



caused by a measles, mumps, and rubella (“MMR”) vaccination. For the reasons set forth below, I conclude that the Petitioners are not entitled to an award.

## I

### THE APPLICABLE STATUTORY SCHEME AND CASE LAW

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient’s injury was “caused-in-fact” by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;” the logical sequence must be supported by “reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the “causation-in-fact” standard, as follows:

Concisely stated, *Althen*'s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

*Althen*, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id.* at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id.* at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe II v. HHS*, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony

and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

## II

### FACTS AND PROCEDURAL HISTORY

#### A. Facts

A.M. was born on December 5, 1993. (Ex. 12.<sup>3</sup>) The records of A.M.'s pediatric visits at the Addabbo Center during his first years of life appear on their face to indicate generally normal health. (Ex. 13.) During his fifteen-month routine physical exam, A.M.'s pediatrician noted that he was "doing well" and was a "well child." (Ex. 13, p. 1.) The record largely lacks medical documentation regarding A.M.'s first fifteen months of life, but the usually recommended vaccinations were administered. (Ex. 14, p. 9.)

A.M. visited the Addabbo Center for an illness on May 31, 1995, and received a diagnosis of otitis media, which was treated with an antibiotic. (Ex. 13, p. 2.) A.M.'s pediatrician noted that A.M. was active and alert at this visit. (*Id.*) Notes from his follow-up examination, two weeks later, indicate that A.M. was "doing well, active, alert," and generally, a "well child." (*Id.* at 3.) During a routine check-up on December 11, 1995, A.M.'s pediatrician again described A.M. as a "well child." (*Id.*, p. 4.) With regard to development, he noted that A.M. responded to sound, used 4 to 10 words ("mama" and "dada" were noted specifically), walked up stairs, and walked independently. (*Id.*)

A pediatrician at South Island Pediatrics, Dr. Mitchell Weiler, treated A.M. for a rash on April 25, 1996. (Ex. 14, p. 1.) At this examination, when A.M. was two years and four months of age, Dr. Weiler made a developmental notation that he could speak "several words." (*Id.*) During A.M.'s next visit, on December 5, 1996, Dr. Weiler noted that A.M. could speak some words in English.<sup>4</sup> (*Id.*, p. 2.) Additionally, during this visit, A.M. was diagnosed with a "possible inguinal hernia." (*Id.*) On February 12, 1997, Dr. Coren performed bilateral inguinal hernia surgery on A.M., from which he "recovered well." (*Id.*, p. 7.) A.M. visited Dr. Weiler's office again, on October 17, 1997, for a routine examination at age three years and ten months. The developmental assessment stated, "full diet: drinks milk. ABC (only), 1-2-3, dresses self: social with peers." (*Id.*, p. 8.)

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<sup>3</sup> Petitioners filed Exhibits 1 through 10 on January 31, 2001. Petitioners filed additional consecutively-numbered exhibits on several additional occasions. Respondent filed Exs. A and B on March 27, 2008, and additional consecutively-lettered exhibits on several occasions thereafter.

<sup>4</sup> A.M. was raised in a predominantly Polish-speaking household.

On January 29, 1998, at age 4 years and one month, A.M. received his second measles, mumps, and rubella (“MMR”) inoculation at Dr. Weiler’s office. (Ex. 14, pp. 9-10.) A.M. returned to Dr. Weiler eleven days later, on February 9, 1998. (*Id.*, p. 13.) The pediatrician’s notes concerning that visit noted a complaint of a “sore throat.” (*Id.*) Dr. Weiler diagnosed A.M. with pharyngitis (throat swelling) and otitis media (ear infection), and treated him with an antibiotic. (*Id.*, p. 13.)

During a follow up visit, on February 23, 1998, A.M.’s ears were re-checked, and Dr. Weiler’s notes from this visit also stated “Trauma. Slipped/Fell.” (*Id.*) A.M. was “noted to have a limp [and was] seen by podiatry [and] x-rays were negative.” (*Id.*) On March 2, 1998, A.M. presented to Dr. Weiler’s office again with complaints of continued limping. (*Id.*, p. 14.) A.M. was seen earlier that day by an orthopedist, Dr. Futterman, who reported that although A.M. had “full symmetrical range of motion of the hips and knees,” he had an abnormal gait, and recommended that A.M. see a neurologist. (Ex. 17, pp. 44-45.)

Also on March 2, 1998, A.M. saw Dr. Joseph Maytal, a pediatric neurologist. (Ex. 15, p. 1.) Dr. Maytal’s report and summary of his initial examination noted a history of limping that began one week earlier after a fall, an awkward gait, and some language difficulties. His report to Dr. Weiler summarized some of his developmental observations and conclusions as follows:

[A.M.] frequents nursery school and plays interactively. In the office he was able to awkwardly copy a circle. He could not copy a cross or square. He could not pick the longest line of three out of three. He knew colors. He did not understand cold but he understood tired and hungry. He recognized colors. He could follow simple directions. He knew his first name but not his last name. Parents are not sure if he can use plurals. His pronunciation in English was rather difficult to understand. I did not hear him say any sentences in English, only single words. His parents felt also that his language is not fluent or grammatically correct in either English or Polish (Polish is his mother tongue.) . . . The youngster until one week ago was walking fine. He had no difficulties climbing steps, etc. There is no recent history of acute illness, i.e. fevers, vomiting, headaches, irritability, etc. past medical history is otherwise unrevealing . . . He is alert and willing to cooperate . . . He spoke in English and answered what he knew in one sentence. He was able to identify and name pictures. He knew body parts . . .

(Ex. 15, pp. 1-2.<sup>5</sup>) Dr. Maytal offered a provisional diagnosis of “Ataxia/Unsteadiness and Developmental Delay.” (*Id.* at 3.) Additionally, he opined that A.M. had two issues:

One is the *longstanding* issue of this youngster who is globally delayed mostly in the language/communicative skills but also in his fine motor and possibly in his gross motor skills . . . The second issue is his acute symptoms of “limping”. As a precaution I would like to consider the reason for this limping. . . with an MRI.

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<sup>5</sup> Dr. Maytal examined A.M. on March 2, 1998, but the date of this letter describing that visit is March 3, 1998. (Ex. 15, p. 1.)

(*Id.* at 2, emphasis added.) An MRI was performed on A.M.'s brain between his first visit to Dr. Maytal on March 2, 1998, and a second visit that took place on March 25, 1998. Dr. Maytal wrote, on March 25, 1998, that A.M.'s MRI showed "diffuse white matter demyelination which is consistent with demyelinating process most likely some form of leukodystrophy." (*Id.* at 5.)

There are several other comments in the record by A.M.'s treating physicians as to the appropriate *diagnosis* for A.M.'s condition. During a nerve conduction study completed on September 22, 1998, Dr. Madrid suggested "leukodystrophy" as a possible diagnosis for A.M.'s condition. (Ex. 17 at 75.) On May 5, 1998, Dr. Berlin, a psychiatrist, provisionally diagnosed A.M. with "spastic paraplegia right greater than left." (Ex. 17 at 55.) Additionally, Dr. Wisniewski, a pediatric neurologist who was part of an interdisciplinary team of specialists at the George A. Jervis Clinic, likewise diagnosed A.M. with "spastic diplegia, more right than left," on July 29, 1998. (*Id.* at 9.) Dr. Wisniewski conferred with the whole interdisciplinary team, on November 17, 1998, concerning A.M.'s treatment plan. Her report, with the concurrence of the entire team, included the diagnosis: "Diplegia (ICD-Code 343.0)." (Ex. 17 at 80.)

In the intervening period, A.M. also received a bilingual psychological evaluation by Maria Malinowska, Ph.D., on September 7, 1998. She assessed his developmental status, taking into account the difficulties posed by his limited comprehension of English. She stated in her summary that:

[A.M.], a four year and nine month old Polish boy is currently functioning within a Low Average range of intelligence. However, he experiences motor and speech/language difficulties as well as attentional problems. These difficulties which are most likely due to an organic brain dysfunction interfere with his intellectual and adaptive functioning.

(Ex. 19 at 9.)

There were also some differences of opinion among physicians regarding the *origins* of A.M.'s condition. Following a neuromuscular evaluation on September 23, 1998, Dr. Madrid opined that A.M.'s symptoms were "suggestive but not diagnostic of post infectious or post vaccination acute encephalomyelitis." (Ex. 17 at 3.) But Dr. Madrid then indicated that he *doubted* that A.M.'s disorder arose from a "neurological complication associated with MMR vaccination," because if that had happened, then likely A.M. would have had an "altered mental state," "seizures," and "fever," which in fact he did not experience. Dr. Wisniewski, similarly, wrote on November 20, 1998, that A.M.'s history was "suggestive but not diagnostic of post infectious or post vaccination acute disseminated encephalomyelitis." (*Id.* at 80.) But she then added a sentence indicating that A.M. likely did *not* suffer from a "neurological complication associated with MMR vaccination," because he did *not* manifest the symptoms to be expected with such a complication soon after vaccination, including "an altered mental state and seizures in a background of fever." (*Id.*) Dr. Brooks, a medical geneticist, explained that A.M.'s symptoms were "suggestive of MLD [metachromatic leukodystrophy]."

The medical records filed in this case do not provide much information about A.M.'s care during the next several years after 1998.

However, after a review of A.M.'s case on October 10, 2007, Dr. Adrian Logush, a pediatric neurologist, supplied a document to Petitioners that opined as follows:

The acute onset of neurological signs and symptoms, and extensive negative diagnostic work-up to date for leukodystrophy are suggestive but not diagnostic of post infectious or post vaccine immunologically induced acute disseminated encephalitis vs. encephalomyelitis.

(Ex. 22 at 1.) Dr. Logush further commented on the case during a telephonic status conference, which was transcribed and filed into the record of this case. *See* attachment to my Order dated December 21, 2007. (Hereinafter, "Logush Conf.") In response to questioning, Dr. Logush explained that the expression "post infectious" should be understood to mean an infection resulting "from the vaccine." (Logush Conf. at 1.) He reiterated that the many medical tests performed to identify A.M.'s condition had yielded negative results. This outcome was "highly suggestive... of the post-vaccine immunologically induced encephalitis." (*Id.* at 1-2.) Upon further questioning, Dr. Logush stated that vaccine causation of A.M.'s encephalitis was "very probable." (*Id.* at 2.) He then affirmed that "very probable" meant "more than 50 percent likelihood." (*Id.*)

A.M. was further re-evaluated by a group of physicians in 2011 and 2012. (Exs. 25, 26.) In 2011, Dr. Proteasa, a pediatric neurologist, reported that A.M. was wheelchair-bound, and concluded that A.M.'s history is "consistent with disseminated encephalitis versus encephalomyelitis likely autoimmune in etiology." (Ex. 27 at 3.) On October 1, 2011, Dr. Vinh Nguyen performed an enhanced MRI test of A.M.'s brain, without contrast. Dr. Nguyen noted that A.M. had a history of "Dystonia" and "Encephalopathy." (Ex. 25 at 15.) He concluded that the test revealed "Diffuse abnormal parenchymal signal abnormality reminiscent of a toxic versus metabolic encephalopathy." (*Id.*) He further stated that "findings may represent a stage disease for metabolic abnormalities affecting the white matter, and may include vanishing white matter disease." (*Id.*)

On March 29, 2012, Dr. Martin Bialor, a specialist in medical genetics, examined A.M. and stated that A.M. "still has trouble with ambulation and requires full time care." (Ex. 25 at 3.) His clinical impression of the case follows:

In the last year, [A.M.] has had onset of tremors, ataxia and apparent myoclonus. An extensive metabolic workup has ruled out many genetic causes of demyelination. The finding of apparently normal development follow by a sudden loss of abilities following an insult with severe demyelination is suggestive of vanishing white matter disease. This often presents during childhood with ataxia following infection or fright. There is episodic deterioration. It is caused by mutations in one of 5 EIF2B genes, which are transcription initiation factors. These genes are responsible for 90% of cases. The condition is inherited as an autosomal recessive. The possibility of this

diagnosis was suggested by Dr. Nguyen on his last MRI scan and, in my opinion, is a good fit for clinical presentation

(*Id.* at 4.)

Finally, a March 2014 letter by Dr. Maytal was introduced into the record of this case in which Dr. Maytal states that the etiology of A.M.'s neurodegenerative disorder is "unclear." (Ex. 38.)

