educational disability of Developmental Delay in February 2004," but "updated assessments [were] needed to determine current levels of functioning and to establish a new educational disability should special education services continue to be warranted." *Id.* at 1. It was noted that M.M. "was initially referred to the Infants and Toddler program at Triadelphia Ridge Elementary RECC by his parents at around age 2 ½," and "[p]arental concerns at that time included lack of speech / language skills and social behaviors, little eye contact, and not responding to his name or following directions, and hand flapping." *Id.* at 2. Consistent with past assessments, however, M.M.'s constellation of behaviors was deemed as fitting the diagnosis

The Murphys thereafter embarked on a comprehensive effort to treat M.M.'s developmental problems, seeking input from a variety of medical specialists and attempting many different treatments. In September 2003, they began taking M.M. to Richard E. Layton, MD (an allergist[11]) (Pet'rs' Ex. 4 at 1) to start M.M. on what was then referred to as the Defeat Autism Now ("DAN!")[12] Protocol (Tr. at 27) for treatment of his speech delay and social skill/developmental problems, along with some other physical conditions (allergies, recurrent loose bowel movements, and decreased attention span). Pet'rs' Ex. 4 at 1, 12-14. Dr. Layton ordered various testing (including testing conducted by Great Plains Laboratory, Inc. and Doctor's Data, Inc.), including blood, hair, and stool sample analysis, as well as tests to measure food intolerance. *See generally Id*. Some testing revealed purported elevation of metals in M.M., including beryllium and uranium. *Id*. at 44. In response, Dr. Layton placed M.M. on a variety of supplements and also recommended certain dietary restrictions, as well as chelation therapy.[13] *Id.* at 10-62.

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of autism, and the recommendations section of the report states that "[i]t is recommended that the IEP team consider [M.M.] eligible for special education and related services under the category of Autism." *Id.* at 9.

[11] The Office of Dr. Richard E. Layton, Allergy Connection, http://www.allergyconnection.com/laytonaboutfr.html (last visited Mar. 29, 2016); *see also* ECF No. 102-2 at 45 (note from Dr. Hickey's office indicating that Dr. Layton is an allergist rather than autism specialist).

[12] DAN! is composed of doctors and medical professionals who believe, among other things, that autism can be caused by vaccines. *See Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250, at *165 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). The Autism Research Institute ("ARI"), which was founded by Bernard Rimland, MD in 1967, created the DAN! Protocol in 1995. *Moving Forward: The Expanding Mission of ARI*, Autism Research Institute, http://www.autism.com/expanding_2014 (last visited Mar. 29, 2016). "DAN! Doctors [were] trained in an approach to autism treatment that begins with the idea that autism is a biomedical disorder caused by a combination of lowered immune response, external toxins from vaccines and other sources, and problems caused by certain foods." DAN! PROTOCOL, Autism Services and Resources Connecticut, http://www.autismconnecticut.org/dan-protocol (last visited Mar. 29, 2016). Accordingly, DAN! "doctors may recommend treatments including nutritional supplements, special diets, testing for hidden food allergies, treatment of intestinal yeast or bacterial overgrowth, and detoxification of heavy metals." *Id.*

However, ARI discontinued the DAN! Protocol in 2011, indicating that individuals included on the list of providers were merely doctors who attended training seminars, and there was therefore no way to assure that such practitioners were providing high quality services. Lisa Jo Rudy, *What Was the DAN! (Defeat Autism Now) Protocol?*, About Health (updated Dec. 30, 2015), http://autism.about.com/b/2011/09/02/dan-defeat-autism-now-is-no-more htm.

[13] Chelation therapy has been used for many years as a treatment for mercury and lead poisoning, but it is not a proven treatment for autism and it can have serious side effects including potentially fatal liver and kidney damage. Rekha Mankad, M.D., *Can Chelation Therapy Treat Heart Disease*?, Mayo Clinic (Feb. 11, 2016), http://www mayoclinic.org/diseases-conditions/heart-disease/expert-answers/chelation-therapy/faq-20157449; Jay L. Hoecker, MD, *Is Chelation Therapy an Effective Autism Treatment?*, Mayo Clinic (July 9, 2013), http://www mayoclinic.org/diseases-conditions/autism-spectrum-disorder/expert-answers/autism-treatment/faq-20057933. Dr. Layton's chelation treatment of M.M. included prescribing DMPS cream, which is intended to act as a specific chelator of mercury. Pet'rs' Ex. 4 at 10-62

On May 26, 2004, M.M. underwent audiology testing at Kennedy Krieger Institute in Baltimore, Maryland, due to concerns for his "delay in the acquisition of speech and language skills." Pet'rs' Ex. 5 at 7; Pet'rs' Ex. 8 at 7-14. However, the results of this testing were generally within normal limits. Pet'rs' Ex. 5 at 7, 13. The report accompanying the test results included the suggestion that M.M. be evaluated by a developmental pediatrician, but (as the report also indicated) Mrs. Murphy did not express an interest in pursuing such an evaluation. Pet'rs' Ex. 5 at 13. At this time and thereafter, M.M. continued to be seen by Dr. Layton on numerous occasions (much as he had previously). *See* Pet'rs' Ex. 4 at 27-32, 49, 51-52, 54-56.

On October 20, 2005, M.M. was examined by Mary Megson, MD, FAAP, a developmental pediatrician at Pediatric and Adolescent Ability, in Richmond, Virginia "for evaluation of his language disorder." Pet'rs' Ex. 10 (ECF No. 64-3 at 3-6). In her notes from the visit, Dr. Megson stated that M.M. had been diagnosed with developmental delay, dyspraxia, and apraxia, and she noted that he had "features of autism" (although she also observed that M.M. had "not really had a diagnosis of autism"). *Id.* at 3-5. However, under the impressions section of her write-up, Dr. Megson listed the following differential diagnosis: (1) autism, (2) mercury poisoning, (3) yeast, (4) gluten/casein sensitivity, and (5) multiple food sensitivities. *Id.* at 5. That assessment was based on the history provided by M.M.'s parents; the records from that visit say nothing about Dr. Megson's review of M.M.'s prior pediatric records.

Dr. Megson's treatment report specifically incorporated Petitioners' theory in this case – that M.M.'s regression was related to his October 2002 vaccinations. Thus, she stated that M.M. had exhibited high pitched screaming on the same day of the DTaP and MMR vaccinations in October 2002, along with "head banging." Pet'rs' Ex. 10 (ECF No. 64-3 at 3-5). He thereafter began gradually to lose language, "lost interest in fine motor skills," and also displayed at two years of age a "high pain tolerance," which was effectively treated by magnesium dietary supplements. *Id*. at 3. It was also noted in Dr. Megson's records that "[i]n motor development [M.M.] was relatively normal with sitting at 6 months, walking at 9 months" but then "[h]e lost this ability and started to crawl poorly after his shots." *Id*. at 4.

A physical examination performed by Dr. Megson during M.M.'s first visit to see her was unremarkable (although some laboratory test results were viewed as abnormal). Pet'rs' Ex. 10 (ECF No. 64-3 at 4). M.M. returned to Dr. Megson in January 2006 and several times thereafter, with similar reports included in notes from subsequent visits.[14] *Id.* at 5-13, 15-16. Dr. Megson subsequently ordered various testing (*see generally id*.) in addition to those previously performed

[14] For instance, at M.M.'s April 5, 2007, visit, Dr. Megson noted that he was doing better (although he was still non-verbal). Pet'rs' Ex. 10 at 8-10.

by Dr. Layton, including some conducted by Genovations for the Methylene Tetrahydrofolate Reductase ("MTHFR") genotype – a key enzyme in folate metabolism (*Id.* at 14).[15] The results of this testing conducted in the spring of 2006 revealed that M.M. was homozygous for the c667t mutation, resulting in a 60 to 70 percent reduction in MTHFR enzyme sensitivity and increased risk of elevated homocysteine. ECF No. 64-5 at 13. Thereafter, M.M. continued to be seen by Dr. Megson, undergoing various testing and treatment at her direction. *See, e.g.*, *Id.* at 4.

Two years later, on June 8, 2009, M.M. was seen by Andrew Zimmerman, MD (and Andrew Schultz, MD, an attending physician) at the Kennedy Krieger Institute in order to obtain a professional review of magnetic resonance imaging ("MRI") results previously obtained for M.M. in order "to rule out structural malformations that can possibly be surgically corrected." Pet'rs' Ex. 8 at 4-6; Pet'rs' Ex. 12 at 6-7. The medical history recited by M.M.'s parents during this visit is significant to the resolution of this case, and provides as follows:

> *Mom states* that they last tried imaging in 2002 via CT scan without success secondary to his inability to stay still. *He was diagnosed with vaccine related encephalopathy in October 2002* after receiving multiple vaccines at that time. Prior to receiving those vaccines in October 2002 (17 month) he was healthy and age appropriate developmentally. Four hours after receiving the vaccines he developed dilated pupils, drooling, high pitched squealing, facial droop, and a reduction in pain sensitivity. Since then he has tried many different types of therapeutic intervention. . . [16]

Pet'rs' Ex. 8 at 4 (emphasis added). Dr. Zimmerman accepted the Murphys' history without question, assessing M.M. as "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 5. The attending note from this visit added that it would be important to evaluate any genetic and metabolic studies previously performed on M.M. *Id*. However, there is no evidence

[15] According to the laboratory report, MTHFR is a key enzyme in folate metabolism, facilitating the formation of methyl tetrahydrofuran (methyl-THR), a required cofactor in the remethylation of homocysteine to methionine. Pet'rs' Ex. 10 (ECF No. 64-5 at 14). The failure of the methylation process is purported to lead to an increased risk of certain diseases (including autism). *Id.*

[16] M.M.'s mother subsequently wrote a letter, included in the medical records, indicating two corrections to be made to the June 8, 2009, evaluation report notes. Pet'rs' Ex. 8 at 2. Of most relevance to this case was her acknowledgment that M.M. ***did not*** receive a diagnosis of vaccine related encephalopathy in October 2002 following the October 14, 2002, vaccine reaction; rather, the medical records from "October 18, 2002 [] did list on the office visit notes some of his symptoms which [purportedly] ultimately allowed other doctors to later diagnosis him with 'Severe Apraxia Secondary to Vaccine Encephalopathy' and 'Vaccine Encephalopathy.'" Pet'rs' Ex. 8 at 16.

that any such tests were at the time ordered by Drs. Zimmerman or Schultz – and indeed, no prior treater had in fact requested metabolic testing, let alone suggested it was appropriate, and thus such studies were nonexistent.

M.M. was subsequently seen by Dr. Zimmerman on two more occasions. *See, e.g.*, Pet'rs' Ex. 8 at 2-3; Pet'rs' Ex. 12 at 3-4. First, M.M. returned to Dr. Zimmerman on September 21, 2009, "for follow-up of a vaccine related encephalopathy and features of apraxia and autism." Pet'rs' Ex. 8 at 2-3; Pet'rs' Ex. 12 at 4. At this time, Dr. Zimmerman discussed the MRI findings as negative. Pet'rs' Ex. 8 at 2. He did not, however, mention again the need for any metabolic testing, or that he wanted to review the results of testing previously performed. Second, on June 24, 2010, M.M. returned to Dr. Zimmerman for a follow-up evaluation. Pet'rs' Ex. 12 at 3. The report generated from that evaluation specifically states that M.M.'s "**[p]arents** attribute his rapid changes to his two immunizations, which have been documented and they have applied to the Vaccine Injury Program." *Id.* (emphasis added). But it contains no discussion of Dr. Zimmerman's clinical perspective on the proper diagnosis, and is again silent about the significance of metabolic testing in deriving a possible cause of M.M.'s condition.

Petitioners have continued their tireless efforts to treat M.M.'s developmental problems. Concerns regarding M.M.'s inability to communicate through use of spoken language are consistently echoed by his parents throughout the medical records, and (among other therapies attempted to remedy M.M.'s symptoms) to that end Petitioners have enlisted the services of speech and language pathologists. *See, e.g.*, Pet'rs' Ex. 16 at 1-3. A progress report from "1,2,3 Speak to ME!" (in Reisterstown, Maryland) from January 2013 indicated that M.M. had seen a speech-language pathologist once per week since March 2011. *Id*. It noted that at the time of his initial consultation, M.M. presented with severe verbal apraxia and since then he has made "nice gains in the targeted areas of therapy." *Id.* at 1.

On October 10, 2013, M.M. was again referred for a County Diagnostic Center Interdisciplinary Collaborative assessment based on being "identified with an educational disability of Autism as well as a significant medical history." Pet'rs' Ex. 18 at 1-2; Pet'rs' Ex. 19 at 2-39. The report from this time provided a review of prior collaborative assessments of M.M., reiterating that he had been assessed as having the disabilities of both autism and developmental delay. Pet'rs' Ex. 18 at 1. It also indicated that "[a]ccording to the current IEP, M[.M.] is identified with an educational disability of [a]utism" (the assessment had been changed from developmental delay to autism). *Id.* at 5. The report also addressed the DSM diagnostic criteria for autism and whether M.M. met those criteria based on reports from his parents and teachers. *See Id.* at 9-12.

II. TESTIMONY PRESENTED AT HEARING

A. Petitioners' Witnesses.

1. Mrs. Murphy

Mrs. Murphy provided fact testimony regarding the circumstances of M.M.'s alleged vaccine reaction and subsequent regression, along with information about his overall health and treatment over the past several years.

Prior to receipt of his October 2002 vaccinations, M.M. appeared to be developing normally (and was actually advanced for his age). Tr. at 14, 17-20. Thus, when Dr. Hickey would routinely ask M.M. to verbally identify and point to objects, M.M. was able to do so, and did on October 14th just as he had at prior visits. *Id.* at 13-14. Mrs. Murphy also acknowledged that M.M. had previously received a number of vaccinations without incident – but she attributed that to the fact that that the October 2002 vaccinations were the first he received without the benefit of the protective components of breast milk (including vitamins and minerals that passed to him through that breast milk) in his body – a factor which she felt was particularly significant given his alleged methylation deficiency and genetic susceptibilities to experience vaccine reactions. *Id.* at 10, 12, 123-25.

Mrs. Murphy testified that when she and M.M. returned home from the pediatrician's office it became apparent to her that something was wrong. Tr. at 28-29. M.M. "would go full scream, high pitch, arched back, shaking, shaking, and then he would go limp" and that this sequence occurred multiple times (although she could not recall exactly how many). *Id.* at 29-33, 38. She now believes M.M. was having seizures. *Id.* at 31-34. The Murphys at this time had to begin feeding M.M. through a syringe due to his difficulty keeping things in his mouth because of excessive drooling. *Id.* at 89-90. In addition, she observed that M.M.'s eyes had become dilated, although she initially attributed this to the fact that M.M. was crying so much. *Id.* at 34, 36, 93. M.M.'s pupil dilation remained, Mrs. Murphy contended, until 2006, and she attributed the amelioration of this condition to the hyperbaric chamber treatments[17] he began to receive. *Id.* at 34-35.