### ***B. Procedural History***

Petitioner Marek Milik,<sup>6</sup> filed a Program petition on January 31, 2001, alleging that his son, A.M., was injured by an MMR vaccination given to him on January 29, 1998. (Petition at 1.) The Secretary of Health and Human Services ("Respondent") filed a report, on June 1, 2001, opposing the petition for compensation. (Report, ECF No. 6.) Proceedings were delayed for several years at the Petitioners' request, to allow time to obtain counsel and to assemble and file expert reports. However, status reports were filed when necessary, and status conferences were held periodically throughout the duration of this case.

On June 24, 2004, the Miliks gave testimony in person in New York City. (Transcript, ECF No. 22, hereinafter "1-Tr.")<sup>7</sup>

Dr. Adrian Logush, a pediatric neurologist, wrote a report, which Petitioners filed on November 21, 2007. (ECF No. 48.) Furthermore, Dr. Logush orally commented on the case in a digitally-recorded telephonic status conference also held on December 18, 2007 (see Fn. 29 below.) (Order, ECF No. 50.) On March 27, 2008, an expert report was filed by Dr. Michael H. Kohrman on behalf of respondent. (Ex. A.) However, the Petitioners then elected *not* to proceed to an evidentiary hearing with Dr. Logush as their expert. They instead continued to search for an expert report for yet another four years. Petitioners filed multiple medical records in 2011 (Exs. 11-23), followed by an expert report by Dr. Nizar Souayah on November 10, 2011 (Ex. 24). Respondent filed a supplemental expert report by Dr. Kohrman, responsive to Dr. Souayah's report, on March 5, 2012. (Ex. C.)

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<sup>6</sup> The original Petitioner was Marek Milik, who represented his minor son, A.M. However, on July 11, 2013, I granted a motion to amend the caption. (Order, ECF No. 142.) The altered caption indicated that A.M. was represented by *both* of his parents, Petitioners Marek Milik and Jolanta Milik. (*Id.*) On April 30, 2014, the caption of this case was further amended both to redact A.M.'s name to protect his privacy, and to indicate that while A.M. is no longer a minor, he is still being represented by his parents because he is a person with a disability requiring guardianship. (ECF Nos. 161, 163.)

<sup>7</sup> I enjoyed meeting the Milik family and found them to be very fine people. I do not doubt that both Mr. and Mrs. Milik were giving me their best memories concerning A.M.'s development and the time period around his MMR vaccination. But I find that the best, most accurate evidence in that regard is that contained in the *medical records* made at the time of the events in question, by medical personnel making notes in the ordinary course of their business.

After Petitioners and Respondent filed their expert reports, and Petitioners filed the appropriate medical records, I conducted an evidentiary hearing on March 7, 2013. (Transcript, ECF No. 129, hereinafter “2-Tr.”) At the hearing, Petitioners presented oral testimony from Dr. Nizar Souayah, while Respondent relied on Dr. Kohrman.<sup>8</sup> (*Id.*)

Petitioners’ post-hearing brief was filed on August 12, 2013 (ECF No. 147.) Respondent filed a post-hearing brief in response on September 30, 2013. (ECF No. 148.) Petitioners filed a reply brief on November 27, 2013. (ECF No. 153.)

On March 10, 2014, Petitioners filed a motion for consideration of new medical evidence (ECF No. 155), which Respondent opposed on March 20, 2014 (ECF No. 157). Petitioners’ motion sought to introduce into the record, as Exhibit 38, a letter by Dr. Maytal addressed “to Whom it May Concern” and dated March 3, 2014, in which Dr. Maytal further commented upon certain notations in his earlier treatment records. (ECF No. 155; Ex. 38.) I issued an order on March 20, 2014, granting Petitioners’ motion and admitting Exhibit 38 into the record of this case. (ECF No. 158.)

This case is now ripe for a ruling concerning the issue of whether A.M.’s condition qualifies for a Program award.

### III

#### ISSUE TO BE DECIDED

Petitioners seek a Program award, contending that their son’s neurologic condition, including extensive developmental delay both mental and physical, was “caused-in-fact” by the MMR vaccination he received on January 29, 1998. After careful consideration, I conclude that Petitioners have *failed* to meet their burden of demonstrating that A.M.’s disorder was vaccine-caused.<sup>9</sup>

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<sup>8</sup> Originally the expert hearing was to be conducted in person in New York City. (ECF No. 100.) However, due to the federal government budget cuts known as “the sequester,” the travel budget for the Office of Special Masters was eliminated during that period. (2-Tr. 4.) As a result, the *parties agreed* that, rather than postpone the hearing, or hold it in Washington, D.C., on the originally - scheduled date, to conduct the expert hearing telephonically, with Dr. Souayah in one location with Petitioners’ counsel, Dr. Kohrman in another location with Respondent’s counsel, and myself and the court reporter at a third location. (2-Tr. 5.) At the conclusion of the hearing, I made a point of assuring the parties that “doing this by telephonic conference call was certainly satisfactory.” (2-Tr. 227.) I specifically noted that I was able to hear and understand both experts and that both sides had a “fair chance” to make their points. (*Id.*) Although I noted a couple of instances where I had difficulty understanding Dr. Souayah, I also noted that on each of those occasions I stopped the proceeding to get clarification, and ultimately understood all of Dr. Souayah’s testimony. (*Id.*)

<sup>9</sup> Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a “preponderance of the evidence.” § 300aa-12(a)(1)(A). Under that standard, the

Petitioners' theory of the case, as expressed by their testifying expert, Dr. Souayah, is that A.M. was a normally-developing child until January 29, 1998, after which his MMR vaccination of that date caused an injury to his brain, resulting in his extensive developmental problems both mental and physical. Dr. Souayah does not purport to know the exact mechanism of how the vaccination caused the injury, but he contends that this theory is supported by the fact that A.M. was healthy prior to vaccination; that his first symptom of brain injury (his limping) occurred 22 days after his vaccination; that the MMR vaccine is suspected to cause brain damage in rare instances; and that an extensive work-up was performed on A.M. and found no other cause for his neurological condition. (Ex. 24, pp. 11-13; 2-Tr. 60-61, 87.)

Respondent disagrees. Respondent disputes Petitioners' claim that A.M.'s condition developed *following* A.M.'s MMR vaccination. That is, Respondent points to numerous indications in A.M.'s pediatric records that A.M. had a *pre-existing* global developmental delay.<sup>10</sup> (2-Tr. 148; Ex. C, pp. 2-4.) Respondent also contends that, even if one were to assume that A.M. had no pre-existing condition, as Petitioners contend, the *infection* that caused A.M. to experience a sore throat and an ear infection shortly after his MMR vaccination would still be *more likely* to have been the trigger of A.M.'s condition. (2-Tr. 169.)

After carefully considering all of the evidence in the record, I must reject Petitioners' claim that A.M.'s neurologic condition was caused by the MMR vaccination he received on January 29, 1998. Petitioners have *failed* to demonstrate that it is "more probable than not" that this vaccination contributed to causing their son's condition. Instead, it appears more likely than not that A.M.'s condition pre-dated that vaccination.

#### IV

### SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

As indicated above, in this case each side relied primarily upon the expert report and hearing testimony of one medical expert. At this point, I will briefly summarize both the credentials and opinions of these expert witnesses.

#### ***A. Petitioners' expert***

##### ***1. Dr. Nizar Souayah***

Dr. Souayah received his medical degree from the Medical School of Tunis (Tunisia) in 1990. (Ex. 31 at 1.) He trained in primary care and family practice at the Hospitals of the Medical School at Tunis from 1987 through 1990. (*Id.*) Dr. Souayah trained in internal medicine at the Hospitals of the Medical School of Strasbourg, France, from 1992 through 1997 and at

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existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

<sup>10</sup> I note that *both* experts in this case discuss A.M.'s condition in terms of being a "global" developmental delay, a *single disorder* involving both motor and cognitive delays, although they totally disagree as to the *cause* of A.M.'s global delay. See Section X of this Decision, below.

Presbyterian Medical Center in Philadelphia, Pennsylvania, from 1997 through 1999. (*Id.*) Additionally, he trained in neurology at Temple University Hospital in Philadelphia from 1999 to 2002, where he also served as Chief Resident from 2000 to 2002. (*Id.*) From there, he served in two clinical and research fellowships, one in electromyography/neuromuscular disease at Harvard Medical School, and the second in neuroscience/neuroinflammation in neurodegenerative disorders at Drexel Medical School. (*Id.*) Dr. Souayah then became an Assistant Professor of Neurology at New Jersey Medical School in Newark, New Jersey. (*Id.* at 2.) Since 2004, Dr. Souayah has served as the Director of both the Peripheral Neuropathy Center and EMG laboratory and the Neuromuscular Medicine Fellowship program at the New Jersey Medical School. (*Id.*) Dr. Souayah is board-certified in neurology, electrodiagnostic medicine, and neuromuscular medicine. (*Id.* at 1-2.) Within his field of expertise, he has published more than 180 professional abstracts and papers and two books. (Ex. 31 at 13-21; 2-Tr. 8.) Furthermore, Dr. Souayah has served as the Executive Editor of the *Journal of Vaccines & Vaccinations* since 2010, and also serves as reviewer of various publications, including the journal *Vaccine*. (Ex. 31 at 3-4.)

## **2. Summary of opinion of Petitioners' expert**

In his written report (Ex. 24), and in his hearing testimony (2-Tr. 6-142), Dr. Souayah opined that the MMR vaccine that A.M. received on January 29, 1998 caused A.M.'s motor dysfunction and developmental delay, primarily because of the temporal association between the vaccine and A.M.'s symptoms. (*E.g.*, 2-Tr. 18-20.) He stated that A.M.'s "condition is consistent with an extensive white matter disease that started approximately 3 weeks after MMR vaccination." (Ex. 24 at 7.) He believes that A.M. suffered an "encephalopathy or encephalitis"<sup>11</sup>, caused by the MMR vaccine, at that time. (Ex. 24, pp. 8-9; 2-Tr. 130.) In both his written report and his testimony, Dr. Souayah contended that the MMR vaccine caused A.M.'s condition chiefly because (1) A.M.'s allegedly normal health and development before the vaccine; (2) the development of his limp about 22 days after receiving the vaccine; (3) the lack of another specified cause; and (4) the fact that the MMR vaccine has been suspected to be capable of causing brain damage. (Ex. 24, p. 11; 2-Tr. 60-61, 87.) Dr. Souayah admitted that he could not specify the exact *mechanism* by which the vaccinations damaged A.M., but suggested several possibilities. (Ex. 24, pp. 10-11; 2-Tr. 87.)

### **B. Respondent's expert**

#### **1. Dr. Michael H. Kohrman**

Dr. Michael H. Kohrman received a combined Bachelor of Science degree and Master of Science degree in chemistry from Stanford University in 1977. (Ex. D at 1.) He graduated from Rush Medical College in 1981 with a degree in medicine. (*Id.*) From 1981 through 1983, Dr. Kohrman served as an intern, then a resident in pediatrics at the University of Chicago Hospitals and Clinics. (*Id.* at 2.) He also trained in a fellowship for pediatric neurology at the University

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<sup>11</sup> "Encephalopathy" means "any degenerative disease of the brain," while "encephalitis" specifically means "*inflammation* of the brain." *Dorland's Illustrated Medical Dictionary* (32<sup>nd</sup> ed. 2012), pp. 612, 614.

of Chicago Hospitals and Clinic from 1983 through 1986. (*Id.*) Additionally, Dr. Kohrman trained in a fellowship for electroencephalography at the University of Illinois from 1986 to 1987. (*Id.*) He is board-certified in neurology and psychiatry, with a special competency in child neurology and sleep medicine, and also board-certified in pediatrics. (*Id.* at 4; 2-Tr. 143-44.) Currently, Dr. Kohrman serves as the Director of Pediatric Clinical Neurophysiology at the University of Chicago Children’s Hospital and as a Professor of Pediatric Neurology and Neurosurgery at the University of Chicago. (*Id.* at 1.) Furthermore, Dr. Kohrman serves as the Medical Director of the Epilepsy Unit of Hinsdale Hospital, and as the Director of both the Tuberos Sclerosis Clinic and the Pediatric Epilepsy Program at the University of Chicago. (*Id.*) He has published more than 100 book chapters, professional abstracts, presentations, and papers. (*Id.* at 17-29.)