[17] Hyperbaric oxygen therapy (which is used to treat a variety of conditions) involves breathing pure oxygen in a pressurized room or body-sized tube. *Tests and Procedures: Hyperbaric Oxygen Therapy*, Mayo Clinic (Nov. 25, 2014), http://www mayoclinic.org/tests-procedures/hyperbaric-oxygen-therapy/basics/risks/prc-20019167?p=1. When an individual is placed in a hyperbaric oxygen therapy chamber, air pressure is increased to three times higher than normal, permitting the lungs to gather more oxygen than would be possible at normal air pressure. *Id.* The individual's blood then carries this oxygen throughout the body, which purportedly helps fight infection and promotes healing. *Id.* However, medical science has not confirmed that hyperbaric oxygen therapy is an effective autism treatment. *Id.* Moreover, although hyperbaric oxygen therapy is generally a safe procedure, it does involve risks, including the possibility of lung collapse, middle ear injuries, and seizures. *Id.*

Based upon such immediate post-vaccination behavior, Mrs. Murphy called Dr. Hickey's office within three hours of leaving.[18] Tr. at 29-30, 33. By that time, Mrs. Murphy claimed, M.M. had a fever of 105 degrees.[19] *Id.* at 45. According to Mrs. Murphy, throughout this period in October 2002, M.M. continued to experience a high fever, and developed a rash[20] on his neck and chest. *Id.* at 54, 58, 129. In addition, she testified, M.M. stopped identifying things and pointing (as he had done at the prior visit on the 14th) and he was not even sitting up (and accordingly no longer able to play). *Id.* at 96. Mrs. Murphy also testified that M.M. had dilated pupils post-vaccination, indicating that she initially attributed it to the fact that he had been screaming. *Id.* at 32-33, 35-37. There are no contemporaneous medical records to support this assertion about M.M.'s pupil dilation.

Given her concerns, Mrs. Murphy spoke with a nurse practitioner who tried to assure her that M.M.'s reaction to vaccination was normal ("a healthy immune response"), indicating that he was "just worn out, because he was crying so much." *Id.* at 33, 40. Mrs. Murphy believed she should take M.M. to the hospital, but Dr. Hickey's office told her that "they would laugh at us if we went to the [emergency room] with a child who's having a healthy immune response to a vaccination." *Id.* at 41-42. Consistent with her affidavit (Pet'rs' Ex. 29), Mrs. Murphy testified that she called the pediatrician's office again a second time that same day when M.M.'s symptoms did not improve after treating the fever with acetaminophen, but was again discouraged from returning to the office. Tr. at 49-50, 52.[21] Mrs. Murphy also claimed that she would have sought medical attention prior to the 18th, but was worried about the ongoing "Beltway Sniper" incident that was then occurring in the Washington, D.C. metropolitan area.[22] *Id.* at 95, 129-31.

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[18] As noted above, however, Petitioners have been unable to provide corroborative evidence of any such calls. *See* ECF No. 102-1 at 2.

[19] Mrs. Murphy specifically recalled measuring M.M.'s fever using a device placed on a child's forehead (and that M.M. had never previously had a fever that high). Tr. at 45. But there is no independent record establishing this as a fact.

[20] The medical records from the October 18th visit make no reference to a rash. Pet'rs' Ex. 2 at 15. Mrs. Murphy nevertheless insisted in her testimony that the rash not only existed, but that it had been characterized by treaters at the time as "a measles-like rash," and deemed a normal vaccine reaction. Tr. at 55-57, 60-61, 100-02. Ms. Murphy admitted that there was no other evidence (such as a photograph) to corroborate this claim. *Id.* at 127-128.

[21] Mrs. Murphy acknowledged that she did not again contact the pediatrician's office until October 18th (several days post-vaccination). Tr. at 95. However, she testified that it was originally the Murphys' intent to take M.M. to the emergency room, but that they were dissuaded from doing so by Dr. Hickey's office based on their assertions that M.M.'s reaction was completely normal. *Id*.

[22] In October 2002, John Allen Muhammad and Lee Boyd Malvo engaged in a weeks-long shooting spree, which resulted in 13 individuals being shot (ten of whom died). Seth Cline, *A Decade After Killings, D.C. Sniper Malvo Speaks*, U.S. News & World Report (Oct. 2, 2012, at 3:30 PM), http://www.usnews.com/news/articles/2012/10/02/a-decade-after-killings-dc-sniper-malvo-speaks. The shootings took place in public places (including parking lots and

In the period of time thereafter until sometime before M.M. was two years old, Ms. Murphy testified, M.M. displayed progressively worsened developmental and physiologic symptoms. He had trouble sleeping, his "bowels fell apart" (where he was having 10 to 14 acidic and liquid bowel movements per day), and his belly became distended. Tr. at 63-64, 67. At some unspecified point, the Murphys returned to Dr. Hickey to seek treatment for the gastrointestinal issues that M.M. was experiencing, but were again informed that his symptoms were not out of the ordinary.[23] *Id.* at 66-67. She claims to have been similarly told that language and developmental problems they observed were normal. *Id.* at 108.

Mrs. Murphy explained the absence of medical records for M.M. between December 2002 and May 2003 corroborating her claims about his developmental problems as attributable to the fact that the pediatric office had recommended that the Murphys wait six months post-vaccination to see if M.M. "bounced back" (although this ultimately did not happen). Tr. at 132, 134. She took M.M. to the pediatrician on May 9, 2003, after he had pulled pots and pans out of a cabinet and cut his toe on the lid of one of the pots. *Id.* at 27, 133-34. The incident was significant to her because M.M. was laughing and appeared to have "no sense of pain." *Id.* at 27, 51, 134-35. However, Mrs. Murphy later acknowledged that she also took M.M. to the pediatrician's office during this time because M.M. had been experiencing fever and a URI for two days (Pet'rs' Ex. 2 at 11). Tr. at 97. She also claimed that M.M. was non-responsive during this time and was still displaying developmental problems, and thus disputed the accuracy of a handwritten statement in the contemporaneous medical records from this doctor's visit suggesting the contrary ("[t]alking more, more playful"). Tr. at 97-98; Pet'rs' Ex. 2 at 11.[24]

After May 2003, the Murphys opted to obtain treatment from other providers, due to concerns that Dr. Hickey's practice had been unresponsive to M.M.'s developmental problems. Tr. at 24. But rather than obtain a new pediatrician, Petitioners began taking M.M. to different

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gas stations) throughout the District of Columbia, Maryland, and Virginia. *Id.* Until these individuals were apprehended on October 24, 2002,"[t]he shootings paralyzed the area, as residents kept their children home and themselves out of public as much as possible." D.C. Sniper shootings: 23 days of terror, The Washington Post (Sept. 20, 2013), https://www.washingtonpost.com/local/dc-sniper-shootings-23-days-of-terror/2012/09/30/41a4c768-098e-11e2-858a-5311df86ab04_video.html.

[23] However, Petitioners did not cite to portions of the contemporaneous medical records that support this assertion (nor was I able to find such information in those records).

[24] Mrs. Murphy in several instances questioned the accuracy of medical records that did not comport with or reflect her testimony, but admitted that generally she did not review M.M.'s medical records for accuracy, except on one occasion (pertaining to the evaluation M.M. received from Dr. Zimmerman). Tr. at 115-16. With respect to her claim that M.M. had a rash at the time of his October 18th pediatric visit, however, Mrs. Murphy insisted that she would have sought the record's correction had she realized it omitted this fact. *Id*. at 117.

kinds of specialists. *Id.* at 27. Thus, they began to work with Dr. Layton (who appealed to the Murphys because of his utilization of the DAN! Protocol). *Id.* at 27, 110. As Mrs. Murphy understood it, DAN! Protocol practitioners were trained to treat food allergies and gastrointestinal issues, as well as the other symptoms that M.M. was experiencing (some of which were understood, she claimed, as post-vaccination reactions). *Id.* at 110-11. After initially seeing Dr. Layton, the Murphys later sought out Dr. Megson due to their ongoing concerns about M.M.'s pupil dilation. *Id.* at 111-12.

During her testimony, Mrs. Murphy consistently disputed the contention (reflected in some of the treatment records) that M.M. had been properly diagnosed as suffering from an ASD (and testified that she has declined to have him so labeled in school even though she was informed that it would allow for additional treatment coverage). Tr. at 85, 118-19. Instead, she insisted that M.M.'s correct diagnosis is severe apraxia, secondary to vaccine encephalopathy. *Id.* at 66-67. Although she stated that this diagnosis first came from Dr. Megson, it was Dr. Layton who connected M.M.'s symptoms to his receipt of vaccination. *Id*. Because of her confidence in that diagnosis's accuracy, Mrs. Murphy stated that there was no need to seek out other opinions. *Id.* at 112-14. She did, however, admit that M.M. exhibits some autistic features (including stereotypical mannerisms), and that he requires the same level of educational services as someone properly diagnosed as autistic. *Id*. at 119-20.

Today, Mrs. Murphy stated, M.M. (who was 14 years old at the time of the hearing) is enrolled in a school for students with special needs in Baltimore, Maryland and is now beginning to speak (something she attributed to him working with a specialized instructor). Tr. at 9. She attributes many of the improvements that M.M. has experienced to some of the treatments the Murphys have pursued, including hyperbaric chamber treatments and dietary supplements. *See, e.g.*, *id*. at 27, 70, 72-74, 84, 91-92, 113-14. She acknowledges that M.M. has not reached developmental milestones expected for an individual of his age, but remains committed to the course of treatment the Murphys have pursued despite the personal and financial hardships the treatments impose. *Id*. at 14-15, 70, 122.

2. Mr. Murphy

Mr. Murphy also briefly testified, mostly about his observations of M.M.'s changes after the October 2002 vaccinations. Tr. at 137-45, 149-50. Prior to the vaccinations, Mr. Murphy recalled boasting about M.M. at work (who by his estimation was developmentally advanced, as he was almost completely toilet trained and able to walk around with a push cart). *Id*. at 142. He

also noted that he still has video tapes of M.M. from around this period of time that he views on occasion, and that would presumably provide evidence of M.M.'s status at the time.[25] *Id.*

Consistent with his affidavit, Mr. Murphy testified that in the days immediately after M.M.'s receipt of vaccination, he noticed a dramatic change in M.M.'s behavior, even though M.M.'s treaters were dismissive of the Murphys' concerns. Tr. at 141; ECF No. 73-1. Mr. Murphy believed that M.M.'s brain was affected by the vaccinations "because he went from being ahead of the curve to behind the curve." *Id.* at 137, 143. Mr. Murphy echoed his wife's testimony about the changed nature of M.M.'s bowel movements (*id.* at 142), and also testified that he saw the same rash Mrs. Murphy claimed to have existed (*id.* at 150).

In the months that followed, other changes became apparent to Mr. Murphy. M.M. appeared to have a reduced amount of energy, going from being a child that laughed and was happy to being a very "stoic child." ECF No. 73-1 at 2. He also observed M.M. not noticing when left with a babysitter, whereas prior to receipt of vaccination M.M. would be upset if he could not see his mother. *Id*. Additionally, Mr. Murphy indicated that M.M. stopped trying to walk. *Id.*

The Murphys thereafter spent over a year asking about M.M.'s post-vaccination symptoms – including "why the bowels are a problem and his speech just went away." ECF No. 73-1 at 2. Mr. Murphy indicated that they "were concerned that he was not progressing as he was before," but that the doctor assured them that "everything was alright; he is young and [it] was too early to determine if anything was wrong." *Id.* Petitioners only began seeking treatment from other doctors after the pediatrician could provide no answers and M.M. failed to show improvements. *Id.* And Mr. Murphy agreed with his wife's testimony that some of the subsequent treatments pursued, such as those involving a restricted diet, proved effective. *Id.* at 2-3. He recalled being informed at some point after such treatments were implemented that M.M.'s immune system was not working correctly – and that M.M. "may have had a stroke or seizure when he got the vaccines since he had dilated pupils, the thrashing of the body, global apraxia and the apraxia of speech." *Id.* at 3.

Mr. Murphy acknowledged that The County Diagnostic Center (in Columbia, Maryland) had classified M.M. as having autism, and that both Drs. Zimmerman and Megson had agreed that M.M. displayed autistic features. Tr. at 139, 140. However, although Mr. Murphy admitted being aware of the fact that autism occurs on a spectrum based on symptom severity, he rejected the notion that M.M. is autistic, given that he is affectionate and somewhat social. *Id.* at 143-45.

[25] Upon conclusion of the hearing, I ordered Petitioners to produce any such video documentation of M.M.'s behavior pre-vaccination. ECF No. 97 at 1. However, Petitioners indicated that they were unable to locate those home videos. ECF No. 106.

3. Dr. Megson

Dr. Megson (who, as noted above, was one of M.M.'s treaters) offered an expert report and testimony at the entitlement hearing in support of Petitioners' theory that M.M. experienced a vaccine-induced encephalopathy that was the cause of his subsequent developmental regression and speech apraxia.

Dr. Megson graduated from the University of Virginia School of Medicine in 1978 (after completing her undergraduate degree at Hollins College). ECF No. 66-4 at 1; Tr. at 151. Dr. Megson went on to complete an internship at Tuffs University followed by a residency at Tufts New England Medical Center. *Id*. She then completed a one-year fellowship in Ambulatory Pediatrics at Boston Children's Hospital followed by a two-year fellowship in Child Development at the Medical College of Virginia. *Id*. Dr. Megson subsequently ran the Child Development Program at the Children's Hospital in Richmond, Virginia before setting up her own private practice, the Pediatric and Adolescent Abilities Center, in Richmond, Virginia at the end of 1998 – where she currently works full-time with children with developmental disabilities. Tr. at 151-52.

Dr. Megson is a board-certified pediatrician licensed in the Commonwealth of Virginia, and whose practice involves working with children with learning disabilities and developmental issues (including intellectual disability, attention deficit hyperactivity disorder, and autism). Tr. at 152; ECF No. 66-4 at 1. She is also a fellow in the Medical Academy of Pediatric Special Needs.[26] Tr. at 192. In the course of her career, she has seen over 13,000 children with developmental disabilities (the majority of whom were children with autism, although most come to her already so diagnosed). *Id.* at 158, 194-95. However, Dr. Megson estimated that she had diagnosed less than 50 children with vaccine-related encephalopathy. *Id.* at 158-59.[27]

Dr. Megson first met M.M. when he was brought by Petitioners to her office for an evaluation at four years, five months of age, nearly three years after the events in question. Tr. at

[26] Dr. Megson testified that she initially started to see children with developmental regression in the 1990s, which made her curious about the possible causes of such regression; her investigation eventually resulted in her contacting a group of biochemists whom she has since met with twice a year to share findings. Tr. at 192. However, she denied affiliation of this group with DAN!. *Id*. at 193.

[27] Throughout the course of her testimony, Dr. Megson attempted to bulwark her assertion that she is not a practitioner of alternative medicine when it comes to treating children with an autism spectrum disorder ("ASD"). Thus, she emphasized that 98 percent of her treatments rely on vitamins rather than treatment approaches the efficacy of which is unconfirmed, such as chelation therapy (which she noted M.M. received from Dr. Layton, not herself). Tr. at 219-21. However, she does advocate the use of hyperbaric oxygen treatments for children with symptoms similar to M.M.'s, arguing that there are 17 published studies showing improvements resulting from such treatments, and about 75 percent of her patients use this treatment (although she acknowledged that it not as popular as it used to be, which she attributed mainly to cost). *Id.* at 220.