## **2. Summary of opinion of Respondent’s expert**

In his two written expert reports (Exs. A, C) and in his hearing testimony (2-Tr. 143-223), Dr. Kohrman opined that A.M.’s delay began *before* he received the MMR vaccine, and that there is insufficient evidence to diagnose A.M. with a vaccine-caused brain injury. (Ex. A at 5; 2-Tr. 148.) Dr. Kohrman referenced medical records by several of A.M.’s treating physicians in support of his position, and stated that A.M.’s delay “predated the MMR vaccination.” (*Id.*) Rather, Dr. Kohrman opined that A.M.’s condition is likely to be a result of a “vanishing white matter” disease, such as an unidentified form of leukodystrophy, that began around two years of age when the first signs of developmental delay appeared. (2-Tr. 164-65, 187-88.) Alternatively, Dr. Kohrman argued that *even if* the first symptoms of A.M.’s disorder did not appear until *after* the MMR vaccination, as Petitioners argue, nevertheless the cause would still more likely have been an *infection* from which A.M. was suffering at the time, rather than his vaccination. (Ex. A, p. 5; 2-Tr. 168-69.)

## **V**

### **SUMMARY OF MY OPINION**

In this case, the two opposing testifying experts agree that A.M. suffers from a severe developmental disorder, involving deterioration of the white matter of his brain, resulting in severe disabilities both mental and physical. They disagree, however, concerning the *cause* of his disorder. After reviewing the record of this case, I have found Dr. Souayah’s view of the case to be quite unpersuasive, while Dr. Kohrman’s opinion was far more persuasive. There are several reasons for this conclusion.

First and foremost, Dr. Souayah based his opinion on an *incorrect* assumption as to the *onset* of A.M.’s condition. Dr. Souayah assumed that A.M. was completely neurologically normal prior to the vaccination in question. Dr. Kohrman, however, demonstrated that there are multiple references in A.M.’s medical records that indicate that his developmental delay *pre-existed* the vaccination in question. Most important among these records, the first neurologist to examine A.M. concluded, only a month following his MMR vaccination, that A.M. had a “*longstanding*” developmental delay. Dr. Souayah failed to offer any specific counter-opinion regarding that pre-existing developmental delay in A.M. posited by Dr. Kohrman. Instead, Dr. Souayah simply relied upon the fact that there was no *diagnosis* of developmental delay prior

to A.M.'s receipt of the MMR vaccination. For all the reasons discussed below, I *reject* Dr. Souayah's argument that A.M. was neurologically normal prior to the vaccination in question.

Second, even setting aside the onset issue, there are other deficiencies in Dr. Souayah's presentation. For example, there were gaps in Dr. Souayah's logic, and his points were effectively refuted by Dr. Kohrman. Moreover, as Dr. Kohrman argued persuasively, even if the first symptoms of A.M.'s disorder did not appear until *after* the MMR vaccination, nevertheless the cause would still more likely have been an *infection* from which A.M. was suffering at the time, rather than his vaccination.

## VI

### **DR. SOUAYAH'S OPINION IS BASED ON THE INCORRECT ASSUMPTION THAT A.M. DID NOT HAVE A PRE-EXISTING DEVELOPMENTAL DELAY**

The most obvious deficiency in Dr. Souayah's causation opinion in this case is that he based his opinion on a *mistaken assumption* as to when the onset of A.M.'s symptoms occurred. Dr. Souayah concluded that A.M.'s neurological symptoms began shortly after his second MMR vaccination of January 29, 1998, when he began limping about 22 days later. (Ex. 24, ¶¶ 6-14; 2-Tr. 54.) Dr. Souayah specifically testified that his causation opinion was based, *inter alia*, on "the fact that the patient was healthy prior to vaccination." (E.g., 2-Tr. 60-61, 87.) In this regard, Dr. Souayah stressed that A.M. was never *diagnosed* as having any developmental delay prior to his MMR vaccination on January 29, 1998. (2-Tr. 224.) Dr. Kohrman, however, has pointed out several references in the medical record which, in his opinion, indicate that, despite the failure of his pediatricians to diagnose it, A.M. did in fact experience *cognitive* developmental delay *pre-dating* the vaccination, which was first *diagnosed* on March 2, 1998, by the first pediatric neurologist to examine A.M., Dr. Joseph Maytal, as a "longstanding" problem. (Tr. 151-52, 155-58; Ex. A, p. 4). Because I agree with Dr. Kohrman that the references in the medical records more likely than not point to a *pre-vaccination* developmental delay, I find that Dr. Souayah's testimony on vaccine causation is *not* persuasive because it is based on an *incorrect* assumption that the onset of A.M.'s developmental delay post-dated his MMR vaccination.

#### ***A. Dr. Maytal's diagnosis of "longstanding" global developmental delay shortly after A.M.'s MMR vaccination contradicts Dr. Souayah's assumption regarding onset.***

One major problem with Dr. Souayah's assumption that the onset of A.M.'s developmental delay post-dated his MMR vaccination of January 29, 1998, is that A.M. was diagnosed as experiencing "*longstanding*" developmental delay by a pediatric neurologist, Dr. Joseph Maytal, on March 2, 1998, only a month after the administration of his MMR vaccination in question. (Ex. 15, pp. 1-2.) A.M.'s referral to Dr. Maytal was the result of his parents' concern that he had developed a limp after what was characterized as a "trivial" fall. (Ex. 15, p. 1.) After examining A.M., Dr. Maytal indicated that there were two issues. One issue was the acute onset of limping, for which he urged an MRI study. (Ex. 15, p. 2.) Dr. Maytal also indicated, however, that there was also "the *longstanding* issue of this youngster who is globally delayed mostly in the language/communicative skills but also in his fine motor and possibly in his gross motor skills." (Ex. 15, p. 2, emphasis added.)

Dr. Souayah acknowledged the fact of this diagnosis of “longstanding” delay (2-Tr. 18), but sought to dismiss Dr. Maytal’s diagnosis for multiple reasons. He argued that Dr. Maytal failed to explicitly indicate that he was accounting for A.M.’s bilingual upbringing (A.M. was raised in a predominantly Polish-speaking household). (2-Tr. 43-44, 47-48.) He was also critical of Dr. Maytal’s report for its failure to indicate that Dr. Maytal had reviewed A.M.’s medical history, in particular his prior MMR vaccination. Dr. Souayah saw no basis for Dr. Maytal’s characterization of A.M.’s condition as “longstanding.” (2-Tr. 47-51.) In light of these alleged deficiencies, Dr. Souayah argued that Dr. Maytal’s conclusion “could be really not very accurate.” (2-Tr. 50.) Dr. Souayah’s arguments on these points, however, are entirely unpersuasive.

First, Dr. Souayah’s interpretation of Dr. Maytal’s record is not credible. For example, Dr. Souayah testified on direct examination, without qualification, that “Dr. Maytal didn’t even mention about the fact that [A.M.] is Polish speaking.” (2-Tr. 47-48.) Based on this, Dr. Souayah argued that a doctor failing to account for a patient’s bilingualism “will draw probably not a good conclusion.” (2-Tr. 50.) On cross-examination, however, Dr. Souayah was forced to admit that Dr. Maytal’s report *did*, in fact, explicitly indicate that Dr. Maytal was aware that A.M. was bilingual. (2-Tr. 109-10.) Indeed, Dr. Maytal’s report of March 2, 1998, explicitly stated of A.M. that “Polish is his mother tongue,” and further that “the parents felt also that his language is not fluent or grammatically correct in either English or Polish.” (Ex. 15, p. 1.)

Similarly, Dr. Souayah argued that Dr. Maytal’s review of A.M.’s case on March 2, 1998, was “not complete,” and indicated that he considered this a reason to call Dr. Maytal’s conclusion into question. (2-Tr. 50.) Specifically, Dr. Souayah argued that Dr. Maytal’s conclusions are suspect in part because there is no evidence that Dr. Maytal reviewed A.M.’s prior medical records, and because there is no evidence that he considered A.M.’s MMR vaccination of January 29, 1998. (2-Tr. 44.) However, Dr. Maytal *did* specifically note the fact of the MMR vaccination in his March 25, 1998, report. (Ex. 15, p. 5.) Further, Dr. Souayah’s claim that there is no evidence that Dr. Maytal reviewed A.M.’s medical records is *contradicted* by Dr. Maytal’s statement in his report of his March 2, 1998, exam that “Past medical history is otherwise unrevealing.” (Ex. 15, p. 1.) Although this notation does not specifically note exactly what measures Dr. Maytal took to review that history, it does explicitly indicate that, contrary to Dr. Souayah’s speculation, Dr. Maytal *did* engage in a review of A.M.’s history. In this regard, I also note that there is also a notation in A.M.’s pediatric records showing that Dr. Maytal conferred with Dr. Weiler (A.M.’s pediatrician) on the day of A.M.’s exam of March 2, 1998, indicating that Dr. Maytal likely was informed by Dr. Weiler of A.M.’s past history. (Ex. 14, p. 14.)

Dr. Souayah was also critical of Dr. Maytal both for conducting his exam of A.M. on March 2, 1998, in English (Ex. 24, ¶ 15), and for measuring A.M.’s development on that day against the Denver Developmental Screening Test, which he argued is inadequate for the assessment of a Polish-speaking child<sup>12</sup> (2-Tr. 112-13). Dr. Kohrman, however, effectively

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<sup>12</sup> In addition to Dr. Souayah’s criticism, Petitioners argue in their post-hearing briefs that the 1988 version of the Denver test filed in this case (as an attachment to Respondent’s Report filed on June 1, 2001) has been criticized in the medical community and superseded by a new version that takes into account a more heterogeneous population. (ECF No. 147, pp. 58-60, fn.

refuted Dr. Souayah's criticisms regarding the extent to which Dr. Maytal accounted for A.M.'s bilingualism. Given that Dr. Maytal clearly documented that he was aware of the Polish language issue, Dr. Kohrman opined that there would have been little to no difficulty in applying the Denver test to A.M., as Dr. Maytal did on March 2, 1998. (2-Tr. 149-50, 153-54, 204.) Dr. Kohrman indicated that he routinely uses the Denver Developmental test in his practice to measure the developmental level of children. (*Id.*) He added that the Denver test can be "highly suggestive of developmental problems in young children." (*Id.*)<sup>13</sup>

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12.) Petitioners suggest that the record of this case should be reopened, because it was incumbent upon Respondent, as the party relying upon Dr. Maytal's use of the Denver criteria, to file all of the literature concerning the Denver test as used subsequent to the version used on A.M. on March 2, 1998. Petitioners argue that later versions of the Denver test "may well" have shown that A.M. was not developmentally delayed once his background as the son of Polish immigrants was taken into account. (ECF No. 147, fn. 12.) This argument is unavailing. Despite raising the existence of updated Denver testing, Petitioners offer no evidence whatsoever that the 1998 version of the Denver test was defective, or that a later version of the test might have yielded a result other than the conclusion reached by Dr. Maytal on March 2, 1998, that A.M. had "longstanding" cognitive delay. Moreover, in claiming that it was the *Respondent* who failed to complete the record on this point, Petitioners mischaracterize the issue. Contrary to their argument, *Petitioners' own expert* acknowledged that he recognized Dr. Maytal's report as reflecting an application of the Denver test. (2-Tr. 112.) Thus, to the extent that Petitioners wished to dispute the accuracy of Dr. Maytal's conclusion based on applying that test, it was incumbent upon them, *not Respondent*, to make the necessary filings that would support that argument. Moreover, Petitioners could have at the very least raised the issue by posing questions about the quality of the Denver test to either expert during the hearing, which they did not do. I note in particular that upon cross-examination of Dr. Kohrman, Petitioners' counsel failed himself to differentiate between the different versions of the Denver criteria while posing his questions, and failed to ask about any of the criticisms in this regard that were later raised, for the first time, in Petitioners' post-hearing brief. (2-Tr. 204.)

Petitioners post-hearing brief indicates that "in a separate filing, Petitioners will move to reopen the hearing for the purpose of filing the medical literature relevant to the developmental issue." (ECF No. 147, p. 60, fn. 12.) However, Petitioners never filed such a motion, and I would deny such motion if filed. For *many years*, it has been *obvious* that Dr. Maytal's notation of "longstanding" developmental delay, based on his application of the Denver test, would play a key role in the resolution of this case. Petitioners and their counsel had the opportunity to develop that issue by filing medical literature before trial, and/or by questioning the experts about such literature at trial. Petitioners were generously permitted to keep this case open for a period of nearly *twelve years* before they were finally able, on November 10, 2011, to file a written opinion of an expert willing to testify for Petitioners under oath at an evidentiary hearing. They then had more than another year to develop their theory of causation before the expert hearing took place. It is, thus, much too late now in this case for Petitioners to attempt a new line of attack to prove their causation claim.