156. Dr. Megson specifically testified that she was very concerned about his circumstances, because of the rapid onset of M.M.'s symptoms after his October 14th vaccinations, as reported by his parents, which resulted in her diagnosing him with a vaccine-related encephalopathy. *Id.* at 160, 188. By her own admission, however, these concerns arose from the Petitioners' rendition of M.M.'s medical history rather than from an independent review of his medical records.[28] *Id.* at 244. Nevertheless, based on what the Murphys relayed to her about their observations of M.M. over the four-day period between October 14th and October 18th, she concluded that M.M. had likely experienced an adverse reaction to vaccination because his behavioral change was so quick and dramatic (and she could not otherwise identify a neurological explanation). *Id.* at 189-90.[29]

Consistent with Mrs. Murphy's views, Dr. Megson opined that M.M. displayed features of autism rather than an ASD, given that his competency at social interaction was distinguishable from an individual with classic autism. Tr. at 195. However, she acknowledged that when she first evaluated M.M. in October 2005, she had listed a number of diagnoses – with the first one being autism (Pet'rs' Ex. 10-2 at 5). Tr. at 195.

Dr. Megson proposed a complicated theory of vaccine causation – a "perfect storm" of disparate factors, as she characterized the theory, working in concert to produce the post-immunization developmental symptoms that M.M. experienced. Tr. at 186-88. Consistent with her expert report, Dr. Megson testified that M.M.'s injury was caused primarily by the pertussis component of the DTaP vaccine he received in October 2002, although she also implicated the MMR vaccination. *Id*. at 171. Highly relevant to her theory were M.M.'s alleged genetic defects or susceptibilities that purportedly rendered him more sensitive to the stress caused by the vaccines he had received.

The first aspect of Dr. Megson's theory was the purported impact of a component of the DTaP vaccine on M.M. given his individual genetic makeup. M.M.'s alleged immediate reaction (as illustrated by high-pitched screaming, back arching, and fever of 105 degrees), Dr. Megson

[28] Dr. Megson justified the fact that she did not review M.M.'s pediatric records when she initially evaluated him in October 2005 by stating that she does not like to be biased in advance of her examination. Tr. at 196-97.

[29] Besides testifying in support of Petitioners' causation theory, Dr. Megson also repeatedly attempted to identify record support for the Murphys' reported diagnosis of vaccine-induced encephalopathy, despite the absence of a contemporaneous treater actually having ever made that diagnosis. For example, she cited in her report the fact that the Beltway Sniper incident had likely discouraged the Petitioners from seeking immediate treatment for M.M. despite the vaccination reaction they purport to have observed. ECF No. 65-8 at 1. She excused the lack of record corroborative proof of M.M.'s purported rash contemporaneous with the vaccination as the product of foreseeable human error on the part of his pediatric treaters, proposing that such treaters may simply have failed to document it. Tr. at 230-32. In that same vein, she explained away the fact that M.M.'s medical records from December 2002 (two months post-vaccination) assessed him as being a well child as attributable to the fact that general pediatricians are not trained in child development, making them unlikely to detect more subtle problems. *Id.* at 197.

asserted, was the product of his genetic susceptibility to the pertussis toxin present in that vaccine. Tr. at 177, 185-86. His reported post-vaccination screaming was direct evidence that a pertussis reaction had occurred, as medicine recognizes.[30] ECF No. 64-1 at 4. The active pertussis toxin "is known to induce the release of inflammatory cytokines, and produce dendritic cell activation." ECF No. 65-8 at 1 (citing Pet'rs' Ex. 23 (Diana L. Vargas, et al., *Neuroglial Activation and Neuroinflammation in the Brains of Patients with Autism*, 57 Ann Neural 67, 67-81 (2005)) [hereinafter Vargas]). Increased levels of pro-inflammatory cytokines, Dr. Megson opined, have been found in the spinal fluid and brains of autistic patients, thereby providing a purported link between the pertussis toxin and the resulting developmental problems alleged to have occurred in this case. *Id.*

Yet there was a central flaw to this aspect of her theory – since it is undisputed that M.M. received the *acellular* pertussis vaccine, which contains only the pertussis toxoid rather than the live toxin itself (which is detoxified via a chemical or genetic process).[31] She nevertheless proposed that retoxification had occurred (or that there was some unidentified problem with the DTaP vaccination that M.M. received), which resulted in the pertussis reaction that he allegedly experienced. Tr. at 164, 166. Thus, her theory maintained that even the acellular vaccine (designed specifically not to include pertussis toxin) still contains a small component of active pertussis toxin left in the vaccine sufficient to cause the reaction alleged. *Id*. at 163, 211-12 (citing Pet'rs' Ex. 20, "In Response to the Retort on [M.M.]"). But Dr. Megson could not pinpoint the basis for this assertion – offering neither a reliable measure of how much active toxin remains, nor an estimation of the amount of toxin sufficient to cause the reaction alleged. Indeed – by her own admission the literature cited in her report did not support this proposition. *Id*. at 212.[32] Moreover, she is

[30] To explain this correlation, Dr. Megson testified that "[b]y 1990, high pitched screaming was considered an absolute contraindication to further pertussis vaccines by the vaccine manufacturers, the Public Health Services Immunization Practices Advisory Committee (ALIP), and the American Academy of Pediatrics." ECF No. 64-1 at 4 (citing Harris L. Coulter & Barbara Loe Fisher, *A Shot in the Dark* 33 (Avery Publishing Group, 1991)). She admitted in her supplemental expert report, however, that this reaction is now viewed as merely a "precaution against repeating pertussis vaccine." ECF No. 65-8 at 1. Also, as noted in previous Vaccine Program cases, *A Shot in the Dark* does not provide particularly probative medical or scientific evidence regarding vaccine causation, as information contained in the book is largely anecdotal. *See, e.g.*, *Watson v. Sec'y of Dep't of Health & Human Servs.*, No. 89-92V, 1990 WL 293420, at *3, n. 16 (Cl. Ct. Spec. Mstr. Sept. 14, 1990).

[31] A toxoid is a bacterial toxin whose toxicity has been inactivated or suppressed while other properties (namely, immunogenicity – its ability to provoke an immune response in the body) are maintained. Tr. at 435 (testimony from Dr. Wiznitzer). The term toxin is "frequently used to refer specifically to a protein that is produced by some higher plants, certain animals, or pathogenic bacteria and is highly toxic for other living organisms." *Dorland's Illustrated Medical Dictionary* 1942 (32d ed. 2012) [hereinafter *Dorland's*]. In contrast, a toxoid is "a modified or inactive bacterial exotoxin that has lost toxicity but retains the properties of combining with, or stimulating the formation of, antitoxin." *Id*. at 1943.

[32] Thus, Dr. Megson cited Sandrine Tonon, et al., *Bordetella Pertussis Toxin Induces the Release of Inflammatory Cytokines in Dendritic Cells Activation in Whole Blood: Impaired Responses in Human Newborns*, 32 European Journal of Immunology 3118, 3118-125 (Nov. 2002) (Pet'rs' Ex. 22) [hereinafter Tonon] in her report as evidence of

admittedly not an immunologist or vaccine expert even qualified to offer such testimony. *Id*. at 193-95.

Moving on, Dr. Megson opined that M.M. possessed genetic deficiencies (as supported by a family history of vision issues) that made him more susceptible to an adverse reaction to the pertussis toxin that she believed he had experienced. Tr. at 171. Specifically, M.M. has a defect in the G protein,[33] inherited from one of his parents, and that this is where the pertussis toxin inserts itself after its introduction into the body.[34] *Id*. at 169, 174. Because there is no evidence in this case of testing to establish this purported defect, however, Dr. Megson referred to M.M.'s reported family medical history. She found it significant that M.M.'s maternal grandfather is colorblind, because she opined that the pertussis toxin inserts itself adjacent to the genetic defect for color blindness in G proteins. ECF No. 64-1 at 4. Dr. Megson also found it significant that M.M.'s father suffered from migraines, caused by a double defect in the G protein. ECF No. 64-1 at 4. And both Petitioners have symptoms of incomplete congenital stationary night blindness, which is caused by G protein defects (and is seen in the histories of about 30 percent of patients who have symptoms similar to those exhibited by M.M.).[35] Tr. at 170-71.

Given the above, Dr. Megson proposed that the "[t]wo defects in this G protein block acetylcholine, the main neurotransmitter of the autonomic nervous system." ECF No. 64-1 at 4. As discussed above, G proteins play an important role in transmitting signals from a variety of stimuli outside of a cell to its interior. Farfel at 1012. Dr. Megson explained that when the body is functioning normally, the calcium channels receive a stimulus (such as acetylcholine) causing them to open briefly, allowing a small amount of calcium to enter the cell. Tr. at 169-70. For an

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the concept that pertussis toxin remained even in the acellular version (Pet'rs' Ex. 21, n. 1), but was unable to pinpoint the portion of the article that stood for this proposition, indicating that this article was cited because it refers generally to inflammatory response. Tr. at 212-16. My review of this piece of literature reveals that it expressly *does not* support the contention for which it was cited – nor have Petitioners offered any other reliable scientific or medical proof establishing that the acellular form of pertussis vaccine contains sufficient amounts of pertussis toxin to have the effect alleged in this case by Petitioners.

[33] G proteins, also known as guanine nucleotide-binding proteins, are involved in transmitting signals from a variety of stimuli outside of a cell to its interior. ECF No. 113-1 at 1 (Zvi Farfel, et al., *The Expanding Spectrum of G Protein Diseases*, 340 New Eng. J. Med. 1012 (1999) [hereinafter Farfel]). The activity of G proteins is regulated by factors that control their ability to bind to and hydrolyze guanosine triphosphate ("GTP") to guanosine diphosphate ("GDP") – when G proteins are bound to GTP they are "on" and when they are bound to GDP they are "off." Farfel at 1012, 1015. Accordingly, "[m]utations that alter G protein activation may cause disorders characterized by either insufficient or excessive transmission of signals." *Id.* at 1012.

[34] In providing this explanation, Dr. Megson relied on a diagram from Farfel to help illustrate the G Protein's function in connection with her theory. Tr. at 174.

[35] However, Dr. Megson acknowledged that in the notes from the initial history that she took of M.M. (Pet'rs' Ex. 10-2), she documented only that his maternal grandfather had colorblindness. Tr. at 216-17.

individual with two deficits in the G protein, however, the pertussis toxin inserts itself and those neurotransmitter-mediated L-type calcium channels remain "stuck open" because they are not receiving the appropriate signal to close. *Id*. at 170. Dr. Megson opined that this disturbance in the calcium channels upsets the homeostasis in the body, leading to a variety of problems that could include autism (or autism-like features). *Id*. As evidence, Dr. Megson argued that some of the nutritional supplements effective in treating autism, including vitamin D3, docosahexaenoic acid ("DHA"), and magnesium, do so by helping to close the calcium channels. *Id*.

Further evidence, Dr. Megson testified, for the purported defects in G protein blocking acetylcholine transmission in M.M.'s case was to be found in his reported pupil dilation[36] and gastrointestinal issues. ECF No. 64-1 at 4. She maintained that "dilated pupils are a sign of acetylcholine being blocked" (because acetylcholine is responsible for pupillary constriction), and "[w]hen acetylcholine is blocked, it affects the secretory function of the gut leading to poor excretion of digestive juices, and enzymes to break down food, leading to malabsorption and diarrhea."[37] *Id.*; Tr. at 175-76. Thus, the G protein defect impacted by the pertussis toxin (and purportedly resulting in M.M.'s developmental problems) was evidenced by M.M.'s pupil dilation and gastrointestinal disorders. ECF No. 64-1 at 4.

The second component of Dr. Megson's theory involved another genetic predisposition M.M. allegedly possessed, rendering him susceptible to an adverse reaction to vaccination: a double homozygous single nucleotide polymorphism ("SNP")[38] (C677 gene mutation) in the methylenetetrahydrofolate reductase enzyme ("MTHFR"). ECF No. 65-8. Methylation involves the transfer of a methyl group (one carbon and three hydrogen atoms) from one compound to

[36] As evidence of dilation, Dr. Megson relied partially on Mrs. Murphy's claim that on "the day of the shot, [M.M's] pupils became dilated and they remained that way for years." Tr. at 175, 205. Dr. Megson further testified that when she first examined M.M. she put him in a dark room, but his pupils remained dilated even when she shined a bright light in his eyes. *Id.* at 175. Dr. Megson acknowledged that her typewritten notes from her initial visit with M.M. seem to suggest that he no longer had dilated pupils. *Id.* at 205; Pet'rs' Ex. 10-2 at 3 ("[h]e used to drool in the past and had very dilated pupils. This has improved."). However, Dr. Megson countered that his pupils were huge every time she saw M.M., and speculated that the note may have merely indicated that they had gotten a little better. Tr. at 206.

[37] Dr. Megson explained that acetylcholine is important for secretory functions in the gut, indicating that the gut can be viewed as a long muscular tube that should squeeze in a coordinated fashion, but for many children like M.M. this stops happening. Tr. at 175-76. She explained that it also stimulates the muscles around the pancreas to get enzymes in to digest food and around the gallbladder to get toxins out of the body. *Id.* at 176. However, if acetylcholine is blocked, the gut cannot do that which results in a change in bowel function, similar to the one seen in M.M. post-vaccination (and that persisted for many years) as per parental reports. *Id*.

[38] "A single nucleotide polymorphism or SNP (often pronounced "snip") is a DNA sequence variation occurring when a single nucleotide - A, T, C, or G - in the genome (or other shared sequence) differs between members of a species (or between paired chromosomes in an individual)." Single Nucleotide Polymorphism Analysis and Mutation Detection, http://www.dnabaser.com/articles/SNP/SNP-single-nucleotide-polymorphism.html (last visited Mar. 29, 2016).

another, which is important for a variety of important bodily functions, including detoxification of toxins that come from exposure to environmental factors or that are byproducts of biochemical reactions that occur at the cellular level. Tr. at 183-84. Glutathione, which Dr. Megson described as the "trash can," is involved in the oxidation-reduction reactions that occur in the body and is responsible for removing toxins from the body. *Id*.

As Dr. Megson testified, "[a]t the end of this [methylation] pathway, homocysteine is shunted into glutathione, which helps children deal with toxins and oxidative stress." ECF No. 65-8 at 2. But the double homozygous SNP in MTHFR (which post-vaccination testing revealed M.M. possesses) slowed down M.M.'s methylation pathway by 60 percent,[39] making him more susceptible to an adverse reaction to vaccination because he was unable to deal with the toxins and oxidative stress caused by the vaccinations he received. ECF No. 65-8.[40] In particular, Dr. Megson opined that the MTHFR gene defect impacting M.M.'s methylation cycle resulted in him having lower availability of glutathione (which she purported to be associated with developmental problems). Tr. at 183-84, 199-200.

To support the assertion that methylation deficiencies could be adversely impacted by vaccination, Dr. Megson cited a study looking at genetic factors increasing an individual's risk of adverse events following receipt of the small pox vaccination. ECF No. 65-8 at 2 (citing David M. Reif, et al., *Genetic Basis for Adverse Events after Smallpox Vaccination*, 198 J. Infect. Dis. 16, 16-22 (2008)). She noted that "[i]n two trials, a single SNP [] in MTHFR at C667T was significantly associated with an increased risk of an adverse event following this vaccine" (and observed that genetic testing revealed that M.M. has two SNPs). ECF No. 65-8 at 2. She also relied on certain studies (not included in the materials filed in this case)[41] showing that children with developmental disabilities possessed lower levels of glutathione. Tr. at 199. However, Dr. Megson acknowledged that she did not test M.M.'s glutathione levels before deciding that he was deficient in it and should start taking a supplement, but instead relied on different tests conducted by Dr. Layton revealing that M.M. had high levels of certain metals. *Id.* at 200-01.