<sup>13</sup> Dr. Kohrman's full sentence about the Denver test is that "while it's not authoritative, it is highly suggestive of developmental problems in young children." Dr. Kohrman did not explain what he meant by "not authoritative," but from the overall context of his discussion he

Dr. Kohrman explained that the Denver test seeks to find skills which should be typical of all four-year-olds regardless of language. For example, the screening seeks to discover whether a child knows his last name, which A.M. did not. (2-Tr. 150.) Dr. Kohrman argued that when dealing with a non-English speaking child, answers to the screening questions can be elicited from the parents speaking the child's native tongue, as well as through parental reporting. (2-Tr. 150.) In this regard I note, for example, that Dr. Maytal clearly indicated that it was A.M.'s *parents* who reported A.M.'s inability to use plurals. (Ex. 15, p. 1.) Significantly, Dr. Kohrman also seemed to indicate that A.M.'s was not a "close case" in this regard. Dr. Kohrman testified that failing one language domain is a cause for concern, and that failing two domains indicates a high level of suspicion of developmental delay. (Tr. 154-55.) Dr. Maytal noted that A.M. failed *three* language domains--A.M. could not use plurals, could not use his last name, and failed to comprehend cold. (2-Tr. 154-155; Ex. 15, p. 1.)

I find the testimony of Dr. Kohrman more persuasive both because his testimony evinces a more detailed understanding of the application of the Denver test, and because he has superior credentials and experience in this area. While Dr. Kohrman offered a relatively detailed analysis of A.M.'s scoring under the Denver criteria, Dr. Souayah, in contrast, despite questioning in a general manner whether A.M. would be sufficiently able to understand English, did not touch on any of the specifics of the Denver test. (*See, e.g.*, 2-Tr. 112-14.) Moreover I note that whereas Dr. Souayah is an adult neurologist who rarely sees children under the age of five (2-Tr. 100-02), Dr. Kohrman is board-certified in both neurology and *pediatrics*, has a special competency in *child neurology*, sees children in his regular practice, and regularly teaches his residents how to apply the Denver test (2-Tr. 144-45, 153). Dr. Kohrman persuasively explained that *pediatric neurologists*--both Dr. Kohrman and Dr. Maytal are such--are clearly much more qualified than other physicians to diagnose developmental delay in small children. (2-Tr. 144, 151-53, 203.)

I also note that Dr. Maytal's finding of pre-existing developmental delay was corroborated approximately six months later in a *bilingual* psychological evaluation conducted by a licensed psychologist, Dr. Maria Malinowska, on September 7, 1998. (2-Tr. 155-58; 205-208; Ex. 19, pp. 5-9.) Dr. Malinowska took a history of A.M.'s development, noting, *inter alia*, that A.M. did not start using simple sentences until age three, while this skill typically develops by age 2 ½. (Ex. 19, p. 5; 2-Tr. 155-156.) Therefore, Dr. Malinowska's history confirmed that A.M. was suffering from developmental delay *long before* his MMR vaccination at age 4.

### ***B. Petitioners are unpersuasive in arguing that Dr. Maytal retracted his diagnosis***

Subsequent to filing their post-hearing briefs, Petitioners moved to supplement the record with a further letter of explanation by Dr. Maytal regarding his use of the term "longstanding" in particular. (ECF Nos. 155, 156.) On March 20, 2014, I issued an order allowing the record of this case to be supplemented to include that letter. (ECF No. 158.) In the letter, Dr. Maytal states with regard to his diagnosis of "longstanding" global delay that "the used term 'longstanding' should be interpreted as 'a condition existing prior to examination.' We are unable to determine the time length of symptoms." (Ex. 38, p. 1.)

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seemed to indicate that the Denver test was a reputable, accepted test commonly relied upon by pediatric neurologists to measure development in young children, so that it appears that the "not authoritative" remark meant only that the test is not "foolproof" or "conclusive" by itself.

While I have considered Dr. Maytal's letter (Ex. 38), it is not persuasive evidence concerning this issue. There are several reasons why I should not credit Dr. Maytal's later, litigation-driven letter, in preference to a *plain reading* of his *original* medical record.<sup>14</sup> First I note that the very term "longstanding" itself contradicts Dr. Maytal's recent letter. Dr. Maytal performed his exam on March 2, 1998, only *one month* after the MMR vaccination in question. The ordinary use of the term "longstanding" would indicate that the delay had lasted substantially longer than one month.<sup>15</sup> Moreover, I find it significant that at the time he wrote his report in 1998, Dr. Maytal was specifically contrasting a "longstanding" global developmental delay with an "acute" onset of limping. (Ex. 15, p. 2.) The definition of "longstanding" suggested in Dr. Maytal's subsequent letter--*i.e.*, as nothing more than "a condition existing prior to the examination"--would completely erase the distinction he originally drew between the "longstanding" global delay and the "acute" symptom of limping, and would make the original record *incoherent* as actually written. Special masters in this Program, moreover, have traditionally declined to credit later testimony over contemporaneous records.<sup>16</sup> *Vergara v. HHS*, 08-882V, 2014 WL 2795491,\*4 (Fed. Cl. Spec. Mstr July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.") *See also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight.")

Therefore, I simply do not credit Dr. Maytal's recent assertion that the term "longstanding" was meant to convey merely "a condition existing prior to the examination" and nothing more.

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<sup>14</sup> Unlike the original record, Dr. Maytal's letter, written nearly sixteen years following his examination of A.M., was not contemporaneous to the events to which it speaks. Moreover, outside of the context of diagnosis and treatment, the letter is entitled to less deference. (*See, e.g. Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events."))

<sup>15</sup> The dictionary definition of "longstanding" is "of long duration." *American Heritage Dictionary*, 2<sup>nd</sup> College Edition, 1985, p. 742.

<sup>16</sup> Although this standard is typically applied with regard to the testimony of lay witnesses, the fact that it is Dr. Maytal rather than Petitioners contradicting the contemporaneous medical records is of no moment. The fact remains that the Petitioners in this case have introduced into the record a statement by Dr. Maytal, seemingly made for the purposes of litigation, which creates a conflict with the original medical record, without a persuasive explanation of how or why the original record was incorrect.

In any event, even if I were to fully credit Dr. Maytal's new letter--which I do not--the Petitioners' claim that Dr. Maytal's letter constitutes "the collapse of the foundation of [Dr. Kohrman's] claim that [A.M.] had a pre-vaccination developmental delay" (ECF No. 159, p. 5) is clearly not true. As described in sections VI(C) and VI(D) of this Decision below, there are a number of *other* notations in A.M.'s medical records where Dr. Kohrman finds support for his opinion of pre-existing developmental delay. Moreover, I note that, even in his more recent letter, Dr. Maytal has not actually *contradicted* Dr. Kohrman's opinion, but instead has professed a *lack of certainty* regarding the onset of A.M.'s condition. In total, Dr. Kohrman has presented a compelling case that A.M. *did* experience significant developmental delay prior to the vaccination of January 29, 1998.

To the extent that Petitioners' also argue that Dr. Maytal's subsequent treatment records indicate that he abandoned his initial diagnosis of global developmental delay, I do not find that argument persuasive either. Although Petitioners are correct to note that "global developmental delay" was never again explicitly mentioned in those exact words, none of the subsequent records contradict or retract that initial diagnosis.

***C. Other notations in A.M.'s medical records also contradict Dr. Souayah's opinion regarding onset.***

Dr. Maytal's diagnosis is not the only piece of evidence pointing to a pre-existing developmental delay. In addition to Dr. Maytal's explicit diagnosis, Dr. Souayah's assumption that A.M. did not have any pre-existing developmental delay is also contradicted by a number of A.M.'s *pre-vaccination* medical records. In Dr. Souayah's interpretation of A.M.'s medical history, he believes Dr. Maytal's statement of "longstanding" global delay on March 2, 1998, to be an unsupported outlier among A.M.'s treating physicians. (Ex. 24, ¶ 21.) Dr. Kohrman, however, points out several records which, he persuasively argues, identify signs of developmental delay that *pre-existed* the vaccination of January 29, 1998, but were at the time unrecognized as such.

According to Dr. Kohrman, the signs of A.M.'s developmental delay stretch as far back as his early pediatric records from the Addabbo Family Health Center. (2-Tr. 151-52.) Comparing the records of A.M.'s 15-month and 2-year visit (Ex. 13, pp. 1-4), Dr. Kohrman points out that at 15 months A.M.'s pediatrician "check marked" that A.M. had achieved a milestone of "3-6 words" (2-Tr. 151-52; Ex. 13, p. 1), while at his 2-year visit the "3-6 words" milestone is *not* check-marked (Ex. 13, p. 4). Instead, Dr. Kohrman points out that the 2-year visit indicates, under the "4-10 words" milestone, that A.M. says "mama" and "dada." (2-Tr. 151-52.) Dr. Kohrman argues that these records show not only a lack of progress, but a possible *regression*, to the extent that A.M. may have gone from 3-6 words to just two, "mama" and "dada." (*Id.*)

In addition, on April 25, 1996, A.M. was seen by a new pediatrician, Dr. Weiler, at two years, four months, of age. (Ex. 14, p. 1.) His developmental progress was listed as "several words." (*Id.*) According to Dr. Kohrman, by this age A.M. should have been speaking in short phrases and simple sentences. (2-Tr. 151.) Moreover, Dr. Kohrman further argues that if A.M. was developing normally, he should have achieved two-word phrases and knowing body parts by two years and four months of age. There is no indication in Dr. Weiler's evaluation of "several

words,” however, that A.M. had achieved these milestones. Nor were they previously checked off on the Addabbo forms during earlier pediatric visits. (*Id.*; Ex. 13, pp. 1, 4; Ex. 14, p. 1.)

Dr. Souayah testified, on the other hand, that the Addabbo reports reflected a “normal physical evaluation,” concentrating in particular on notations indicating A.M. to be “doing well, active, alert, well child.” (2-Tr. 27.) Dr. Souayah, however, despite indicating that he believed these reports to be describing normal development, seemed to be basing that opinion not on the specific childhood developmental milestones noted in the records, but on the fact that the pediatricians did not *explicitly* note any *developmental delay*. (*See, e.g.*, Ex. 24, ¶ 6.) In fact, I do not see any evidence in this record where Dr. Souayah has specifically pointed to A.M.’s early records and opined concerning what age-specific milestones A.M. actually achieved. Indeed, when specifically asked whether Dr. Weiler’s April 25 notation of “several words” constituted an assessment of “normal” development, Dr. Souayah declined to answer, arguing that offering such an opinion would be beyond the data since it was impossible to tell from the record whether Dr. Weiler did a full assessment. (2-Tr. 115-16.) Ultimately, Dr. Souayah acknowledged that Dr. Weiler again documented on December 5, 1996, that A.M. spoke only “2 to 3 words in English” (2-Tr. 116-17; Ex. 14, p. 2), yet at no point did Dr. Souayah offer an expert opinion on whether that observation is consistent with normal development.

Moreover, Dr. Kohrman discussed the fact that the pediatricians in question did not specifically note in their early medical records that A.M. was “developmentally delayed” at the time. Dr. Kohrman noted that as pediatric *neurologists*, both he and Dr. Maytal are far more qualified than pediatricians to diagnose developmental delay. (2-Tr. 144, 151-53, 199-205.) Further, he explained that, in his own practice, it is “not uncommon” for pediatricians to record notes of development that, in retrospect, indicate to a pediatric neurologist that the child was developmentally delayed, but the pediatricians *at the time* do *not* reach a conclusion of developmental delay. (2-Tr. 199.)

Further, Dr. Kohrman’s interpretation of Dr. Weiler’s record is further verified by Dr. Malinowska’s subsequent records, as previously noted. In September of 1998, Dr. Malinowska elicited a history indicating that A.M. began speaking in simple sentences at the age of three. (Ex. 19, p. 5.) According to Dr. Kohrman, this in itself identifies a six-month delay, which indicated developmental delay *long before* A.M. received his January 1998 MMR vaccination at age four. (2-Tr. 155-56.) It also lends further support to Dr. Kohrman’s interpretation of Dr. Weiler’s record, in that it confirms that A.M. did *not* have simple sentences at the time Dr. Weiler noted that he had only “several words.”