[39] At hearing, Dr. Megson modified this assertion, stating that this alleged double hit to M.M.'s methylation pathways actually slowed down the methylation process by 70 to 90 percent. Tr. at 183.

[40] The fact that M.M. was no longer breastfeeding when he received the relevant vaccines in October 2002 was significant to Dr. Megson. In her view, a child with a double C677T double mutation like M.M. would experience a protective effect from breastfeeding because of the folic acid obtained by Mrs. Murphy from vitamin supplements and passed on in her milk. Tr. at 185-86. This, in Dr. Megson's view, was likely sufficient to protect M.M. from metabolic overload despite his genetic susceptibilities when he received prior vaccinations. *Id.* at 185.

[41] This included work purportedly done by Jill James and Dr. Richard Deth (although articles written by these individuals supporting this assertion were not filed in this case). Tr. at 200.

As with the pertussis toxin aspect of Dr. Megson's theory, however, there were notable gaps in scientific support for the G protein/methylation deficiency aspects of her overall theory that Dr. Megson could not deny. Despite her reliance on MTHFR polymorphism testing as demonstrating the role of vaccination in M.M.'s developmental problems, Dr. Megson admitted that the American College of Medical Genetics ("ACMG") practice guidelines observe a lack of evidence supporting the utility of such testing. Tr. at 202. Indeed, she admitted an absence of evidence that methylation deficiencies *themselves* are related to developmental regression or autism. *Id.* at 203. Thus, she acknowledged that 10 to 15 percent of the Caucasian population has homozygous polymorphism in the MTHFR gene, yet a similar rate of autism in that population is not observed (contrary to what would be expected if methylation problems were causally associated with autism). *Id*. at 204. She similarly agreed that the fact that 25 percent of Hispanic children have this polymorphism does not mean there is a higher rate of autism among Hispanic children (although she qualified the admission by noting that she did not know their vaccine schedule, metal sensitivity, or other risk factors in that population). *Id.* at 204-05. Faced with this line of questioning on cross-examination, Dr. Megson clarified that she was not trying to say that this polymorphism specifically caused autism, but rather that it was a likely component of the "perfect storm" of conditions she observed with respect to M.M. *Id*. at 204.

The next element of Dr. Megson's theory related to the purported contributory role of the MMR vaccine that M.M. received at the same time as the DTaP vaccine. She proposed that M.M. had experienced "leaky gut" (and a similarly porous blood-brain barrier). Tr. at 178-79. After a child receives the measles vaccine, she explained, the antibodies produced by the immune system in reaction to the measles component of the vaccine cross-react with host tissues, called intermediate filaments, which form the tight junctions that hold the cells that line the gut wall and blood-brain barrier together. *Id*. at 177-78. Dr. Megson indicated that this porous blood-brain barrier thereby increases the chances of vaccine components (such as pertussis toxin) getting into the brain.[42] *Id*. at 180.

To support this aspect of Petitioners' causation theory, Dr. Megson relied on the Murphys' contention that M.M. had developed a high pain tolerance post-vaccination, as evidenced in the spring of 2003. Pet'rs' Ex. 2 at 12; Tr. at 185-86. Some children, she testified, fail to digest wheat and milk proteins completely following receipt of the MMR vaccine, as evidenced by measuring the levels of gluteomorphin (which is morphine from wheat) and caseomorphin (which is morphine from milk) in a child's urine. *Id.* at 178. Under those circumstances, the milk and wheat protein

[42] Dr. Megson also opined that having a leaky gut wall as a result of receipt of the MMR vaccination could undermine the natural way that the body's cells protect an individual from "intestinal bacteria and food and garbage from the blood stream." Tr. at 178.

remaining in a child's diet will begin acting like opiate peptides, such as the ones present in painkillers, producing a very high pain tolerance. *Id.* at 178-79.

Finally, Dr. Megson implicated some of the adjuvants[43] present in the vaccines M.M. received as contributing to his developmental problems. As she testified, aluminum is a toxic metal present in some vaccines. The chance of aluminum entering the brain increases when an individual has an MMR-induced gut or blood-brain barrier leak. Tr. at 180. However, Dr. Megson did not propose a specific mechanism by which this process would occur, and she admitted uncertainty as to the actual effect that the aluminum in the DTaP vaccine had on M.M. (nor did she propose what amount of aluminum would be necessary to cause such a reaction).[44] *Id.* at 179-80. At best, she opined that Mrs. Murphy is metal-sensitive,[45] a condition Dr. Megson reported was common (in her experience) to families with children who have experienced symptoms similar to those of M.M. *Id*.

4. Dr. Zimmerman

Dr. Zimmerman was one of M.M.'s treaters[46] many years after the relevant 2002 vaccinations, and he testified about the circumstances of his examination of M.M. and conclusions he drew from the same. Dr. Zimmerman based his testimony on his recollection surrounding his treatment of M.M. (including information reported to him from M.M.'s parents), as well as a more recent review of M.M.'s medical records. Tr. at 254-55.

[43] An adjuvant is a substance that is added to a vaccine to increase the body's immune response, which is necessary to develop immunity (and in turn reduces the amount of antigen – the pathogen component of the vaccine that elicits an immune response – needed for the vaccine's efficacy). Tr. at 414 (Dr. Wiznitzer's explanation); *Dorland's* at 32 (defining adjuvant – as the term is used in immunology – as "a non-specific stimulator of immune response . . .").

[44] Petitioners' counsel also asked Respondent's expert, Dr. Wiznitzer, about aluminum and its potential role in causing the injuries alleged in this case. Dr. Wiznitzer testified that aluminum is present in small quantities in the DTaP vaccination, but denied its capacity to pass into the brain, let alone harm it. Tr. at 413-14.

[45] Dr. Megson based this opinion not on any formal medical diagnosis or test, but rather on the fact that Mrs. Murphy does not wear jewelry because of the reaction that her skin has to it. Tr. at 180.

[46] As noted above, Dr. Zimmerman testified as a fact witness (although he has offered expert testimony in other Program cases). Accordingly, his credentials and qualifications have somewhat less bearing on analysis of his testimony herein. However, Petitioners (perhaps anticipating their desire to make him an additional expert witness) did question him on his qualifications. *See generally* Tr. at 252-53. Such testimony established that Dr. Zimmerman is a pediatric neurologist who has been employed by The University of Massachusetts in Worcester for the past 18 months, and who was formerly employed at Kennedy Krieger Institute in Baltimore, Maryland where he worked for 16 years (and treated M.M.). *Id*. at 252. Dr. Zimmerman is licensed to practice medicine in Massachusetts and Maryland. *Id.*

Based on the history provided to him in 2009, Dr. Zimmerman had accepted the accuracy of M.M.'s diagnosis of vaccine-related encephalopathy[47] with apraxia[48] and features of autism. He specifically relied on M.M.'s purported history of high fever and persistent behavioral problems within a week after the October 14, 2002, vaccinations reported to him by M.M.'s parents. Tr. at 259, 265-66. But Dr. Zimmerman did not recall reviewing M.M.'s medical records as a basis for obtaining the history upon which the diagnosis was based. *Id*. at 256. Rather, it was Dr. Schultz (the attending physician) who took the history and drafted it, and then Dr. Zimmerman merely reviewed it. *Id.* at 287. At bottom, Dr. Zimmerman was simply echoing what had already been reported about M.M.'s condition (because at the time he did not have a better explanation for the situation). *Id.* at 271-72.[49]

After his initial examination of M.M., Dr. Zimmerman recommended (in a letter dated June 8, 2009) that his office review any metabolic or genetic testing previously performed, in order to screen for possible causative elements such as an underlying mitochondrial disease. Tr. at 256, 263. Dr. Zimmerman explained that he was seeking information regarding whether M.M. had a mitochondrial disorder because that might reveal an underlying sensitivity or susceptibility to vaccination that could in turn produce a developmental regression. *Id.* at 257.[50] He admitted, however, that at no time did he directly "order" that any such testing occur – and indeed, as noted above, the relevance of such testing to M.M.'s situation was raised only in the June 8, 2009, record from the Murphys' visit to Kennedy Krieger (Pet'rs' Ex. 12 at 7), and is not mentioned again thereafter. He also acknowledged that he did not have any information regarding mitochondrial testing performed on M.M. Tr. at 259. The record contains no other treater opinions that M.M.

[47] In Dr. Zimmerman's view, vaccine encephalopathy is an untoward reaction to a vaccination affecting the nervous system. Tr. at 265.

[48] Dr. Zimmerman explained that apraxia is a problem with motor planning as "directed" within the brain, which is very common in children with autism. Tr. at 270.

[49] With the benefit of having reviewed the medical records he had not seen at the time he first examined M.M., Dr. Zimmerman was able to acknowledge discrepancies between the history reported to him by M.M.'s parents and those records. For instance, the notes from M.M.'s December 10, 2002, pediatric visit (indicating that M.M. was a well child with the exception of mild eczema) suggested to Dr. Zimmerman that M.M. was not encephalopathic at that particular point in time. Tr. at 288.

[50] As Dr. Zimmerman explained, mitochondrial disorders are usually defined abnormalities in the DNA in the mitochondria, whereas mitochondrial dysfunction means that there are signs that the mitochondria are not working optimally. Tr. at 258. Many children with autism have mitochondrial dysfunction but do not actually have a recognized mitochondrial disorder. *Id.* at 257. Dr. Zimmerman also opined that vaccine encephalopathy and mitochondrial dysfunction are commonly associated, but admitted that a direct cause has yet to be established. *Id.* Certain children with underlying metabolic disorders or dysfunction are believed susceptible to regression with metabolic stress / oxidative stress and immune stimulation (receipt of vaccine being one such form of immune stimulation). *Id.* at 257, 260.

might have suffered from some kind of mitochondrial disease (and thus no other treater ever proposed testing that would have produced the results Dr. Zimmerman wished to review).

As noted above, Petitioners made it clear (both during and after the hearing) that they wished to offer Dr. Zimmerman as a causation expert rather than merely as a fact witness. In an attempt to lay some of the groundwork required to do so, counsel asked some questions of Dr. Zimmerman about a possible alternative causation theory relevant to Dr. Zimmerman's treatment: that M.M. suffered from a preexisting mitochondrial disease or disorder that was exacerbated by oxidative stress caused by the relevant vaccinations. Tr. at 282-84. Although Dr. Zimmerman answered such questions, he admitted that he lacked the direct expertise to opine on the topic, even though he had read enough to be knowledgeable about it. *Id.* at 266-67.

B. Respondent's Expert – Max Wiznitzer, M.D.

Dr. Wiznitzer offered testimony responding to Petitioners' general assertion that M.M. did not suffer from an ASD, as well as a critique of Dr. Megson's causation theory.

Dr. Wiznitzer graduated from the honors program in medical education at Northwestern University where he received a bachelor's of science in medicine in 1975, and his medical degree in 1977. Tr. at 304. He went on to complete a three-year internship and residency in pediatrics at Cincinnati Children's Hospital in Cincinnati, Ohio, followed by a one-year fellowship in child development and developmental disorders at the Cincinnati Center for Developmental Disorders. *Id.* at 304-05. He also completed a three-year child neurology fellowship at the University of Pennsylvania and Children's Hospital of Philadelphia, followed by a two-year National Institute of Health fellowship in disorders of higher cortical function in children at the Albert Einstein College of Medicine in the Bronx, New York (which involved working with children with ASDs). *Id.* at 304-06. Dr. Wiznitzer currently works at Rainbow Babies and Children's Hospital in Cleveland, Ohio. *Id.* at 304. Dr. Wiznitzer also serves as a journal reviewer and on two editorial boards (the Lancet Neurology and the Journal of Child Neurology). *Id.* at 308. Dr. Wiznitzer is board certified in pediatrics, neurology (with special qualification in child neurology), and neurodevelopmental disabilities. *Id.* at 305.

Dr. Wiznitzer has an active clinical practice, and he estimates that more than a quarter of the patients he sees have autism (many of whom receive that diagnosis from him). Tr. at 307, 309-11.[51] He also has ASD-related research and teaching experience. When Dr. Wiznitzer started his current job at Rainbow Babies and Children's Hospital in 1986, he immediately got involved in autism research, and his most recent work (which is yet to be published) involves looking at

[51] When he is in Cleveland, Dr. Wiznitzer normally sees patients at least seven half-days a week, and he also sees inpatients about two months a year. Tr. at 307, 309-310.

treatment protocols for autism. *Id.* at 305-06. Additionally, Dr. Wiznitzer is on the Autism Subcommittee of the American Academy of Pediatrics and the American Academy of Neurology, both of which are working on new guidelines for the diagnosis and management of autism. *Id.* at 307-08. And he is also involved in teaching individuals about autism both at the medical center, as well as in the Cleveland area and nationally. *Id.* at 306-07.

Based on information obtained from the medical records, Dr. Wiznitzer expressed the opinion that M.M. has an idiopathic ASD. Tr. at 320-21. In his view, M.M. most likely developed autism because he was born with the genetic predisposition (which gradually showed itself), and not as a result of his October 2002 vaccinations. *Id.* at 366-67, 442. As he explained, newly developed testing can identify a defined genetic component as present in a quarter of individuals with autism, although this still leaves 75 percent of children where the cause of autism has not been identified. *Id.* at 311-13.

Dr. Wiznitzer opined that the record strongly supported an ASD diagnosis over the apraxia and regressive development "with features of autism" diagnosis urged by Petitioners. In support, he noted M.M.'s history of impairments in socialization and communication and the presence of repetitive behaviors documented in the contemporaneous medical records. ECF No. 42-1 at 8.[52] Dr. Wiznitzer also indicated that contrary to Petitioners' assertions, M.M.'s capacity to show affection (especially toward his parents) did not rule out that he had an ASD, since even young children with ASD can interact positively with their primary caregiver, and that in any event such factors are less important to the diagnosis than others (such as the display of intense, single-minded behavioral "fascinations"). Tr. at 311, 323-24.

Consistent with his views about the most likely origin of M.M.'s ASD, Dr. Wiznitzer disputed Petitioners' factual contention that M.M. had experienced a severe reaction to the October 2002 DTaP and MMR vaccines, producing an encephalopathy and subsequent developmental regression. Tr. at 342-43. Dr. Wiznitzer began by defining encephalopathy as an impairment in consciousness that can be associated with other neurological symptoms or signs, such as unsteadiness or seizures.[53] *Id*. But he saw nothing in the contemporaneous medical records

[52] M.M. had problems with socialization (citing comments such as no socializing, poor eye contact), he did not respond to voice, and he was described as not having good pretend play. Tr. at 321. There were also repetitive behaviors documented in the records, including hand flapping and finger flicking. *Id*. Moreover, the County Diagnostic Documents (Pet'rs' Ex. 13 at 2) stated that "[p]arental concerns at the time included lack of speech/language skills and social behaviors, little eye contact, not responding to his name or following directions, and hand flapping" – all features consistent with a diagnosis of ASD. Tr. at 322.

[53] Dr. Wiznitzer contrasted an acute encephalopathy with a chronic encephalopathy characterized by ongoing dysfunction of the brain (which could be defined to include autism). Tr. at 352. However, he stressed that based on the medical records he saw no evidence that M.M. had a chronic encephalopathy that is not better explained by his autism diagnosis. *Id.* at 353.

supporting the conclusion that M.M. exhibited features of a sudden encephalopathy in the days immediately following vaccination. *Id.* at 343. For instance, Dr. Wiznitzer cited M.M.'s October 18, 2002, pediatric visit (Pet'rs' Ex. 2 at 15), a few days after vaccination, where no changes in M.M.'s mental status were reported – contrary to what would be expected if M.M. had actually experienced an encephalopathy. Tr. at 343-45. The next pediatric record (from December 2002) was similarly unremarkable, with M.M. presenting as a well child. *Id.* at 348; Pet'rs' Ex. 23 at 14.[54]

Dr. Wiznitzer did not accept the Murphys' assertions that M.M.'s reported immediate reactions were evidence of encephalopathy. Thus, he disputed the meaningfulness of claims M.M. had engaged in high-pitched screaming, noting that such behavior was actually *inconsistent* with an acute encephalopathy, as it would be very difficult to calm a child under such circumstances. Tr. at 347-48. Rather, the fact that M.M.'s alleged screaming occurred when lying down, but ceased when he was picked up, suggested to Dr. Wiznitzer that M.M.'s distress was physical pain from the vaccinations rather than something more severe. *Id.* Dr. Wiznitzer also pointed to pediatric records indicating that M.M. had not lost any weight, and actually had gained a few pounds (*compare* Pet'rs' Ex. 2 at 15 *with* Pet'rs' Ex. 2 at 16) as an indicator of his well-being during this period of time; if M.M. had actually been encephalopathic, he would not have been feeding well or taking in adequate fluids, and would have lost weight. Tr. at 345.[55]

Dr. Witznitzer similarly disputed Petitioners' claims that M.M. experienced seizures in the days immediately following his October 2002 vaccinations. In his clinical practice, Dr. Wiznitzer stated that he regularly follows and treats seizure patients, and therefore is aware of what would constitute seizure activity. Tr. at 349-51. The record facts in his view did not support the conclusion that seizures had occurred, because the descriptions of arching and thrashing provided by Mrs. Murphy were not congruent with what a medical professional would expect to see reported when a child experiences a seizure (stiffening of the body and a rhythmic jerking, not thrashing).[56] *Id.* In addition, seizures do not spontaneously stop within a few days without intervention, yet that is

[54] Dr. Wiznitzer also took issue with Petitioners' assertions that M.M. was suffering at the time from great gastrointestinal distress, observing the note in the December 2002 record that M.M. had "one to two stools, plenty of wet diapers," which he felt was inconsistent with Mrs. Murphy's testimony. Tr. at 348.

[55] Dr. Wiznitzer expressed the opinion that notations in the medical records that M.M. was pulling on his ears in reaction to ear infection pain (Pet'rs' Ex. 2 at 13) was similarly inconsistent with the existence of an acute encephalopathy, because it was evidence of deliberate action in response to discomfort rather than a generalized involuntary reaction. Tr. at 346.

[56] Dr. Wiznitzer acknowledged that thrashing (such as that reported by M.M.'s parents) could be part of the clinical picture of someone with an encephalopathy. Tr. at 398. However, he reiterated his opinion that the thrashing reported with M.M. was more likely a result of the pain or discomfort that he was experiencing as a result of the vaccinations he had just received. *Id.* at 398-99.

what is alleged to have occurred in this case (as the purported seizures are not mentioned after any October 2002 records). *Id.* Accordingly, in Dr. Wiznitzer's estimation, M.M.'s movements were more consistent with a reaction to transitory pain caused by the vaccinations rather than a neurologic injury. *Id.*

In addition to contesting Petitioners' allegations that M.M. had experienced an encephalopathy after his vaccinations, Dr. Wiznitzer challenged their assertion that M.M. thereafter experienced a sudden developmental regression. Tr. at 324-25. He acknowledged that regression may occur in autism,[57] but opined that the contemporary medical records described a gradual evolution of a "typical" ASD. ECF No. 42-1 at 8. In so maintaining, he questioned the reliability of the Murphys' personal allegations about M.M.'s regressive development in light of the contrary medical records, which did not corroborate their assertions. *Id.* at 9. Rather, the pediatric care records in the second and third year of M.M.'s life – well after the October 2002 vaccinations – reflected concerns about language delay instead of something more widespread or significant. Tr. at 325-26. Indeed, even Dr. Megson's history (Pet'rs' Ex. 10-2 at 3) set forth that M.M. had "gradually lost language," suggesting that the loss occurred over a period of time significantly longer than what is alleged by Petitioners. Tr. at 443.

Beyond his testimony about M.M.'s medical history, Dr. Wiznitzer also offered opinions on the scientific and medical reliability and plausibility of various elements of Dr. Megson's causation theory.[58] In particular, Dr. Wiznitzer disagreed with Dr. Megson's assertions that there is pertussis toxin present in the acellular vaccine that M.M. received. Tr. at 327-28. Rather, the version of the DTaP vaccine that M.M. received, Tripedia,[59] is chemically inactivated using formaldehyde in order to produce pertussis toxoid – which lacks toxicity but maintains its

[57] Dr. Wiznitzer to some extent questioned the very concept of a sudden regression as not normally an aspect of an idiopathic ASD. As he noted, sibling studies suggest that what is termed regression may simply reflect a faster development of ASD (with the term "stagnation" being employed to describe a slower-progressing ASD). Tr. at 324-25.

[58] Although my decision includes review and discussion of all of Dr. Wiznitzer's testimonial points, I note that he is as much of an expert in immunology or virology as Dr. Megson, and therefore his opinions on medical and scientific topics ranging from the content of the DTaP vaccine to the permeability of the blood-brain barrier merit no more weight than I would give to Dr. Megson's testimony given her own expertise and background. Of course, since the Petitioners carry the initial burden of proof, and therefore must offer the proper expert to opine on the matters most relevant to their causation theory, Dr. Megson's overall qualifications to give the opinion she provides in this case are of paramount concern.

[59] Tripedia is composed a diphtheria and tetanus toxoids and acellular pertussis vaccine. Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Tripedia (product information as of Dec. 2005), Sanofi Pasteur Inc., http://www fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM101580.pdf.

immunogenicity, and which is therefore incapable of interacting with the G protein in the manner outlined by Dr. Megson.[60] *Id.* at 329-31, 334-35; ECF No. 42-1 at 9.

Dr. Wiznitzer similarly contested the independent evidence that Dr. Megson said corroborated her pertussis / G protein interaction theory, such as familial colorblindness, noting that (a) no research he was aware of supported the concept, (b) he had seen no record evidence establishing M.M.'s colorblindness, let alone his maternal grandfather's, and (c) any putative dysfunction caused in the pertussis insertion in the G protein would occur in the retina rather than the brain, thus delinking it as proof of a neurologic impact. Tr. at 340. And he did not find persuasive Dr. Megson's claims about M.M.'s purportedly dilated pupils, arguing in response that the record did not establish pupil dilation at the time of the October 2002 vaccinations, that dilation could be consistent with anxiety at doctor's visits, and that (as with colorblindness) pupil dilation is not otherwise associated with clinical pertussis, a respiratory illness (meaning it would similarly not be associated with a pertussis reaction of any kind). *Id.* at 338-40, 411-12, 420, 422.

Next, Dr. Wiznitzer took issue with the concept that (assuming pertussis toxin persisted in the acellular form of the DTaP vaccine in sufficient amounts to cause injury) the pertussis toxin could have crossed the blood-brain barrier to cause M.M.'s developmental symptoms, asserting that the relevant molecule was too large to do so (and unlikely to make the journey from injection point to brain in any event), and that the argument lacked reliable scientific support. ECF No. 42-1 at 9; ECF No. 68-1 at 2; Tr. at 335, 337. He similarly challenged Dr. Megson's assertion the measles component of the MMR vaccine could permit the entry of toxins through the gastrointestinal system (or permeate the blood-brain barrier) causing an autistic phenotype, arguing that the position was not supported by science and that he was unaware of any plausible biologic mechanism by which this process could occur. Tr. at 327, 341-42. And he disagreed with Dr. Megson's opinion that (as an alternative causative factor) vaccination could elicit a pathologic cytokine response in the brain capable of causing neurologic harm of the sort alleged in this case. *Id.* at 329-34.[61]

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[60] Dr. Wiznitzer also questioned the timing of the alleged G protein interaction mechanism. Because G protein has a half-life of approximately 24 hours, Dr. Wiznitzer opined that even if pertussis toxin could remain in the acellular form of vaccine in sufficient amounts to interact with the G protein, it would all be gone within five days and, therefore, an affected child would no longer be symptomatic after that period of time. Tr. at 338.

[61] Dr. Wiznitzer's attack on this aspect of Dr. Megson's theory included discussion of some of the scientific and medical literature she cited in her reports. For example, he pointed out that the authors of the Tonon article (Pet'rs' Ex. 22) expressly acknowledged that the chemically modified pertussis toxin, such as that contained in the Tripedia vaccine that M.M. received, *did not* elicit a significant cytokine response (and they actually stopped using it in future experiments for that reason). Tr. at 329-31. He also addressed Vargas (Pet'rs' Ex. 23), noting that it was published ten years ago and, therefore, does not take into account developments in the most current understanding of cytokine effects. *Id.* at 332-33. The most up-to-date understanding of cytokines, Dr. Wiznitzer explained, is that their expression in the brain reflects the brain's attempt to fix existing dysfunction, rather than an inflammatory *cause* of dysfunction – a fact that Vargas anticipates. *Id*. at 333-34; Pet'rs' Ex. 23 at 12-15.

Finally, Dr. Wiznitzer addressed Dr. Megson's arguments about M.M.'s purported methylation deficiencies as established by testing showing M.M. was homozygous for the C677T polymorphism. He broadly noted that this particular mutation was not itself associated scientifically with autism (despite his prior assertions that there was an unidentified genetic causal link likely related to ASD),[62] and therefore he would not ever request testing for that polymorphism in his ASD patients. Tr. at 313, 353-55. He also doubted that the methylation capacity of a child testing positive for the polymorphism would be affected in a clinically significant way. *Id.* at 356, 360-61. In the same vein, Dr. Wiznitzer questioned the impact of oxidative stress caused by vaccination in a person like M.M. with the polymorphism. *Id.* at 357. He would expect any injury caused by oxidative stress to be evident on an MRI, but M.M.'s MRIs were normal. *Id.* at 357-58.[63] Dr. Wiznitzer also deemed the assertion that a glutathione insufficiency due to the MTHFR gene could have exacerbated oxidative stress in M.M. resulting in injury was biologically implausible, and not otherwise supported by any reliable data of which he was aware. *Id.* at 364-65.

III. PROCEDURAL HISTORY

A. Early Case History.

As stated above, the Murphys filed this petition in 2005, adopting the "Master Autism Petition for Vaccine Compensation" and providing no further details regarding the nature of the alleged vaccine-related injury. ECF No. 1. On May 6, 2009, Respondent filed a statement expressing no objection to the jurisdiction and appropriateness of Petitioners proceeding within the Omnibus Autism Proceeding ("OAP").[64] However, after the relevant test cases in the OAP

[62] Dr. Wiznitzer attacked the credibility of the an article filed by Petitioners – Marvin Boris, et al., *Association of MTHFR Gene Variants with Autism*, 9 J. Am. Physicians & Surgeons 106-108 (Winter of 2004) purporting to demonstrate an association between MTHFR gene variants and autism (Pet'rs' Ex. 30), arguing that it was published in a journal with highly questionable peer-review practices, plus inherent biases about the safety of vaccines generally. Tr. at 376-77. He also suggested that its authors committed a fatal error of selecting the reference basis to support their ultimate conclusion, because they "cherry-picked" the experimental controls used depending on which variant they were examining. *Id*. at 374.

[63] Dr. Wiznitzer admitted on cross-examination that the MRIs of children with autism generally are negative. Tr. at 385. He nevertheless found it significant in this case that the MRI performed on M.M. did not show signs of abnormalities because Petitioners are claiming that M.M. experienced oxidative stress leading to brain damage, which means that there would be dead brain cells that should show up on an MRI. *Id.* at 386-87.

[64] This case was initially among the more than 5,400 cases filed under short form petition in the OAP, where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

were litigated, and their causation theories rejected, the Murphys elected to remain in the Vaccine Program, filing an amended petition on March 17, 2011, explaining how their revised theory of vaccine causation differed from the decided test cases. ECF No. 23.

Petitioners were instructed on March 12, 2012, to obtain an expert report supporting their claim. ECF No. 24. Thereafter, on July 11, 2012, Petitioners submitted a status report indicating that they were in the process of obtaining an expert report from Dr. Megson. ECF No. 28. Petitioners continued to file such status reports in the ensuing months, eventually indicating that although they still anticipated receiving an expert report from Dr. Megson, they were experiencing difficulties obtaining that report and were now seeking an additional expert. ECF Nos. 30-36. By July 13, 2013, however, because Petitioners had still not filed an expert report, an Order to Show Cause was issued requiring them to so act or risk the action's dismissal. ECF No. 37.

On August 1, 2013, Petitioners finally filed an expert report from Dr. Megson, proposing generally (as reviewed in more detail below) that M.M. had experienced an encephalopathic reaction to the vaccines he received in October 2002. ECF Nos. 39, 64. Respondent's expert report from Dr. Wiznitzer was subsequently filed in November 2013, along with a Supplemental Rule 4(c) report. *See* ECF No. 42. In the latter, Respondent maintained that Dr. Megson's report was based on an incomplete, and after-the-fact treatment history, and also that it was scientifically unreliable, both due to the quality of medical literature offered in support of Dr. Megson's theories, as well as her purported lack of qualifications to opine on the relevant theory. ECF No. 42 at 11-

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The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the MMR vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately a total of 11 lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit, unanimously rejected the petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

12.[65] In reaction to such objections, on June 6, 2014, Petitioners filed a supplemental expert report from Dr. Megson. ECF Nos. 57-58, 65-66.

Before this matter was assigned to me, the parties had scheduled this case for a hearing to be held in September 2014, but the hearing was later continued at the Petitioners' request to January 2015. In her pre-hearing submissions, Respondent reiterated her prior objections to Dr. Megson's opinion. ECF Nos. 67-68. In early 2015, the matter was continued for a second time at Petitioners' request due to their counsel's illness (ECF Nos. 70-72), and I therefore rescheduled the hearing for May 18-19, 2015.

B. Disputes Over Experts and Fact Witnesses.

On March 11, 2015, Respondent filed a Notice of Additional Authority, citing *Long v. Sec'y of Health & Human Servs.*, No. 08-792V, 2015 WL 1011740, at *19-20 (Fed. Cl. Spec. Mstr. Feb. 9, 2015) (a decision issued after the parties had filed their pre-hearing submissions) as additional support for their previous assertion that Dr. Megson was not a reliable expert to offer an opinion in this case. In it, Respondent referenced comments made in that decision by Special Master Hastings about Dr. Megson and the reliability of the opinion she had offered in that case. ECF No. 75.[66]

In reaction, Petitioners filed an opposition setting forth their concern that Dr. Megson might refuse to continue to act as their expert because of what she perceived as prejudicial comments made about her in the *Long* decision, and that as a result Petitioners were evaluating whether to obtain an alternative expert to testify in her place. ECF No. 76 at 2. Petitioners also proposed taking discovery from Dr. Zimmerman, based on their belief that he would not voluntarily appear at trial to testify about his treatment of M.M. (although Petitioners made no mention at this time of

[65] Respondent also questioned whether there was a reasonable basis for Petitioners' claim in this case, as Respondent argued that "this case has no distinguishing characteristics from the issues already litigated in the OAP." ECF No. 42 at 12-13. Accordingly, Respondent requested that this case be dismissed "[i]nasmuch as [P]etitioners have not offered an adequate medical expert opinion or other reliable evidence sufficient to establish a causal relationship between [M.M.'s] vaccinations and his condition," and "[P]etitioners have failed to reasonably distinguish it from issues litigated in the OAP, of which this case was a part." ECF No. 42 at 12.