Dr. Kohrman additionally stressed that Dr. Malinowska’s records indicate that at age four years and nine months A.M. was scored, under the *Vineland* test,<sup>17</sup> at the age equivalent of two years and six months in the communication domain, three years and two months of age in the daily living domain, and two years and ten months of age in the motor skills domain. (2-Tr. 155-56.) Combining these findings with the fact that A.M. did not experience cognitive *regression*

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<sup>17</sup> Significantly, Petitioners accept the validity of the *Vineland* test, arguing in their post-hearing brief that it is an “accurate” test. (ECF No. 147, p. 61.)

following his MMR vaccination,<sup>18</sup> Dr. Kohrman argues that these findings necessarily *must* relate back to a prior failure to achieve appropriate milestones in the first instance. (2-Tr. 155-58.) That is, Dr. Kohrman argues, had A.M. been developmentally normal up until his MMR vaccination at over four years of age, Dr. Malinowska's findings, placing A.M.'s skills at chronological age equivalents in the two-year range, would not be possible absent the type of *regression* that A.M.'s parents specifically reported as absent.

Petitioners argue that Dr. Kohrman's assertion on this point is disingenuous, because he is allegedly "cherry-picking" which parental statements he wishes to credit. That is, he accepts their reports that A.M. did not regress, but implicitly discounts their testimony that A.M. was developmentally normal prior to receiving his MMR vaccination. (ECF No. 147, p. 62, fn. 13.) This argument is not persuasive, because Dr. Kohrman clearly testified that in his experience as a pediatric neurologist, even pediatricians, much less parents, cannot necessarily be expected to recognize *early* signs of developmental delay. (2-Tr. 199-205.) In that regard, I note that although A.M.'s parents testified that they believed A.M. was generally developmentally age-appropriate, Mr. Milik indicated that as young parents they relied on their pediatrician's advice and "would go with it." (1-Tr. 12, 38-39.) Moreover, Mr. Milik specifically testified that Dr. Maytal's diagnosis was "shocking" to them, because they had no prior personal or family experience with neurological conditions. (1-Tr. 20, 34-35.) And in any event, Mrs. Milik testified on cross-examination that she could not actually recall how many words A.M. had prior to his vaccination. (1-Tr. 46-47.)

Petitioners also argue in their post-hearing briefs that Dr. Kohrman admitted that A.M. was developmentally normal approximately three and a half months prior to his MMR vaccine and that he showed regression after that point. (*See, e.g.*, ECF No. 147, pp. 69-70; ECF No. 153, p. 8.) This contention is based on Dr. Kohrman's testimony regarding a notation in Dr. Weiler's notes for A.M.'s October 17, 1997 exam. (*Id.*) In that notation, Dr. Weiler indicated that at three years, ten months of age, A.M. could recite "ABC (only)." (Ex. 14, p. 8.) He also noted that A.M. could dress himself and was social with peers. (*Id.*) Dr. Kohrman characterized A.M.'s ability to recite only "ABC," as opposed to the entire alphabet, as "on the lower end of normal development." (2-Tr. 209.) Dr. Kohrman also acknowledged that in contrast to Dr. Weiler's observation that A.M. was able to dress himself, Dr. Malinowska's later report indicated that A.M. could not use buttons. (2-Tr. 210.) Dr. Kohrman indicated that taking this at face value, it would seem to show a regression, but indicated that A.M.'s declining ability to use buttons might have been a motor problem and not representative of his cognitive functioning. (*Id.*)

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<sup>18</sup> There are several instances in the medical records where A.M.'s parents deny that he has experienced any cognitive regression. In her report following A.M.'s exam of July 29, 1998, Dr. Wisniewski noted under past medical history that "there is no history of regression in cognitive function." (Ex. 17, p. 7.) In a report of an exam of the same date, Dr. Sklower Brooks also states that "the parents do not feel that [A.M.] has had any regression in his cognition." (Ex. 17, p. 16.) In addition, Dr. Madrid noted in his report of his September 23, 1998, exam of A.M. that "since the onset of his difficulties, the parents indicate that the child has not shown any cognitive regression." (Ex. 17, p. 1.)

Petitioners' argument that Dr. Kohnman admitted A.M. was developmentally normal at about three and a half months prior to his vaccination exaggerates the meaning of Dr. Kohnman's testimony. Dr. Kohnman did not testify that A.M.'s *overall* development was normal at the time of the exam by Dr. Weiler on October 17, 1997. (See Ex. 14, p. 8.) Rather, Dr. Kohnman testified that A.M., in October 1997, demonstrated skills at the *lower* end of normal development for a *single metric--i.e.*, reciting of the alphabet. Moreover, Dr. Kohnman's statement was qualified to the extent that he seemed to imply that A.M.'s status based on this metric is *arguable*. He stated that "it's not a *clear* delay, it's lower end of development." (2-Tr. 209 (emphasis added).) Nor is Dr. Kohnman's use of the word "regression" in this context a significant concession. Although Dr. Kohnman candidly acknowledged that taken together Drs. Weiler's and Malinowska's reports seemed to show the loss of a skill, or regression, during the intervening period (*i.e.*, between October 1997 and September 7, 1998), he indicated that it may have been the loss of a *motor* function as distinct from a *cognitive* function. (2-Tr. 210.) In contrast, Dr. Kohnman's reliance on the fact that Mr. and Mrs. Milik did not report any regression during this same period was in reference specifically to A.M.'s *cognitive* abilities. (2-Tr. 158.)

***D. MRI studies showing that A.M.'s condition was static also point to a delay that predated A.M.'s MMR vaccination.***

Dr. Kohnman also found significance in A.M.'s two MRI studies conducted on March 24, 1998, and October 1, 1998. (2-Tr. 162-64.) Dr. Kohnman argued that the fact that the first MRI showed no signs of acute changes approximately one month after the initial symptom of limping, followed by an MRI finding of no interval change and no sign of progression of demyelination several months later, indicates that the process involved in A.M.'s case is a *static* process rather than an ongoing process. (*Id.*) In Dr. Kohnman's opinion, that is consistent with a demyelinating or dysmyelinating process that produced *longstanding* developmental delay dating back to his examination at the age of two years. (*Id.*)

Although Dr. Souayah agrees that A.M.'s MRI studies through February 2005 showed no interval change (Ex. 24, ¶ 28), I find no instance in the record where Dr. Souayah offers a competing interpretation regarding the significance of that lack of change. Nonetheless, Petitioners argue that Dr. Kohnman is conflating two issues. (ECF No. 153, pp. 5-6.) That is, Petitioners argue that because Dr. Maytal noted the existence of two separate issues (longstanding delay on the one hand and acute onset of limping on the other), and ordered the initial MRI in consideration of his belief that the acute onset of limping on February 20 might have been due to ataxia, it would be circular reasoning to then use the MRI as evidence of a pre-existing developmental delay (*Id.*) Dr. Maytal's purpose in ordering that MRI study, however, is not relevant in that Dr. Kohnman is offering his *own* interpretation of these undisputed findings.

Petitioners' argument is therefore unconvincing. Not only have they failed to substantiate their claim that Dr. Kohnman is conflating two issues, they have also failed to address the substance of his interpretation of the MRI reports. Dr. Souayah, in particular, has stated nothing about these reports beyond confirming that they in fact show no interval change, just as Dr. Kohnman asserted.

## ***E. Conclusion***

At close of the expert hearing in this case I indicated that the strongest aspect of petitioners' presentation on the question of onset is the fact that A.M.'s limp clearly began post-vaccination, and that A.M. was never *recognized* as having any cognitive problems until about 22 days following his vaccination. (Tr. 229.) Nonetheless, I noted that Dr. Kohrman made "some very solid points" regarding his review of the medical records and that I was leaning toward finding a pre-existing condition. (Tr. 230-32.) Upon complete review of the record of this case, including the parties' post-hearing briefs and subsequent submissions, I find, for all the reasons discussed above, that it is substantially more likely than not that A.M. had a developmental delay that *pre-dated* his MMR vaccination of January 29, 1998. Thus, I decline to credit Dr. Souayah's opinion regarding causation, because it is premised on the incorrect assumption that the onset of A.M.'s developmental delay occurred *after* the MMR vaccine in question. (Ex. 24, ¶¶ 6-14; Tr. 54). *See, e.g., Dobrydnev v. HHS*, 566 Fed. Appx. 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "when an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)).

## **VII**

### **OTHER REASONS TO CREDIT DR. KOHRMAN'S TESTIMONY OVER THAT OF DR. SOUAYAH**

As noted above, because Dr. Souayah based his testimony on a clearly flawed assumption as to the time of onset of A.M.'s neurological dysfunction, his causation opinion can be readily dismissed for that reason alone. But I will also briefly discuss certain *additional* reasons to discount Dr. Souayah's causation opinion.

#### ***A. Dr. Souayah's presentation regarding causation was flawed, and overall much less persuasive than that of Dr. Kohrman.***

In general, I simply found the presentation of Dr. Kohrman to be more logical and more persuasive. Not only does Dr. Kohrman have far superior qualifications concerning the particular issues in this case, but there also were flaws in Dr. Souayah's presentation that were so obvious that his credibility in general was weakened.

##### ***1. Qualifications***

First, as noted above, Dr. Kohrman is a *pediatric* neurologist (2-Tr. 143-45, 153), while Dr. Souayah is a neurologist who generally treats adults, not children. (2-Tr. 100-02.) Dr. Kohrman is also board-certified in pediatrics, while Dr. Souayah is not. (2-Tr. 143-44.) A primary issue in this case is whether A.M. was developmentally delayed *prior* to the vaccination in question. On this issue, Dr. Kohrman's qualifications are far better. As a pediatric neurologist, Dr. Kohrman sees children with neurological problems on a regular basis. (2-Tr. 146.) Pediatric neurologists are the medical specialists most qualified to diagnose developmental delays in a

child, more so even than pediatricians. (2-Tr. 144, 151-53, 203.) In his practice, Dr. Kohrman is involved in the diagnosis of encephalitis in children 20 to 30 times per year. (2-Tr. 159.) Dr. Souayah, on the other hand, has not diagnosed developmental delay in a child since his residency in 2002. (2-Tr. 102.)

In sum, Dr. Kohrman's superior qualifications as an expert in this case adds a reason to credit his view of the causation issue over that of Dr. Souayah.

## **2. Careless mistake by Dr. Souayah**

As previously noted, Dr. Souayah was quite vociferous in his direct testimony at the evidentiary hearing that Dr. Maytal's diagnosis of "longstanding" developmental delay in A.M. should be disregarded because Dr. Maytal allegedly did not recognize that A.M. lived in a predominantly Polish-speaking household. (2-Tr. 43-44.) Dr. Souayah was quite emphatic on this point--when asked whether Dr. Maytal's report of the exam of March 2, 1998, indicated that Dr. Maytal was aware of that language issue, he replied "No. Absolutely no." (2-Tr. 43.) However, as detailed above, in two different places in his report, Dr. Maytal *plainly indicated* that he was aware of the Polish language issue (Ex. 15, p.1), as Dr. Souayah was forced to admit on cross-examination (2-Tr. 109-10). The fact that Dr. Souayah made such a *careless mistake* on such a crucial point, failing to carefully read perhaps the most crucial medical record in the case, casts doubt on whether he *carefully* studied the medical records, with an open mind, or instead merely looked for any evidence that might offer support to a preconceived conclusion of vaccine-causation. It casts doubt on his credibility in general.

### **B. Dr. Souayah's assertion that A.M. suffered an "encephalopathy" or "encephalitis" shortly after his vaccination is not supported by the evidence.**

Although his opinion was quite vaguely stated concerning exactly *how* A.M.'s MMR vaccination allegedly caused his global neurological disorder, Dr. Souayah indicated at various places in his expert report and hearing testimony that A.M.'s MMR vaccination caused him to suffer an "encephalopathy" or "encephalitis"-- *i.e.*, swelling or other injury to his brain -- with the first symptoms of such conditions being A.M.'s limping that began about 22 days after his vaccination. (*E.g.*, Ex. 24, p. 7; 2-Tr. 130.) But the overall record makes this assertion of Dr. Souayah seem quite dubious.

Dr. Kohrman, who sees children with encephalopathy or encephalitis regularly in his medical practice (2-Tr. 146), testified quite persuasively that A.M. did *not* display the type of symptoms that one might expect in an encephalopathy or encephalitis triggered by an MMR vaccination (*E.g.*, 2-Tr. 159-60, 167-68.)

To be sure, Dr. Kohrman acknowledged that there is at least *some* reason to believe that in *extremely rare* instances, a recipient of an MMR vaccination might suffer an encephalitis or encephalopathy as a result. (*E.g.*, 2-Tr. 165-66.) But he explained convincingly that the history of *A.M.'s own case* is *quite different* from the history that would be expected in such a situation.

Dr. Kohrman explained that prior to widespread use of the MMR vaccination, it was not uncommon for the "*wild*," naturally-occurring form of the measles, mumps, and rubella viruses to cause encephalopathy or encephalitis in infected persons. Dr. Kohrman explained, however,

that the advent of the MMR vaccination made cases of encephalopathy, previously frequently caused by the “wild” measles, mumps, and rubella viruses, “exceedingly rare.” (2-Tr. 135, 167.) Specifically, Dr. Kohrman drew attention to a large surveillance population study cited by Dr. Souayah following more than half a million doses of MMR, that found *no* causal relationship between MMR and brain injury. (2-Tr. 135-36, 167; Ex. 24, reference 19.)<sup>19</sup> Dr. Kohrman also noted that a 2011 Institute of Medicine report<sup>20</sup> found no causal link between MMR and either encephalopathy or encephalitis other than through measles inclusion-body encephalitis (2-Tr. 173-74), which, Dr. Souayah acknowledged, would impact only an immunocompromised individual, and thus would not be relevant to A.M.’s case, since he is *not* immunocompromised (2-Tr. 83-84).

Nevertheless, Dr. Kohrman acknowledged the possibility that the “attenuated”--*i.e.*, weakened--versions of measles, mumps, or rubella viruses, which are included in the MMR vaccine, might be capable, in extremely rare circumstances, of causing an encephalopathy or an encephalitis in a vaccinee. (*E.g.*, 2-Tr. 171.) But he persuasively argued that A.M.’s clinical presentation in February of 1998 clearly was *not* the presentation that one would expect in such a post-vaccine encephalitis or encephalopathy. (2-Tr. 159-60, 171.) Dr. Kohrman, who diagnoses between 20 to 30 cases of encephalitis in children per year, explained the typical symptoms of encephalitis and encephalopathy. (2-Tr. 159.) Those symptoms would include an acute alteration of consciousness, and/or an abrupt loss of developmental milestones, often accompanied by high fever and seizures. (*Id.*) A.M., in contrast, did *not* suffer such symptoms at any time after his MMR vaccination on January 29, 1998. In sum, stated Dr. Kohrman, “there’s no evidence of an encephalitis in this child. There are no symptoms consistent with that diagnosis.” (2-Tr. 160.)

In A.M.’s case, in the post-MMR period he did *not* experience the symptoms described above of encephalitis or encephalopathy. He did not suffer high fever, seizures, altered consciousness, or an abrupt loss of developmental milestones. Dr. Souayah so admitted. (2-Tr. 132.) Rather, he experienced only the onset of limping, about 22 days post-vaccination.

Dr. Kohrman, in this regard, also made a strong point concerning the *timing* of symptoms that would occur in any MMR-caused encephalopathy. He noted that in such cases there would be a history of fever and the other symptoms between *6 and 11 days* after immunization. (2-Tr. 165-66.) In this regard, he pointed to two articles filed by Dr. Souayah, the Ward and Weibel articles,<sup>21</sup> which noted that encephalopathic reactions to MMR typically occurred on days 6 to 11 (Ward) or days 8 to 9 (Weibel) after vaccination. (Ex. 165-66, 168-69; Ex. 24, references 27 and

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<sup>19</sup> Rantala, H. and M. Uhari, *Occurrence of Childhood Encephalitis: a Population-Based Study*, 8 PEDIATR INFECT DIS J 7 (1989), pp. 426-30 (Ex. 24, Ref. 19).

<sup>20</sup> Ex. F, filed February 7, 2013--see discussion at p. 29 below.

<sup>21</sup> Ward, K.N., et al., *Risk of Serious Neurologic Disease After Immunization of Young Children in Britain and Ireland*, 120 PEDIATRICS 2 (2007), pp. 314-21 (Ex. 24, Ref. 50).

Weibel, R.E., et al., *Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: a Review of Claims Submitted to the National Vaccine Injury Compensation Program*, 101 PEDIATRICS 3 (1998), pp. 383-87 (Ex. 24, Ref. 27).

50.) He further noted that the Ward article stated that “as regards to MMR vaccine, we found no evidence of a raised relevant incidence of serious neurologic disease between days 15 and 35 after immunization.” (2-Tr. 170.) In contrast, in the six cases in the Ward study that *did* show serious neurologic disease, symptoms first occurred between days 6 and 11 post-vaccination, and *all six* involved complex febrile convulsions lasting 30 minutes or more. (2-Tr. 170). Even Dr. Souayah acknowledged that the timing in A.M.’s case did not conform to the timing in the Ward article. (2-Tr. 94-95; Ex. 24, pp. 8-9.) He acknowledged that it is “well known” that the chance of a causal connection to an MMR vaccine would be stronger if the time interval between A.M.’s MMR vaccination and his limping had been more similar to the 6-to-11-day window described in the Ward article. (Ex. 24, p. 10; 2-Tr. 94-95.)

In sum, there is a genuine question, based on the Rantala study discussed at p. 24 above, whether the MMR vaccine *ever* causes a serious encephalopathic complication. Second, A.M. clearly *never* exhibited, on any date, the *type of symptoms* that would be expected if there did occur an MMR-caused encephalopathy. And third, based on the Ward and Weibel studies and Dr. Kohrman’s testimony, A.M.’s only symptom after his MMR vaccination in question, the limping that started 22 days after vaccination, started *far outside* the expected 6-to-11-day window.

### ***C. Issues of other possible “mechanisms” of causing an encephalopathy or encephalitis***

As previously noted, Dr. Souayah was extremely vague, in both his expert report and his hearing testimony, regarding what “mechanism” the MMR vaccine might have caused an encephalitis or encephalopathy in A.M. Again, I found his testimony in this regard to be quite unpersuasive, and this is yet another reason for rejecting Petitioners’ causation claim.

Dr. Souayah stated that the “most plausible” mechanism by which the MMR vaccine might have damaged A.M.’s brain was by a “viral reactivation” or “viral infection.” (Ex. 24, ¶ 60; *see also* 2-Tr. 85.) But in the prior section of this Decision, I have explained that such a phenomenon in A.M. would be *extremely unlikely*, given that A.M. failed to display any of the *typical* symptoms of a MMR-caused encephalopathy, and experienced his only symptom, the limping at the 22-day mark, well outside the likely 6-to-11-day window.

But Dr. Souayah also mentioned a number of additional potential causal mechanisms in his report and hearing testimony. (Ex. 29, ¶ 60; 2-Tr. 86-87.) Dr. Souayah mentioned “molecular mimicry,” “epitope spreading,” “bystander effect,” “polyclonal activation,” and “nonspecific activation of the [immune]<sup>22</sup> system,” as other possible mechanisms, despite implying that they are less important or otherwise secondary to his main “viral invasion” theory. (Ex. 24, ¶ 60; 2-Tr. 86-87.) However, while Dr. Souayah raised these additional concepts in both his expert report (Ex. 24, ¶ 60) and his testimony (2-Tr. 86-87), he made no attempt in either instance to explain *how* they might be relevant to A.M.’s case. And Dr. Kohrman, on the

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<sup>22</sup> The transcript mistakenly indicates that Dr. Souayah referenced “nonspecific activation of the human system.” (2-Tr. 87.)

contrary, explained why “molecular mimicry” was an unlikely mechanism given the facts of A.M.’s case. (2-Tr. 173.)<sup>23</sup>

Moreover, in his attempts to introduce as many potential mechanisms as possible, Dr. Souayah even advanced a possible mechanism that he himself later admitted was *not* relevant to the case. That is, in his expert report, Dr. Souayah initially devoted significant attention to a disease known as “measles inclusion-body encephalitis.” (*See, e.g.*, Ex. 24, ¶¶ 38, 39, 41, and 42.) He explained that measles inclusion-body encephalitis occurs when the measles virus invades the brain of an *immunocompromised* person. (2-Tr. 84.) Yet, Dr. Souayah also acknowledged in his testimony that A.M. is *not* an immunocompromised patient. (2-Tr. 83.) At times it appeared that Dr. Souayah was indicating that his citations regarding measles inclusion-body encephalitis were meant only to support the idea that the measles virus is neurotropic--*i.e.*, it “like[s] the brain.” (2-Tr. 83-84.) Ultimately, however, Dr. Souayah explicitly and confusingly testified that measles inclusion-body encephalitis is “one possible mechanism” explaining A.M.’s condition (2-Tr. 85), despite also testifying that in an immuno-competent patient, “the mechanism would be different” (2-Tr. 86).

In addition, Dr. Souayah himself acknowledged he does *not* know the mechanism of A.M.’s injury (2-Tr. 77), and that *all* of his potential mechanisms were merely “speculative” or “hypothetical” (2-Tr. 77-78).

To be sure, Petitioners are *not* obligated to prove the *mechanism* of injury as part of their burden of proof. (*See, e.g., Knudsen v. HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994).) Nonetheless, Dr. Souayah’s inability to logically articulate a theory of causation, and the blunderbuss manner of his approach, undermine Petitioners’ case as a whole. Although Dr. Souayah in his expert report cited a great deal of literature regarding the various mechanisms that he postulated *could* be at work in A.M.’s case, he did very little to actually link these concepts to A.M.’s case, or to identify which mechanisms among the many he cited could *reasonably* explain A.M.’s condition. On the whole, Dr. Souayah’s presentation regarding causation was weak and less persuasive than Dr. Kohrman’s opposing testimony.<sup>24</sup> (*See, e.g., Hennessey v. HHS*, 2009 WL 1709053, \* 42 (Fed. Cl. Spec. Mstr. May 29, 2009) (“When experts disagree, many factors influence a fact-finder to accept some testimony and reject other contrary testimony. Objective factors, including the qualifications, training, and experience of the expert witnesses and the extent to which their proffered opinions are supported by reliable medical research, other testimony, and the factual basis for their opinions, are all significant in determining what testimony to credit and what to reject.”).)

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<sup>23</sup> Further, Dr. Souayah acknowledged that a positive lumbar puncture test could have yielded evidence of molecular mimicry, but no such test was performed on A.M. (2-Tr. 128.)

<sup>24</sup> I stress that I have *not* required petitioners to demonstrate a *mechanism* of injury in this case. In that regard I note in particular that to the extent Dr. Kohrman conceded that the MMR vaccine is *capable* of causing encephalitis or encephalopathy (2-Tr. 171), I find that Petitioners did meet their burden under *Althen Prong 1*. *See* Section XI (B), below. (Most of Dr. Kohrman’s argument relates to *Althen Prong 2*.)

***D. Even if one were to conclude that A.M. suffered an encephalopathy in February 1998, the cause would more likely be his infection than the MMR vaccination.***

Even if I were to conclude that A.M. suffered an encephalopathy or encephalitis in February of 1998, I would also conclude that A.M.'s *infection*, which he was clearly undergoing at the time, would be a much more likely cause of his encephalopathy than his MMR vaccination.

I note that on February 9, 1998, A.M. reported to Dr. Weiler with a complaint of a "sore throat." (Ex. 14, p. 13.) Dr. Weiler diagnosed A.M. with "pharyngitis" (throat swelling) and "otitis media" (ear infection), and treated him with an antibiotic. (*Id.*) Thus, clearly, A.M. *did* have some type of infection on February 9, 1998. (2-Tr. 158, 183-84.) And that infection was diagnosed only about *eleven days* prior to A.M.'s onset of limping, while the MMR vaccination occurred *22 days* prior to the limping onset. Accordingly, Dr. Kohrman testified, if A.M.'s condition were actually caused by an infection-caused encephalopathy in February of 1998, the likely cause of that encephalopathy would "much more likely" be the infection that caused the sore throat/ear infection, rather than the "attenuated" (weakened) virus forms contained in the MMR, which are specifically *weakened* so as *not* to cause such an effect. (2-Tr. 168-69.) As Dr. Kohrman stressed, the "attenuated" virus forms used in the MMR vaccination, specifically because they are attenuated, typically do not even enter the vaccine's central nervous system, and thus would be very unlikely to cause a neurologic reaction.

Dr. Kohrman's point in this regard was persuasive, and Dr. Souayah made no persuasive rebuttal thereof.

***E. Lack of another specific cause***

One factor in this case is that there has been no consensus among A.M.'s treating physicians as to what is the actual cause of his severe neurological disorder, resulting in both mental and physical handicaps for A.M. Nor can Dr. Kohrman tell us exactly what caused the white matter deterioration in A.M.'s brain. Dr. Souayah, therefore, has argued that the lack of another obvious cause is a factor pointing to A.M.'s MMR vaccination as the cause. (*E.g.*, Ex. 24, pp. 11-13; 2-Tr. 60-61, 87.)

I do not find this argument of Dr. Souayah to be persuasive. First, as stressed above in Section VI of this decision, it seems very likely that A.M.'s disorder began *prior* to the MMR vaccination in question, so that vaccination clearly could not have been the cause.