[66] As with this case, *Long* involved the claim that a child's ASD was impacted and/or caused by receipt of a vaccine. The *Long* petitioners specifically proposed that the flu vaccine significantly aggravated their son's pre-existing neurologic problems – in particular by causing oxidative stress in a child with a similar genetic mutation in the MTHFR gene as alleged herein. *Long*, 2015 WL 1011740, at *8. Special Master Hastings not only rejected the theory as implausible and unreliable (since Petitioners had failed to link the relevant vaccine to the purported reactions), but stated that, because the theory relied heavily on specific causation theories addressed at length, but rejected, in the OAP decisions, he was unlikely in the future to compensate Dr. Megson for such testimony (or other experts who embraced such theories in other cases before him). *Id.* at *20.

designating him as an additional expert).[67] *Id.* Shortly thereafter, Petitioners filed a written motion asking for issuance of a subpoena to depose Dr. Zimmerman as a fact witness. ECF No. 79. Petitioners again did not propose that Dr. Zimmerman would act as an additional expert; indeed, in a subsequent filing Petitioners specifically stated that they desired discovery from Dr. Zimmerman (among others) solely to "bolster the credibility of the expert witness Dr. Megson." ECF No. 82 at 2, 5.

After reviewing the parties' respective arguments, I denied the request for discovery in advance of the hearing, but proposed instead that Petitioners determine Dr. Zimmerman's availability at trial, and that his presence be compelled by subpoena (although he could testify remotely to reduce the burden placed upon him). ECF No. 83 (Status Conference Order, dated Apr. 20, 2015). No further references were made to Dr. Megson's unavailability, however, and I indicated my intent to proceed to hearing as scheduled based on the assumption that she would still appear. *Id.* Petitioners subsequently subpoenaed Dr. Zimmerman, and formally confirmed that both he and Dr. Megson would be testifying on their behalf. ECF No. 84. At all times, however, I informed Petitioners that Dr. Zimmerman was to testify as a fact witness only, as he had not offered an expert report on behalf of Petitioners' claims, nor had he ever been identified as a possible expert in the many years leading to hearing. *See* May 15, 2015, Status Conference Order (ECF No. 96).

C. Post-Hearing Matters.

The hearing occurred as scheduled on May 18-19, 2015. At its close, Petitioners requested the opportunity to obtain and file an expert report from Dr. Zimmerman regarding his theories on mitochondrial disorders or other vaccine causation possibilities, in order to bolster Dr. Megson's expert opinion regarding oxidative stress. Tr. at 277-78, 284. Petitioners' counsel also requested an opportunity to have M.M. tested for a mitochondrial disorder. *Id*. Respondent opposed the requests as dilatory. *Id.* at 455-56. Despite my concerns about the untimely nature of the request, and the fact (as admitted at trial) that Dr. Zimmerman was not actually an expert on the subject of mitochondrial diseases, I nonetheless gave Petitioners an opportunity to move formally for permission to offer such an additional report. *Id.* at 454-57; ECF No. 97.[68]

On June 26, 2015, Petitioners filed their motion. ECF No. 104 at 4. In it, Petitioners represented that Dr. Zimmerman (whom they identified as an expert in vaccine injury) was

[67] Petitioners also asked for discovery from M.M.'s pediatrician, Dr. Hickey, and initially suggested he was also a fact witness with potentially relevant testimony, but ultimately dropped him as a witness without explanation.

[68] I also instructed Petitioners to file information regarding the potential for conducting additional metabolic testing and its relevance to preparation of such an expert report. ECF No. 97.

prepared to offer an expert opinion on their behalf if certain additional genetic, metabolic, and mitochondrial disease testing of M.M. were performed (and paid for in advance). ECF No. 104.[69] Petitioners offered two grounds for this request expanding upon their previous arguments. First, Petitioners repeated their earlier assertion that by calling into question Dr. Megson's credibility (specifically through reference to discussion of Dr. Megson in *Long*), Respondent had "opened the door" to additional expert testimony generally, because the credibility challenge went to the overall sufficiency of Petitioners' expert support. ECF No. 104 at 2-3. Second, Petitioners claimed that they could not meet their burden to demonstrate causation by a preponderance of the evidence without an additional report. *Id.*

On July 17, 2015, Respondent opposed Petitioners' request. ECF No. 108 at 4-6. Respondent observed in her opposition that any questions about the validity and/or reliability of Dr. Megson's opinion had been made clear to Petitioners long before, and as early as the Supplemental Rule 4(c) report filed in the fall of 2013. *Id.* at 2 (citing Supp. Rep. at 11-13). Respondent also questioned whether the Notice she previously filed referencing the *Long* decision was unreasonably prejudicial. *Id.* at 3. At bottom, however, Respondent objected that Petitioners had had ample time to fully investigate their case and designate experts, and should not be allowed to propose an effectively new causation theory (that M.M. suffered from an underlying mitochondrial disorder) at the end of the matter's procedural history. *Id.* at 5.

After reviewing the motion and opposition, I held a status conference with the parties on August 28, 2015, and informed them of my proposed means of resolving the expert dispute. Order, dated Aug. 28, 2015 (ECF No. 110). Rather than decide the pending motion, I asked the parties to brief further (in the context of their post-hearing briefs) the grounds for an additional expert – and particularly directed the Petitioners to set forth how the anticipated opinion from Dr. Zimmerman would materially alter the outcome of the matter in their favor. *Id.* Petitioners filed this brief on December 7, 2015 (ECF No. 115), and Respondent filed her brief on February 1, 2016 (ECF No. 117). The matter is now ripe for resolution.[70]

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[69] Petitioners represented that they identified a facility where such testing could be conducted, Courtagen Diagnostics Laboratory, and that the cost of such testing would be approximately $33,518.00. ECF No. 104 at 3. Respondent argued in response that there was no basis for payment of such a cost in advance of its having been incurred. ECF No. 108 at 5. Because I decide Petitioners' motion on other grounds, the propriety of reimbursing the costs of testing requested by Dr. Zimmerman in advance of an expert opinion is moot – although I note that very clear Vaccine Program precedent suggests that only *incurred* costs may be reimbursed under the Act. *See, e.g.*, *Barrett v. Sec'y of Health & Human Servs.*, No. 09-389V, 2014 WL 2505689, at *6 (Fed. Cl. Spec. Mstr. May 13, 2014) (anticipated legal costs associated with a guardian's future exercise of its duties could not be reimbursed because they were not "incurred" within the meaning of the Act).

[70] In addition to addressing the motion for a new expert, I granted Respondent's motion to strike an exhibit. Order, dated October 8, 2015 (ECF No. 111). Petitioners had previously filed as an exhibit an expert report prepared by Dr. Zimmerman in support of an older Program case involving a Table injury, *Poling v. Sec'y of Health & Human Servs.*, No. 02-1466V. Respondent moved to strike the exhibit on the grounds that it was not material to this case, and that its

IV. SUMMARY OF RELEVANT MEDICAL CONCEPTS

Prior to analyzing Petitioners' claims, it would be beneficial to consider some medical concepts at issue in this case. The summary below is derived from materials filed by both parties in this case, as well as discussions of the conditions set forth in the decisions of other special masters or the Court of Federal Claims.

A. Autism and ASDs.

The term ASD encompasses a group of complex neurodevelopmental disorders characterized by "self-absorption, impairment in social interaction and communication, and a restricted range of activities and interests." *Dorland's Illustrated Medical Dictionary* 180 (32d ed. 2012) [hereinafter *Dorland's*]; *see also* Autism Spectrum Disorder Fact Sheet, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKES, Oct. 7, 2015, *available at* http://www.ninds.nih.gov/disorders/autism/detail_autism.html (last visited Feb. 11, 2016); Resp't's Ex. A, Tab 1 (Johnson, et al., *Identification and Evaluation of Children with Autism Spectrum Disorders*, 120 American Academy of Pediatrics 1183, 1183-215 (Oct. 29, 2007) (discussing ASD screening criteria)). Children diagnosed with ASD are often reported by their parents to have displayed developmental or behavioral problems around 18 months of age, if not by the age of two, and a significant minority of children with ASD experience regression/loss of skills, including language or vocabulary. *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461, at *34-35 (Fed. Cl. Spec. Mstr. July 22, 2015) (discussing the diagnostic criteria and characteristics of ASDs).

Since the resolution of the OAP cases, there have been numerous petitions attempting to establish that a variety of vaccines cause autism or an ASD, based on causation theories highly similar to those asserted in the present action. *See, e.g.*, *Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603, at *4-5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) (petitioners failed to demonstrate that DTaP vaccine caused or significantly aggravated underlying mitochondrial disease resulting in ASD); *Miller v. Sec'y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (petitioners failed to demonstrate that several childhood vaccines caused encephalopathy or aggravated underlying mitochondrial

inclusion violated Section 12(d)(4)(A) of the Vaccine Act (which states that information submitted to a special master or the court in a proceeding on a petition may be disclosed to a person who is not a party to the proceeding only with express written consent of the person who submitted the information). I informed Petitioners prior to the hearing that I would allow the exhibit to remain in the record if they obtained a current, written consent from the petitioners in the *Poling* case specific to this case. ECF No. 96. Petitioners did not do so, however, even after being given multiple opportunities, and therefore I granted Respondent's motion.

disease/dysfunction); *Lehner*, 2015 WL 5443461 (petitioners failed to demonstrate that flu vaccine resulted in autoimmune encephalitis). As Special Master Hastings noted in the recent *Hardy* decision, however, to date *every* post-OAP Non-Table claim seeking compensation for autism injuries purportedly related to a vaccine that has been tried has failed. *Hardy*, 2015 WL 7732603, at *4-5 (referencing eleven autism claims unsuccessfully tried (including *Miller* and *Lehner*), plus six that were rejected (over the petitioners' objections) without trial)).

B. Encephalopathy.

An alleged encephalopathy can be the basis for a Table or Non-Table claim, although the Table's definition of the term "simply does not encompass every type of brain dysfunction to which the broader meaning of 'encephalopathy' applies." *Wright v. Sec'y of Health & Human Servs.,* No. 12-423V, 2015 WL 6665600, at *6 (Fed. Cl. Spec. Mstr. Sept. 21, 2015); *Fester v. Sec'y of Health & Human Servs.*, No. 10-243V, 2013 WL 5367670, at *21, n. 5 (Fed. Cl. Spec. Mstr. Aug. 27, 2013). At hearing, Dr. Witznitzer stated that "[a]n acute encephalopathy, as we define it in neurology, is an impairment in consciousness, and it's a decreased level of consciousness that goes anywhere from basically lethargy, stupor, down to coma, and can be associated with other neurologic symptoms or signs, such as unsteadiness or seizures." Tr. at 342-43. As noted by former Chief Special Master Vowell, the term encephalopathy, "as commonly used in the medical community, encompasses a much broader class of injuries than the more stringent definition of acute encephalopathy found in the QAI [qualifications and aids to interpretation]." *Wright*, 2015 WL 6665600, at *5 (*citing Waddell v. Sec'y of Health & Human Servs.*, No. 10–316V, 2012 WL 4829291, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012)).

According to the QAI, a vaccinee is considered to have suffered a Table encephalopathy if he or she manifests an injury encompassed in the definition of an "acute" encephalopathy within the appropriate time period, *and then* a "chronic" encephalopathy is present for more than six months after the immunization. 42 C.F.R. § 100.3(b)(2) (emphasis added). In accordance with the QAI, an acute encephalopathy must be sufficiently serve to require hospitalization (regardless of whether the vaccinee is actually hospitalized). 42 C.F.R. § 100.3(b)(2)(i). For a child less than 18 months of age who did not experience an associated seizure event, an acute encephalopathy is deemed to be present if there is a "significantly decreased level of consciousness" that persists for at least 24 hours. 42 C.F.R. § 100.3(b)(2)(i)(A). Children less than 18 months of age presenting after a seizure are considered to have an acute encephalopathy if they have experienced a "significantly decreased level of consciousness" that persists beyond 24 hours and cannot be attributed to the seizure or medication. *Id*. The referenced phrase "significant decreased level of consciousness" must be evidenced by the presence of at least one of the following clinical signs for at least a 24-hour period: "(1) [d]ecreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) [d]ecreased or absent eye contact (does not fix gaze

upon family members or other individuals); or (3) [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things)." 42 C.F.R. § 100.3(b)(2)(i)(D).

The QAI defines a chronic encephalopathy to be "a change in mental or neurologic status that first manifested during the applicable time period and that persists for at least six months post-vaccination." 42 C.F.R. § 100.3(b)(2)(ii). Individuals who return to a normal neurologic state after experiencing an acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event, and thus any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. 42 C.F.R. § 100.3(b)(2)(ii). 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." 42 C.F.R. § 100.3(b)(2)(ii). 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).

Program petitioners have pursued Table claims (in which causation is presumed if the factual requirements for the claim are met) based upon an acute encephalopathy by a covered vaccine that later manifested developmental regression or even autism. In a single instance, petitioners (the parents of a vaccinated child) succeeded with such a claim. *Wright*, 2015 WL 6665600, at *30-31. In *Wright*, the petitioners met the Table criteria for an "acute encephalopathy" following vaccination by establishing by preponderant evidence that the vaccinated child experienced a seizure followed by loss of consciousness shortly after receipt of pertussis-containing vaccine; the severe reaction lasted for more than 24 hours, with resulting demonstrable significant changes in behavior. *Id.* But the special master responsible for that decision (former Chief Special Master Vowell) explicitly noted in her decision that petitioners would not have been able to establish entitlement (under the same facts) for a Non-Table claim, because their expert presented a causation opinion that she found "absurd and biologically impossible." *Id.* at *2.[71]

[71] In a different case – *Poling v. Sec'y of Health & Human Servs.*, No. 021466V, 2011 WL 678559 at *1 (Fed. Cl. Spec. Mstr. Jan. 28, 2011) – the petitioners settled their Table claim (that a vaccine produced an encephalopathy that "eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela") before its adjudication. *See also Vernacchio v. Sec'y of Health & Human Servs*., No. 08-504V, 2015 WL 1396357, at *2, n. 6 (Fed. Cl. Spec. Mstr. Mar. 6, 2015), *reconsideration denied*, 2015 WL 1951051 (Fed. Cl. Spec. Mstr. Apr. 10, 2015) (discussing the history of *Poling*).