Moreover, Dr. Kohrman explained another reason why failure to identify a particular cause for A.M.'s neurological disease does not constitute significant evidence that his *MMR* vaccination was the cause. Dr. Kohrman, as a pediatric neurologist who routinely treats severe neurological disorders in children, explained that the lack of a specific cause is, unfortunately, consistent with the history of many neurologically disordered children. (2-Tr. 171, 182.)

## VIII

### DISCUSSION OF MEDICAL LITERATURE IN RECORD

Petitioners submitted numerous medical articles, materials referenced by Dr. Souayah in his written report, and filed as Exs. 24, references 1 through 140. Respondent also filed three articles on February 7, 2013, Exs. F through H. I have studied all of this literature, and I conclude that, to a very strong degree, it supports *Respondent's* view of this case, not Petitioners.

To begin with, I noted that while Petitioners filed a very large number of medical articles, in his lengthy hearing testimony Dr. Souayah made almost no references to those articles. He failed to specifically explain how any of those articles offered any significant support to his theory that the MMR vaccine caused A.M.'s tragic neurological disorder.

On the other hand, Dr. Kohrman persuasively explained how several items of medical literature in the record supported *Respondent's* view of the case.

For example, Dr. Souayah himself admitted that of the articles referenced by and filed by Petitioners, Articles 3 through 27 serve merely to demonstrate that encephalopathy after infection by the *wild* measles, mumps, or rubella viruses have been virtually eliminated by the MMR vaccine. (2-Tr. 135.) Thus, these articles clearly offer no support to Dr. Souayah's causation theory.

Further, many of the articles filed by Petitioners deal with "measles inclusion-body encephalitis" (MIBE), a disorder from which A.M. clearly did *not* suffer, and which could be caused by the MMR vaccine only in immunocompromised persons--while A.M., as Dr. Souayah himself acknowledged, is *not* immunocompromised. (*E.g.*, 2-Tr. 83.) So again, this group of articles clearly offered no support to Dr. Souayah's causation theory.

On the other hand, Dr. Kohrman used certain of the medical articles filed by Petitioners to Respondent's advantage. As previously noted, Dr. Kohrman pointed to one large study done in Finland, studying childhood encephalitis in that country from 1973 to 1987, the period of time immediately after the MMR vaccine had been instituted in that country. (2-Tr. 135-36, 167; Ex. 24, ref. 19.) That study found *no cases* at all of encephalitis or encephalopathy temporally related to MMR vaccination during the entire study period. (Ex. 135-36, 167; Ex. 24, ref. 19.) Dr. Kohrman also noted that other large surveillance population studies found no causal relationship between the MMR vaccine and encephalopathy and encephalitis. (2-Tr. 167.)

Dr. Kohrman also noted two studies cited by Dr. Souayah that *did* appear to show a *possible* association between MMR vaccination and the onset of neurologic injury—the Ward and Weibel articles—but stressed that both of those articles showed that if such a phenomenon occurred the symptoms would likely begin between *6 and 11* days after vaccination. (2-Tr. 165-66, 169; Ex. 24, references 27 and 50.) The Ward article went on to conclude that the MMR vaccine did *not* raise the chance of serious neurologic injury in the period between days *15 to 35* after vaccination. (2-Tr. 170.) Thus, these articles also strongly supported Dr. Kohrman's view of this case over that of Dr. Souayah, since the onset of A.M.'s limping did not begin until *22 days* after his MMR vaccination.

The record in this case also contains an excerpt of a report of a committee of the prestigious Institute of Medicine,<sup>25</sup> specifically addressing the issue of whether the MMR vaccine can cause encephalopathy. (Ex. F.) As the report indicates, the IOM committee studied many of the same articles cited by Dr. Souayah and discussed in the preceding pages of this Decision. After considering all of the evidence, the Committee reached the conclusion that the “evidence is inadequate to accept or reject a causal relationship between MMR vaccine and encephalopathy.” (Ex. F, p. 26.)

Of course, this IOM committee conclusion is of very slight importance in this case, since the Committee did not find enough evidence to conclude *either way* as to whether the MMR vaccine can cause encephalopathy, and since the Respondent’s own expert in this case, Dr. Kohrman, acknowledges that it is *plausible* that the MMR vaccine might cause an encephalopathy, though in factual circumstances quite different from this case. But since the Petitioners bear the burden of proof to demonstrate causation, this IOM committee conclusion could be said to add very slight additional weight against Petitioners’ causation case.

In short, I have examined the medical literature introduced by both parties in this case. After careful consideration, I conclude that the literature, as a whole, offers strong support to *Respondent’s* view of this case, rather than Petitioners.

## IX

### DISCUSSION OF NOTATIONS AND TESTIMONY OF A.M.’s TREATING PHYSICIANS AND PRACTITIONERS

#### A. General

The U.S. Court of Appeals for the Federal Circuit has stressed that “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 shows that the vaccination was the reason for the injury.’” *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006)(emphasis added, citation omitted). Similarly, in several other cases, judges of this Court, in resolving Vaccine Act causation issues, have relied heavily upon the statements of treating physicians contained in the vaccinee’s medical records. *E.g.*, *Zatuchni v. HHS*, 69 Fed. Cl. 612,

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<sup>25</sup> The National Academy of Sciences (“NAS”) was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (see *An Act to Incorporate the National Academy of Sciences*, ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine (“IOM”) is an arm of the NAS established in 1970 to provide advice concerning medical issues. When it enacted the Vaccine Act in 1986, Congress specifically directed that IOM conduct studies concerning potential causal relationships between vaccines and illnesses (§ 300aa-1 note.) In the intervening years, the IOM has formed committees which have prepared numerous reports, concerning issues of possible relationships between *vaccinations* and injuries. Special masters and judges of this Court have frequently relied upon such IOM reports. *E.g.*, *Terran v. HHS*, 41 Fed. Cl. 330, 337 (1998) (affirming special master’s reliance on conclusion of IOM), *aff’d*, 195 F.3d 1302 (Fed. Cir. 1999); *Ultimo v. HHS*, 28 Fed. Cl. 148, 152-53 (1993) (affirming special master’s reliance on IOM report); *Cucuras v. HHS*, 26 Fed. Cl. 537, 543 (1992) (same); *Ryman v. HHS*, 65 Fed. Cl. 35, 39, (2005) (same).

623 (2006); *Kelley v. HHS*, 68 Fed. Cl. 84, 100 (2005). Accordingly, I have carefully studied all notations of A.M.'s treating physicians and practitioners.

In this case, there are numerous notations of treating practitioners in A.M.'s medical records that are relevant to the causation issue. There is also the fact that one treating physician, Dr. Logush, actually provided some oral testimony supporting Petitioners' causation claim. However, when I weigh all the evidence from the treating practitioners' notations and testimony, on the whole I find that such evidence provides more support to *Respondent's* view of the case than that of Petitioners.

### ***B. Practitioners who treated A.M. in 1998 and 2011-12***

To begin with, in my view the strongest support to either side in this case comes from the record of the very first pediatric neurologist to examine A.M., Dr. Maytal. As stressed above, after his first exam of A.M., Dr. Maytal stated that A.M. had "longstanding" global delay, clearly preceding the vaccination in question. (Ex. 15, p. 2.) This medical record notation, for reasons discussed above, provides a very strong support for Dr. Kohrman's view of A.M.'s care.

Second, we have the medical record indicating that Dr. Maytal's findings of pre-existing developmental delay was *corroborated* approximately six months later in a bilingual psychological evaluation conducted by a licensed psychologist, Dr. Maria Malinowska, on September 7, 1998. (2-Tr. 155-58; 205-08; Ex. 19, pp. 5-9.) Dr. Malinowska took a history of A.M.'s development, noting, *inter alia*, that A.M. did not start using simple sentences until age three, while this skill typically develops by age 2 ½ (Ex. 19, p. 5; 2-Tr. 155-56.) Therefore, Dr. Malinowska's history confirmed that A.M. was suffering from developmental delay *long before* his MMR vaccination at age 4.

Further, the medical notations of another early treating physician, Dr. Krystyna Wiesniewski, also support Dr. Kohrman's view of the case. On November 20, 1998, Dr. Wiesniewski *considered* whether A.M.'s disorder might be "a neurological complication associated with MMR vaccination," but then indicated that she *doubted* that was the case, noting, as Dr. Kohrman did, that if it had been a complication of MMR vaccination, A.M. likely would also have experienced, after the MMR vaccination, "an altered mental state and seizures with a background of fever," which was not the case with A.M. (Ex. 17, p. 80.) At another visit, Dr. Wiesniewski similarly wrote that she doubted that the vaccine had any role in A.M.'s disorder, since A.M. did not have any febrile episodes afterwards. (Ex. 17, pp. 8-9.)

Another treating physician in 1998 was Dr. Richard Madrid, a neurologist. On November 23, 1998, Dr. Madrid wrote that A.M.'s history and symptoms "are suggestive but not diagnostic of post infectious or post vaccination acute disseminated encephalomyelitis." (Ex. 17, p. 3.) But Dr. Madrid, like Dr. Wiesniewski, then indicated that he *doubted* that A.M.'s disorder arose from a "neurological complication associated with MMR vaccination," because if that had happened, then likely A.M. would have had an "altered mental state," "seizures," and "fever," which in fact he did *not* experience. (*Id.*) Interestingly, Dr. Souayah referenced only the *first* part of Dr. Madrid's note quoted above, stating that A.M.'s history was suggestive of "post infectious or post vaccination" causation (2-Tr. 58-59), but failed to quote the later sentence in Dr. Madrid's notes in which Dr. Madrid indicated *doubt* that the MMR vaccination was causally involved.

Similarly, Dr. Souayah was also somewhat disingenuous when he quoted only a brief and misleading portion of the medical notation of Dr. Nguyen, a radiologist who in 2011 interpreted an MRI of A.M.'s brain. (Ex. 25, p. 15.) Dr. Souayah, in response to a question by Petitioners' counsel, stated that Dr. Nguyen's "findings are reminiscent of a toxic encephalopathy." (2-Tr. 57.) However, in the sentence of Dr. Nguyen's notes to which Dr. Souayah referred, Dr. Nguyen was referring to only *one portion* of the MRI. (Ex. 25, p.15.) In his final "Impression," Dr. Nguyen wrote that A.M.'s brain scan was "reminiscent of a toxic *versus* metabolic encephalopathy" (emphasis added), meaning *either* a toxic *or* metabolic encephalopathy. (*Id.*) And, of course, Dr. Nguyen said nothing about even the possible "toxic encephalopathy" being related to an MMR vaccination.

Further, Dr. Martin Bialer, who apparently also reviewed the 2011 MRI that Dr. Nguyen reviewed, wrote on March 29, 2012, that "the finding of apparently normal development followed by a sudden loss of abilities following an insult with severe demyelination is suggestive of vanishing white matter disease. This often presents during childhood with ataxia following *infection* or fright." (Ex. 25, p. 4 (emphasis added).) Thus, Dr. Bialer's impression again does not mention the MMR vaccination, but mentions *infection* as a possible cause of A.M.'s neurological disorder, again contradicting Dr. Souayah's view and supporting the view of Dr. Kohrman.

Another treating physician notation from 2011, emphasized by Petitioners (*e.g.*, ECF 147, pp. 33, 77-78), is a note made on October 20, 2011, by Dr. Simona Proteasa, a "pediatric neurology fellow," after a visit with A.M. In that note, Dr. Proteasa did, in fact, mention that A.M. suffered the acute onset of his "asymmetric spastic ataxic-dystonic quadriplegia...when he was 4 years old shortly after immunization." (Ex. 27, p. 1.) However, that notation by Dr. Proteasa, made more than 11 years after the vaccination in question, does no more than merely accurately record *part* of A.M.'s history. The "asymmetric spastic ataxic-dystonic quadriplegia" refers only to A.M.'s *physical/motor disability*, which, of course, as all agree, *did* first appear, in the form of limping, 22 days after his MMR vaccination. Dr. Proteasa's note says *nothing* about whether or not A.M. had pre-existing *mental* delay *prior* to the onset of his motor issues. Nor does the note indicate that any vaccination had any *causal* role in A.M.'s neurologic disorder. Thus, I find that Dr. Proteasa's note, in contrast to the four 1998 notations described above, does *not* shed any significant light on the causation issue in this case.<sup>26</sup>

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<sup>26</sup> Petitioners also pointed (ECF 147, p. 55) to a notation in a record of Dr. Susanne Sklower Brooks, a geneticist, who wrote on July 29, 1998, that A.M.'s parents reported that "[f]ollowing the [MMR] shot he was very lethargic and sensitive to light." (Ex. 17, p. 16.) (Petitioners' brief erroneously stated this notation appeared at Ex. 17, p. 8.) Dr. Souayah briefly commented on the record, stating that the reported symptoms indicated that A.M. was having a "systemic reaction to the vaccine." (2-Tr. 133.) However, Dr. Brooks' record does not say how soon after the vaccination these alleged symptoms occurred, or how long they lasted. "Lethargy," for example, would not indicate encephalopathy at all, but instead would correspond precisely with the fact that on February 9, 1998, A.M. was suffering from an infection which produced a sore throat and otitis media.