V. APPLICABLE LEGAL STANDARDS

A. Petitioner's Overall Burden in Vaccine Program Cases.

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 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).[72] In this case, Petitioners assert both kinds of claims.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, 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) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

When a Table Injury claim is successfully established, causation is presumed. 42 C.F.R. § 100.3. To prove a Table Injury, a petitioner 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. § 11(c)(1)(C)(i)). Accordingly, to establish a Table encephalopathy in this case, Petitioners must demonstrate that M.M. suffered an "encephalopathy"

[72] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs*., No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

as defined by the QAI section of the Vaccine Injury Table (discussed above) within seventy-two hours of his DTaP vaccination.

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(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.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly

trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Testimony.

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the

record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony.

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*,

509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert is offering an opinion that exceeds the expert's training or competence. *Walton v. Sec'y of Health & Human Servs.*, No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I heard and have considered all of the testimony of the experts offered at the entitlement hearing, I may properly evaluate, and give appropriate weight to, whether certain

testimony is beyond a particular expert's purview. *See e.g.*, *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications). An opinion does not obtain legitimacy in the Program simply because it comes out of the mouth of a medical doctor – especially if that opinion concerns matters outside the doctor's expertise.

VI. ANALYSIS

A. M.M. Did Not Experience a Post-Vaccination Encephalopathy.

Petitioners' two claims depend on a fact finding that M.M. suffered from an encephalopathy prior to his alleged regression. It is thus logical to first determine if the evidence supports that finding. *Broekelschen*, 618 F.3d at 1346 (when an injury or diagnosis is disputed, and "the proposed injuries differ significantly in their pathology," the special master may "first find which of [the] diagnoses was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury").The facts from the medical records, however, do not support the conclusion that M.M. experienced any kind of encephalopathy (whether as defined by the Table or as the basis for a Non-Table claim).

As the records plainly establish, M.M.'s DTaP and MMR vaccinations in October 2002 were not followed by any identifiable, measurable, severe reaction of the kind that would constitute an acute encephalopathy. At most, Petitioners have established that M.M. experienced some transient symptoms, such as a high fever that arguably could be attributed to the vaccinations (although it equally could have been the result of his ear infection). But he quickly recovered from these symptoms, and within two months was deemed a well child at his December 2002 pediatric visit. He was never hospitalized or treated in an emergency room, and there is no persuasive evidence of a significant change in M.M.'s consciousness. There is nothing recorded in the contemporaneous medical history suggesting any immediate encephalopathic reaction. *Blake v. Sec'y of Health & Human Servs.,* No. 03-31V, 2014 WL 2769979, at *6-12 (Fed. Cl. Spec. Mstr. May 21, 2014) (little evidence of acute reaction to MMR vaccine beyond petitioner recollections and allegations of post-vaccine lethargy, therefore Table claim failed).

I reach the same conclusion even if I accept some of the Petitioners' factual testimony about M.M.'s post-vaccination state.[73] Thus, they maintain (although they cannot corroborate the

[73] I do not find persuasive the Murphys' assertions that M.M. had a seizure-like reaction to the vaccinations. Claims of a seizure in this case are uncorroborated by any independent direct or circumstantial evidence. Moreover, Dr. Wiznitzer proposed a persuasive explanation for M.M.'s post-vaccination pain and purported thrashing. In any event,

fact with phone records) that they repeatedly attempted to express to their pediatrician's office concerns about M.M.'s alleged reaction to his vaccinations, but that their concerns were given short shrift[74] dissuading them from taking M.M. to the emergency room. By this, Petitioners suggest it is proper to infer that M.M.'s reaction to the vaccinations was likely far more severe than the otherwise-sparse medical records establish.

There is logic to this line of reasoning. Moreover, the testimony offered in its support does not contradict the existing record but instead supplements it, and was not otherwise rebutted by Respondent. *Stevens v. Sec'y of Health & Human Servs*., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Dec. 21, 1990) ("discrepancies between the testimony and records or gaps in the medical records are not in and of themselves decisive; clear, cogent, and consistent testimony can overcome such missing or contradictory medical records"). And yet – even if I accept these allegations as correct, the record does not *subsequently* corroborate Petitioners' factual assertion that M.M. experienced a chronic encephalopathy. For there is 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" as defined in the QAI. Indeed, there is contrary record evidence that he did not (as suggested by the October 18, 2002, December 2002, and May 2003 pediatric records). Indeed, no pediatric records record any concerns about M.M.'s developmental problems before June 2003, nine months post-vaccination. *See* Pet'rs' Ex. 2 at 10. The probative nature of such proof greatly outweighs the strength of the Petitioners' after-the-fact testimony designed to "fill in" gaps in the medical records with unverifiable assertions about M.M.'s developmental and physical state within 72 hours of his receipt of the DTaP and MMR vaccines.[75]

Petitioners therefore cannot establish by preponderant evidence that M.M. experienced an encephalopathy as defined by the Table. 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. 42 C.F.R. §

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the presence of "[s]eizures in themselves are not sufficient to constitute a diagnosis of encephalopathy." 42 C.F.R. § 100.3(b)(2)(E) ("In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.").

[74] Petitioners are correct that during the time of the Beltway Sniper, many D.C. metropolitan region citizens avoided motor travel. ECF No. 65-8 at 1 (Dr. Megson's expert report). It is therefore credible that the Murphys may have decided not to risk a pediatric visit. Yet it could also be inferred that M.M.'s distress was not at the time sufficiently alarming for them to act. Mrs. Murphy admitted during her testimony that if she had observed M.M.'s condition to be sufficiently concerning, she would have brought her son to the doctor despite the sniper situation. Tr. at 129-30.

[75] The Vaccine Table specifically indicates that "[i]n determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record." 42 C.F.R. § 100.3(b)(2)(iv).

100.3(b)(2)(E). The record similarly does not support the finding that M.M. subsequently experienced a chronic encephalopathy as defined in the QAI. The medical records from M.M.'s second October pediatric visit, as well as his subsequent December visit, simply do not reveal an ongoing problem of the kind alleged. *See* Pet'rs' Ex. 2 at 14-15.

For purposes of comparison, it is instructive to consider the facts of the *Poling* and *Wright* cases, where the petitioners successfully established (or settled) Table claim encephalopathies resulting in ASD-like symptoms. In the *Poling* case, the child in question (who was later diagnosed with a mitochondrial disease) had received several vaccinations (including MMR), and then within 48 hours developed a high fever that became low-grade over the next several days, along with inconsolable crying, sleeplessness, and significant, noticeable motor problems that worsened over the next several days. Pet'rs' Ex. 41, ref. 26 at 170. In *Wright*, the petitioners' child received Pentacel (a multi-virus vaccine),[76] and then, on the drive home from the pediatric visit at which the vaccination was administered, experienced a brief seizure, followed by a week in which he displayed a decreased level of consciousness and lethargy, during which the child's parents made many unsuccessful efforts to convince his pediatric treaters of the severity of his condition. *Wright*, 2015 WL 6665600, at *12-16. Such cases demonstrate the extreme factual circumstances reflecting an encephalopathy – in stark contrast to the evidence here.

I similarly find that Petitioners have failed to establish that M.M. experienced any kind of encephalopathy for purposes of their Non-Table claim, based upon the same evidence discussed above.[77] The weight of the evidence does not establish an encephalopathic reaction to the DTaP or MMR vaccines. No treaters diagnosed M.M. with an encephalopathy, moreover, and to the extent the medical records reference the diagnosis of "encephalopathy after vaccination," that diagnosis is based completely on parental recitations of M.M.'s history rather than an informed professional's reading of the records or relevant test results. Petitioners have thus not established that it is "more likely than not" that an encephalopathy occurred. To conclude otherwise is to give the term such a broad definition as to be meaningless for purposes of determining Vaccine Program

[76] Pentacel is the trade name for a vaccine that consists of combined DTaP, inactivated polio virus, and Haemophilus influenza type B vaccines. *Dorland's* at 1406.

[77] In this case, Petitioners strenuously denied that M.M. suffers from an ASD, arguing that such a condition could not have been brought on so suddenly, and disparaging record evidence in which treaters proposed that M.M. was autistic. Tr. 64, 118-20. Their causation theory instead relies on the concept that M.M. experienced an initial, post-vaccination encephalopathy, producing a subsequent developmental regression "with autistic features," as Dr. Megson stated in her report. Pet'rs' Ex. 9 at 1, 9. Respondent's expert, Dr. Wiznitzer, by contrast, maintained in his testimony that M.M.'s history was merely indicative of a typical presentation of idiopathic autism, given the prevailing view that an individual is born with a predisposition which gradually shows itself (with signs of autism now believed to be present as early as two to six months of age). Tr. 312, 442. As noted here and below, I do not find Petitioners carried their burden to establish either a Table encephalopathy or a Non-Table causation claim, and therefore the burden in this case never shifted to Respondent to establish a more likely alternative cause. *Deribeaux v. Sec'y of Health & Human Servs.*, 105 Fed. Cl. 583, 589 (2012), *aff'd*, 717 F.3d 1363 (Fed. Cir. 2013).

award entitlement.

B. Petitioners Have Not Satisfied the *Althen* Prongs.

1. Petitioners did not Establish a Reliable Causation Theory (*Althen* Prong One)

The theory Petitioners outlined – that pertussis toxin (contained in a vaccine designed specifically to neutralize that very component) could interact with proteins in the body, cause oxidative stress (exacerbated by underlying methylation dysfunction), and thereby produce the kind of brain injury resulting in an encephalopathy sufficient to result in a non-autistic developmental regression – was facially and structurally weak. Significant 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. As another special master noted in considering the *Althen* prong one analysis, "[t]he weight to be given an expert's opinion is based in part on the size of the gap between the science and the opinion proffered." *Isaac*, 2012 WL 3609993, at *17 (citing *Cedillo*, 617 F.3d at 1339). That gap is wide in this case.

Petitioners did not offer direct evidentiary support establishing the capacity of the MMR or DTaP vaccines to function as alleged, in this or other analogous circumstances. Nor did they invoke any studies involving these vaccines, or others, and their roles in incidents of developmental regression. Instead, they relied on a loose chain of propositions in order to make a circumstantial case establishing their causation theory. But those propositions were insufficiently supported with reliable scientific evidence, thereby lacking the support necessary to conclude that the overall theory was plausible.

Thus, Petitioners proposed that the DTaP vaccine, despite its acellular character, could nevertheless still contain sufficient toxin to be harmful, without offering reliable support for that contention (while at the same time allowing the proposition to be voiced by an expert not qualified to testify about vaccine formulation or manufacture). Similarly, they posited that tetanus toxin could interact in a harmful manner with the G protein, citing proof of G protein dysfunction (colorblindness and pupil dilation) not established to be at issue with M.M., and certainly not correlated with his developmental problems. And they purported that a brain injury could occur as a result of the passage of vaccine components through the blood-brain barrier without reliable evidence bulwarking the claim. Indeed, Petitioners' expert invoked theories about "leaky gut" and the MMR vaccine already persausively rebutted in the OAP cases. *See, e.g.*, *Snyder ex rel. Snyder*

v. Sec'y of Dep't of Health & Human Servs., No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009).[78]

Highly relevant to my analysis of the adequacy of Petitioners' theory is the fact that Dr. Megson lacks the qualifications necessary to offer persuasive expert testimony in its support. She is not an immunologist, does not specialize in the study of degenerative encephalopathies precipitated by oxidative stress or other genetic causes, is not notably experienced in treating such diseases, and has no background studying the effect of vaccines on individuals. I have considered her testimony carefully (and was not swayed by the statements from the *Long* case characterizing the merits of her expert testimony), but it is reasonable to afford it significantly less weight since it comes from a person unqualified to give it. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("[o]ne very significant fact to consider is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying").

All in all, the causation theory offered in this case was thin and did not rise to the level of even bare plausibility. It was thus insufficient to meet the evidentiary standards required of the first *Althen* prong.

2. The MMR and DTaP Vaccines did not Cause M.M.'s Developmental Problems (*Althen* Prong Two)

Petitioners have not established by preponderant evidence that the MMR and DTaP vaccines did in fact cause M.M.'s developmental problems – whether directly (by precipitating an encephalopathy that then resulted in a dramatic developmental regression) or indirectly (by impacting M.M.'s metabolic/genetic susceptibility to vaccine stress). Rather, the record suggests that any loss of skills or language M.M. suffered began long after, and independent of, the October 2002 vaccinations.

First, the evidence of a dramatic drop-off in M.M.'s developmental or physiologic state after October 14, 2002, is minimal. At best, the Murphys established that M.M. suffered some kind of immediate reaction to the vaccines – but by the time of his next pediatric visit several days later, his subsequent health was good. That conclusion is further corroborated by the December 2002

[78] This was a repeating deficiency in Petitioners' causation theory. Thus, Dr. Megson also proposed the concept that the "oxidative stress" brought on by vaccination is enough to precipitate an encephalopathy with developmental effects equivalent to an ASD – a theory handily dispensed with in the OAP cases, which also involved autism as the claimed injury. *King v. Sec'y of Health & Human Servs*., No. 03-584V, 2010 WL 892296, at *55 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (describing flaws in the petitioners' general causation theory regarding vaccines causing autism though "oxidative stress" in brain cells).

records. At no time did M.M. require hospitalization, and there are no test results or tertiary evidence providing circumstantial support for the Murphys' version of events.[79]

The evidence from the first half of 2003 further supports this conclusion. There are no troubling medical records, treater opinions, or other evidence suggesting that M.M. was observed as developmentally problematic before June 2003 – approximately nine months after the October 2002 vaccinations. This is too distant in time from the vaccination date to constitute a dramatic or sudden change produced by encephalopathy or other stress to which M.M. was susceptible, and the record similarly does not support the conclusion of downward progression in M.M.'s symptoms. Rather, Dr. Wiznitzer's interpretation of this record – that M.M.'s ASD was idiopathic in nature – is far more persuasive than Petitioners' reading of the facts, and nothing Petitioners said or offered at hearing rebuts this conclusion.[80]

3. Petitioners Did Not Establish a Medically Reasonable Timeframe (*Althen* Prong Three)

Because I have found that Petitioners failed to offer a plausible theory linking the MMR and DTaP vaccines to M.M.'s condition, and because I do not find that preponderant evidence supports the conclusion that M.M. experienced an encephalopathy, I need not also consider if the Petitioners have met the evidentiary requirements of the third *Althen* prong, by establishing a "medically-acceptable temporal relationship" between onset and receipt of the vaccines. But here, too, Petitioners' evidentiary showing is flimsy. The medical records establish that, other than the initial, immediate reaction to the vaccines (assuming for the moment that I accept the Murphys' testimony as correct and unrebutted), M.M. displayed no symptoms of the purported developmental regression until June 2003. Pet'rs' Ex. 2 at 10. And the Petitioners' testimonial claims of an immediate behavioral or developmental change in October 2002 are rebutted by contemporaneous records (for example, M.M.'s December 2002 pediatric visit (Pet'rs' Ex. 2 at 14)) that make no mention of any developmental concerns.

Moreover, Dr. Megson offered nothing (whether in the form of medical or scientific literature, or based on her own personal expertise) that would suggest a medically plausible

[79] In fact, the results that do exist (notably the MRI result reviewed by Dr. Zimmerman) support the opposite conclusion, as no direct evidence of a brain injury was ever revealed. While this may not rule out the existence of an encephalopathy, such unrebutted evidence weighs against Petitioners' arguments.

[80] Even where the burden does not shift to Respondent to establish a more likely alternative cause for a petitioner's condition than the vaccine(s) he received, I may consider evidence offered by Respondent in weighing whether a petitioner has met his initial burden. *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("[t]he 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"); *see also Roberts v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698, at *5 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (internal citations omitted).

timeframe in which the pertussis toxin purportedly remaining in the DTaP vaccine would be expected to produce the reactions alleged, and/or cause the oxidative stress that is alleged to have resulted in M.M.'s developmental problems. And as noted above, she lacks the expertise to opine on the topic, and could therefore only have offered her own interpretation of other medical and scientific literature that, however reliable it might be, would not arise from her personal medical or scientific experience. Otherwise there is no evidentiary support for the plausibility of the vaccines having the temporal effect on M.M. alleged in this action.

VII. REQUEST FOR ADDITIONAL EXPERT OPINION

Resolving Petitioners' request to submit another expert report after conclusion of the entitlement hearing in this case entails consideration of case management in Vaccine Program cases. Special masters have broad discretion in conducting proceedings, including deciding whether, when, and how to take and consider evidence in resolving a petitioner's entitlement to damages. *See Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 400 (1997) (concluding that it was within the special master's discretion to determine whether to allow in new evidence after an evidentiary hearing in the case); § 12(d)(3)(B) (special master afforded discretion when making determinations regarding admission of evidence).[81] However, in accordance with Vaccine Rule 8(b)(1), to ensure fundamental fairness of the proceedings to both parties, special masters must consider "all relevant and reliable evidence." Vaccine Rule 8(b)(1) ("[i]n receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties").

In light of the above, leniency is usually the appropriate response when resolving a request to allow new evidence into the record just before, or even during, an evidentiary hearing. *Tembenis v. Sec'y of Health & Human Servs*., No. 03-2820V, 2010 WL 1508646, at *2-6 (Fed. Cl. Spec. Mstr. Mar. 29, 2010). This is true even where a party seeks to introduce new expert testimony late in a case's life. In *Cedillo v. Sec'y of Health & Human Servs.*, No. 98–916V, 2009 WL 331968, *62 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd,* 89 Fed. Cl. 158 (2009), *aff'd,* 617 F.3d 1328 (Fed. Cir. 2010), for example, a special master permitted two expert reports to be filed only four days before the hearing in the case was to commence. Circumstances excused the dilatory filing: the relevant reports had been previously sealed in prior British litigation, Respondent acted

[81] The statute states in pertinent part as follows: "(B) In conducting a proceeding on a petition a special master— (i) may require such evidence as may be reasonable and necessary, (ii) may require the submission of such information as may be reasonable and necessary, (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary, (iv) shall afford all interested persons an opportunity to submit relevant written information— (I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or (II) relating to any allegation in a petition with respect to the matters described in section 300aa–11 (c)(1)(C)(ii) of this title, and (v) may conduct such hearings as may be reasonable and necessary."

diligently in procuring the reports once she became aware that they were relevant, and Respondent filed the reports within an hour of actually receiving them. *Cedillo*, 2009 WL 331968, at *59. Because of the need to avoid prejudice, however, the special master allowed the petitioner the opportunity to file a response. *Id*. at *62. The special master also acknowledged that permitting the late expert reports could prolong the proceedings, but that doing so served the ultimate purpose of making such the decision in the case was fully informed. *Id.*

Relevant case law does not, however, address whether leniency is still appropriate in the final stages of a proceeding (such as after a hearing), when the record is essentially closed (or should be, especially in an old matter). Such circumstances can be analogized to a request to reopen proceedings to permit the introduction of newly-discovered evidence, and requests in such circumstances have been granted. *See, e.g., Kaminski v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 253, 255 and 258 (1997) (special master erred in denying Respondent's motion to reopen proceedings where Respondent discovered that fact witness possessed relevant information after hearing's conclusion, and where timeliness of request to reopen was not questioned). Even lengthy time lapses between the close of evidentiary proceedings and a subsequent request to reopen the record have been overlooked where the newly-discovered evidence was deemed sufficiently important. *Vant Erve v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 607 (1997) (special master's refusal to reopen a question of liability was an abuse of discretion even though three years had passed since decision; information offered by Respondent was highly probative, there was no showing of prejudice to Petitioners, and Respondent was not at fault for the delay), *aff'd after remand*, 232 F.3d 914 (Fed. Cir. 2000) (unpublished table decision).

A rudimentary test can be applied in evaluating a request to reopen the record. *Vant Erve,* 232 F.3d at 914. These factors are: (1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay. *Vant Erve*, 39 Fed. Cl. at 612 (*cited with approval,* 232 F.3d at 914). Each factor should not be afforded equal weight, however, because "[t]he paramount test is the nature of the proffered new evidence," meaning "the extent to which the new evidence is both relevant and affective of the outcome." *Vant Erve*, 232 F.3d at 612. Where the evidence "is of marginal relevance and impact, the burden on the moving party increases dramatically with respect to the influence of the remaining factors," with the opposite the case if the evidence is "highly relevant and clearly outcome determinative." *Vant Erve*, 39 Fed. Cl. at 612 (citing *Horner*, 35 Fed. Cl. at 27 (fundamental fairness requires admission of highly probative evidence of vaccine record) *and Kaminski v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 253, 258–59 (1997) (error in special master's refusal to reopen entitlement proceedings to hear probative, relevant testimony)).

Applying the above, I deny Petitioners' request to obtain and file an expert report from Dr. Zimmerman. The most important reason for doing so is because the best opinion Petitioners could

hope to obtain from him[82] – that M.M. suffered from a mitochondrial disease (or some other unspecified form of metabolic disorder) that, in turn, interacted with the MMR and DTaP vaccines to precipitate an encephalopathy – would not be sufficiently "affective of the outcome" of this case. My fact-finding in this matter would not be impacted by such a theory – and those facts would still be fatal to the Petitioners' Non-Table claim.[83]

In particular, a new expert opinion would not alter my conclusion, derived from weighing the evidence, that M.M. never experienced an encephalopathy. The testimony of Dr. Zimmerman during the hearing supports this finding. He acknowledged that the sole evidence he relied upon for proof of a vaccine-induced encephalopathy came from the Murphys rather than from his review of the medical records. Tr. at 255-56, 271 ("I was simply echoing what had already been said and what the parents told me"). He also admitted on cross-examination that (at least as of December 2002, at M.M.'s well child visit) the evidence he had seen did not corroborate the existence of a prior encephalopathic event. *Id*. at 288. Dr. Zimmerman himself would thus be unable to offer factual support for the existence of an encephalopathy even if he offered a new causation theory.

The new theory is also unsupported by the existing record. Any new theory that M.M. was metabolically susceptible to stress from a vaccination would still require proof that such stress "more likely than not" precipitated a change in M.M.'s brain. Such proof is lacking in this case. The same goes for the concept that M.M. suffers from an underlying metabolic disorder. The first time in the medical records that metabolic testing was mentioned was at Petitioners' initial visit to the Kennedy Krieger Institute in June 2009. But the intent of that visit was to obtain a professional reading of M.M.'s MRI – not to explore the possibility that M.M. had an underlying mitochondrial disease. Tr. at 80-81 (testimony from Mrs. Murphy); Pet'rs' Ex. 8 at 4. Such metabolic testing was never performed – before or after the visit.[84] The two subsequent visits with Dr. Zimmerman (in September 2009 and June 2010, respectively) make no further mention of such testing, although they do discuss the MRI results (which were normal). I infer from this that after the MRI results

[82] Of course, any putative opinion Dr. Zimmerman might offer is contingent on metabolic testing that remains unperformed – nearly seven years after such testing was first proposed. Pet'rs' Ex. 8 at 5-6. It is far from certain that the results of such testing would persuade Dr. Zimmerman to offer the kind of opinion Petitioners expect; he might well conclude the testing results do not support the conclusion that M.M. had a mitochondrial disease. And Dr. Zimmerman has acknowledged he lacks the specific background in mitochondrial disease necessary for an expert opinion in any event. Tr. at 266. It therefore is speculative to assume the opinion offered would even be favorable for the Petitioners' case, ignoring the extent to which such a favorable opinion is corroborated by the actual record.

[83] The present circumstances are thus much different from those instances (in *Vant Erve* and other cases) where a new expert report builds upon undisputed record facts instead of presenting an entirely new and untested vector for argument. *Vant Erve v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 607 (1997), *aff'd after remand*, 232 F.3d 914 (Fed. Cir. 2000).

[84] Dr. Zimmerman, moreover, testified at hearing that he never formally ordered, as part of his treatment of M.M., that such metabolic testing be performed. Tr. at 265.

were obtained and reviewed, and based on the examination of M.M., no other signs of mitochondrial disease were detected – consistent with the fact that no other treaters ever suggested, based on their evaluations of M.M., that he might have a mitochondrial disease of some kind. Accordingly, there is already an absence of support in the record for the proposition that M.M. has a mitochondrial disease, even if the theory that individuals with such a disease *could* experience injury after vaccination was determined to be plausible.

To the extent Dr. Zimmerman would simply offer the opinion that oxidative stress incited by the DTaP or MMR vaccines was enough to produce a regression or decompensation in M.M.'s circumstances, Dr. Megson has beat him to the punch, eliminating the need for more expert testimony on that subject. More importantly, however, the very theory of "oxidative stress" itself – at least as applied in cases in which autism was the identified vaccine injury – was addressed at length in the OAP cases, but found wanting. *See King*, 2010 WL 892296, at *55-61 (OAP case describing flaws in theory that oxidative stress resulting from vaccination could precipitate autism); *see also Long*, 2015 WL 1011740, at *8, *13-14 (theory proposed by Dr. Megson that excessive oxidative stress can disrupt brain function causing an aggravation in autism lacked merit). A theory already given full consideration in comparable circumstances but rejected will not find new life in this case simply because a different expert (and one less qualified to overall to state the theory, moreover) embraces it.

Because the proposed opinion will not affect the outcome of this case, the other *Vant Erve* factors warrant greater weight – and they do not support Petitioners' request for an additional expert report. First, the evidence to be offered cannot be characterized as newly-discovered. Dr. Zimmerman has been known to Petitioners since 2009, and his views on the possible role that a mitochondrial disorder might have played in M.M.'s regression were expressed six years prior to the hearing.[85] No showing has been made that mitochondrial testing (a prerequisite to the proposed expert opinion) could not have been performed earlier in the case.

Second, the causation theory upon which Dr. Zimmerman would opine is not itself the product of a new scientific development. Dr. Zimmerman was aware in 2009 of a possible link between mitochondrial disease and subsequent developmental problems in children. The theory has also been previously advanced in other contemporaneous cases. *See, e.g.*, *McLaughlin v. Sec'y of Dep't of Health & Human Servs*., No. 07-497V, 2008 WL 4444142, at *1 (Fed. Cl. Spec. Mstr. Sept. 9, 2008) (advancing a theory that an underlying mitochondrial disorder was significantly aggravated by vaccination leading to autism-like symptoms); *Poling v. Sec'y of Health & Human*

[85] Petitioners also acknowledged in their hearing testimony that they have known of the availability of such metabolic testing for some time. Thus, Mrs. Murphy expressed her belief that M.M. has a mitochondrial disorder, but indicated that she had to date refused to allow him to undergo the muscle biopsy necessary to conclusively establish this fact. Tr. at 121.

Servs., No. 02-1466 V, 2008 WL 1883059, at *1 (Fed. Cl. Spec. Mstr. Apr. 10, 2008) (noting that a theory was advanced that vaccination significantly aggravated an underlying mitochondrial disorder, which manifested as a regressive encephalopathy with features of ASD). There is no reason why Petitioners could not have embraced this causation theory earlier in the ten-year history of the matter.

Third, the dilatory character of this request cannot be overlooked. The Petitioners have had four years since the filing of their amended petition to identify an expert. Petitioners chose Dr. Megson. After Petitioners filed Dr. Megson's report in August 2013, and learned of Respondent's objections and challenges to its sufficiency later that fall, they still had time to modify or supplement their causation theory. They did not do so, waiting instead until the eve of trial to ask for an additional expert. For a case filed over ten years ago, that is simply too late.

Petitioners do not effectively contest any of the above points. Rather (and as they admit), their sole rationale for seeking a report from Dr. Zimmerman is to repair a causation theory that they decided, almost immediately before trial, was lacking in probative strength, and/or tainted after the *Long* decision. Pet'rs' Post-Hr'g Brief (ECF No. 115) at 20. Yet as I emphasized to Petitioners in subsequent pretrial status conferences, I was not bound by *Long* to reach the same conclusion about the weight to be afforded Dr. Megson's testimony in this case. Indeed, I emphasized that I was fully prepared to hear her testimony, and to decide this case on its own merits. I have tried to do so herein.

Finally, the prejudice to the timely administration of this case is significant if I allow another expert report to be prepared and then (at some indeterminate time later) filed. As noted above, the amended version of Petitioners' claim has existed for over four years, culminating in a hearing held just last year. Allowing not merely the preparation of a new report, but one that is dependent on unperformed testing which itself could take months (assuming it can be paid for), and then giving Respondent the opportunity to supplement her existing expert reports will only further delay resolution of a case that is now over ten years old. Such delay is not justified given how unlikely it is that the requested expert opinion would alter my current conclusions about entitlement.[86]

[86] I also do not find persuasive Petitioners' reliance on the sole case cited in support of their request, *Jicarilla Apache Nation, formerly Jicarilla Apache Tribe v. The United States*, No. 02-25L, 112 Fed. Cl. 274 (2013) that, because Dr. Megson's report was deemed insufficient in *Long*, it is proper to permit the Petitioners herein to offer a second expert report from a different expert. *Jicarilla* ***does not stand for the proposition*** that a claimant in a legal proceeding should be allowed to submit additional evidence at any juncture of a case, regardless of their ability to do so at an earlier point in time, merely because they fear their existing proof is weak. In fact, it is unclear why Petitioners view this case as supportive of their request. Petitioners indicate that *Jicarilla* is apt precedent because Dr. Megson's report was "deemed insufficient." But that case involved an action brought against the federal government by a Native American tribe seeking an accounting, and to recover for monetary losses and damages, related to an alleged breach of fiduciary duties by the Bureau of Indian Affairs ("BIA") in mismanaging the tribe's trust assets and other funds during a

Under the circumstances, therefore, I find that Petitioners have not established grounds for allowing them to extend this case's life by offering a second expert report. And it is not enough to justify the request by invoking the Vaccine Program's overall goals (which broadly include striving to act in the interests of petitioners generally). For the remedial goals of the Program – so often brought up by petitioners as the basis of motions for extensions of time, or to excuse the missing of deadlines – cannot be so stretched to cover any and all requests a petitioner makes in a case, simply because he perceives it to be in his immediate interest.

CONCLUSION

The Murphys have done much to care for M.M., and have displayed great passion in their efforts to aid him (and in their corresponding conviction about the merits of their claims herein). But that passion is not bulwarked by an evidentiary record supporting their contention that M.M. experienced a vaccine-induced encephalopathy, that the vaccines he received had a causal connection to M.M.'s developmental regression, or even that the DTaP and MMR vaccines *could* produce the kind of regression or ASD symptoms M.M. experienced. This is far from a close case – the evidence does not weigh in favor of the Petitioners in any regard.

I therefore DENY an entitlement award in this case. I instruct the Clerk of Court to enter judgment dismissing the case unless a motion for review is filed.[87]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

specified period of time. It says nothing about expert testimony, or the circumstances in which a party should be permitted to supplement it.

[87] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.