Moreover, whether and/or when these alleged symptoms occurred is in serious question. Dr. Brooks noted the symptoms on July 29, 1998, six months after the vaccination. But in the previous six months, A.M. had visited *many* doctors, and no such symptoms were recorded. For

Accordingly, the 1998 records of Drs. Maytal, Malinowska, Wiesniewski, and Madrid offer significant support to Respondent's view of this case. *No* records from the early years of A.M.'s disorder offer support to Dr. Souayah's view.

Further, the opinions in 2011 and 2012 of both Dr. Nguyen and Dr. Bialer, when read in full, offer more support to Dr. Kohrman than to Dr. Souayah.<sup>27</sup>

### ***C. Dr. Logush***

Finally, I turn to the documents and testimony of another physician who treated A.M. years after the vaccination in question, Dr. Adrian Logush. On November 21, 2007, Petitioners filed a one-page letter of Dr. Logush dated October 10, 2007. Dr. Logush in that letter utilized virtually the exact same language that Dr. Madrid had utilized in 1998--*i.e.*, that A.M.'s history was "suggestive but not diagnostic of post infectious or post vaccine, immunologically induced acute disseminated encephalitis vs. encephalomyelitis."<sup>28</sup>

At that time, I understood that Petitioners were offering Dr. Logush as their *expert witness*, and seeking to schedule an evidentiary hearing at which Dr. Logush would *testify in full*, in opposition to an expert from Respondent. However, the phrase in his letter, quoted above, was ambiguous. Therefore, I scheduled a digitally-recorded telephonic status conference, in which I could briefly ask Dr. Logush whether he could say that the *MMR vaccination was, more likely than not*, the cause of A.M.'s disorder. During that conference, in which Dr. Logush was

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example, he visited Dr. Weiler on February 9, 1998, February 23, 1998, and March 2, 1998. He also visited both Dr. Maytal and Dr. Futterman on March 2, 1998. He visited Dr. Maytal again on March 25, 1998, and on April 30, 1998. He visited Dr. Berlin on May 5, 1998, and Dr. Wiesniewski on July 29, 1998. The fact that no such symptoms were mentioned during *any* of those visits, and were not recorded until July 29, 1998, makes it questionable *whether* they occurred, and certainly doubtful that they occurred in close conjunction to the MMR vaccination.

In any event, Dr. Souayah did *not* explain *how* these alleged symptoms fit within or support his overall causation theory. Therefore, the report of these symptoms on July 29, 1998, does not offer significant support to Petitioners' causation theory.

<sup>27</sup> Remarkably, Petitioners' post-hearing reply brief states boldly that "[m]ultiple treating physicians have supported Petitioners' claim that the MMR vaccine caused [A.M.'s] injury." (ECF 153, p. 10.) But that sentence is *not* followed by any *citations to the record* of this case. Instead, my own careful analysis of the records of all of A.M.'s treating practitioners, set forth in detail above, with exhibit and page citations, shows that *no* treating practitioners, with the exception of Dr. Logush in his unexplained oral testimony (though not in his medical records), has indicated the view that the MMR vaccine caused A.M.'s tragic disorder.

<sup>28</sup> This document was originally filed without an Exhibit number on November 21, 2007. (See Notice of Filing, 11/21/2007, ECF No. 48.) It was subsequently refiled as Exhibit 22 on November 10, 2011. (See Ex. 22, 11/10/11, ECF No. 83-9.)

*not* put under oath, Dr. Logush stated that vaccine causation of A.M.'s encephalitis was "very probable." (Logush Conf. at 2.)<sup>29</sup>

At that point, I was satisfied that Petitioners could proceed to an evidentiary hearing with Dr. Logush as their expert, since Dr. Logush apparently was willing to testify that, more probably than not, A.M.'s MMR vaccination was the cause of his disorder.

However, to my surprise, Petitioners later informed me that they would *not* be proceeding to hearing with Dr. Logush as their expert--instead, they would continue to search for an expert willing to support their causation claim and testify under oath. Finally, in November 2011, nearly 12 years after they first filed their petition, they filed the expert report of Dr. Souayah, who was willing to testify at a hearing.

Petitioners nevertheless filed in 2011 an additional document related to Dr. Logush. On June 7, 2011, Petitioners filed another one-page letter of Dr. Logush, which he wrote after an exam of A.M. on February 8, 2011. (Ex. 11.) In that letter, surprisingly, Dr. Logush merely included the *exact same sentence* quoted above, from his letter dated October 10, 2007. In that 2011 letter, Dr. Logush once again, just as in his 2007 letter, did *not* state that A.M.'s disorder was vaccine-caused.<sup>30</sup>

It is not easy to place an appropriate weight on Dr. Logush's opinion in this case. He did, when brought into a legal proceeding on A.M.'s behalf, state orally that it was "very probable" that A.M.'s disorder was vaccine-caused. On the other hand, in two written *reports*, the second of which was written *after* he gave his oral testimony, and which seems to have been written in the *ordinary course of his medical practice*, he used very *different* language, stating that A.M.'s history was "suggestive but *not* diagnostic" (emphasis added) of *either* a "post infectious *or* post vaccine" (emphasis added) neurologic reaction. And that language, used by Dr. Logush both before and after his oral testimony, seems to have been taken directly from language used in a medical record by Dr. Madrid, who, as noted above (p. 30), added language indicating *doubt* that the vaccination was causally involved.

Further, Dr. Logush's oral comments *do not make sense* given the written medical documents that he produced both before and after his testimony. In these documents, he stated that A.M.'s history was suggestive of a "post infectious *or* post vaccine" (emphasis added) neurologic reaction. But in his oral comments during the status conference, Dr. Logush, when asked what he meant by "post infectious," replied that by "post infectious" he meant caused by the *vaccine*. (Logush Conf., p. 1.) But that would make both of his written documents *illogical*, if by "post infectious *or* post vaccine," he actually meant "caused by the vaccine *or* caused by

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<sup>29</sup> I attached the transcript of the conference, during which Dr. Logush was questioned, as an appendage to my Order filed on December 21, 2007. While my Order stated that the status conference at which Dr. Logush spoke was held on November 21, 2007, I believe that date was mistaken. Based on ECF #49, I believe that the conference was held on December 18, 2007.

<sup>30</sup> On November 10, 2011, Petitioners again filed the *same letter* that Dr. Logush had written after his exam of A.M. on February 8, 2011. (Again, the document was labeled as Ex. 11.)

the vaccine.” There would be no need to use the conjunction “or,” if “post infectious” meant the same as “post vaccine.”

Moreover, Dr. Logush turned out not to be willing, or at least was not selected, to be Petitioners’ expert who would testify *under oath*, and therefore “match up” against a contrary medical expert. And even more importantly, because he failed to testify as Petitioners’ expert, he never provided *any explanation* at all as to *why* he stated that it was probable that A.M.’s disorder was vaccine-caused.

Thus, while I am respectful of Dr. Logush’s oral statements because he was a *treating* physician of A.M., in the final analysis, I find the oral statements of Dr. Logush to be *outweighed* by the medical notations of A.M.’s *other* treating practitioners, for three major reasons. First, Dr. Logush never explained the *reasoning* behind his oral statements. Second, Dr. Logush’s oral statements would render his written reports *illogical*, as explained above. Third, Dr. Logush’s oral statements are *substantially outweighed* by the medical notations of the four treaters who treated A.M. *far earlier*, in 1998, namely Drs. Maytal, Malinowska, Wiesniewski, and Madrid, which, as explained above, support *Respondent’s* view of the case over that of the Petitioners’ view.

#### ***D. Summary concerning treating practitioners***

In sum, after studying the notations and remarks of A.M.’s treating practitioners *as a whole, including* Dr. Logush, I must conclude that the overall weight of the treating practitioners’ evidence supports *Respondent’s* view of the case, not Petitioners’.

### **X**

#### **DOES THE RECORD SUPPORT A FINDING THAT PART OF A.M.’s DISABILITY COULD BE ATTRIBUTED TO THE MMR VACCINATION?**

One might look at this case on its face, and wonder whether *another* approach to proving causation could be advanced by Petitioners--*i.e.*, to *separate* A.M.’s disabilities into two separate problems--*e.g.*, (1) general *mental* delay, which in retrospect was recognizable in A.M. *long before* his MMR vaccination in question (see pp. 13-22, above), and (2) *physical* problems, the first symptoms of which did not occur until 22 days *after* A.M.’s MMR vaccine, in the form of A.M.’s limping.

The simple answer to any such speculation is that Petitioners have *not* so argued. To the contrary, *both* parties’ experts have testified plainly that they view A.M.’s neurological disorder as a *single*, “*global*” *entity*, not as two separate problems. *Both* Dr. Souayah and Dr. Kohrman made this point clear. (*E.g.*, 2-Tr. 130, 213.) Therefore, there is no evidentiary basis for me to find that *part* of A.M.’s tragic disability was vaccine-caused.

### **XI**

#### **PETITIONERS’ CASE FAILS THE *ALTHEN* TEST**

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the “causation-in-fact” issue in Vaccine Act cases. The court stated as follows:

Concisely stated, *Althen*'s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If *Althen* satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

*Althen*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)(citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits specifically within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy the *Althen* test.

#### **A. Relationship between *Althen* Prongs 1 and 2**

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between the "vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee's *own* injury. See, e.g., *Kuperus v. HHS*, 2003 WL 22912885, at \*8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at \*18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. See, e.g., *Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at \*24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at \*25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the type of vaccination in question can cause the type of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the particular vaccination did cause the particular condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is “more probable than not” that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner’s case must be established by a “preponderance of the evidence.” § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is “more probable than not” that any of the vaccines that A.M. received contributed to the causation of A.M.’s tragic neurodevelopmental disorder.

***B. Petitioners have established Prong 1 of Althen in this case***

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. Petitioners’ theory is that A.M.’s MMR vaccination caused his global neurological disorder. (*E.g.*, Ex. 24, ¶ 53.) As part of that theory, Dr. Souayah sought to establish that the MMR vaccination is *capable* of causing an encephalitis or encephalopathy. (*See, e.g.* Ex. 24, ¶¶ 38, 44; 2-Tr. 82.) Notwithstanding significant disagreements regarding A.M.’s clinical presentation in *particular*, Respondent’s expert conceded *as a general matter* that the MMR vaccine might be *capable* of causing encephalitis or encephalopathy under some circumstances. (Tr. 171; 173-74.) It would seem, then, that Petitioners have satisfied the first *Althen* prong--*i.e.*, the evidence in this case preponderates in favor of the theory that the MMR vaccination is *capable* of causing the type of injury Petitioners allege.

***C. Petitioners have failed to establish Prong 2 of Althen in this case***

Under Prong 2, the Petitioners need to show that it is “more probable than not” that A.M.’s MMR vaccination *did* cause A.M.’s *own* severe neurodevelopmental disorder. But this they have failed to do, for all of the reasons detailed above. First, as detailed in Section VI above, Dr. Souayah’s opinion was based on the *clearly mistaken* assumption that A.M. was neurologically *normal* at the time of his MMR vaccination of January 27, 1988. Moreover, in Sections VII, VIII, and IX of this Decision I have listed numerous *other* reasons why Respondent’s presentation in this case was substantially more persuasive than that of Petitioners as to Prong 2. Thus, Petitioners have *failed* to establish Prong 2 of *Althen* in this case.<sup>31</sup>

***D. Petitioners have failed to establish Prong 3 of Althen in this case***

Since I have explained why Petitioners have failed to satisfy the *second* prong of *Althen*, I need not discuss why Petitioners’ case also fails to satisfy the *third* prong. However, in the interest of completeness, I will note again that Dr. Kohrman persuasively established that A.M.’s condition *predated* his MMR vaccination (*see* Section VI above), and also that even if I were to accept (which I do *not*) Dr. Souayah’s assumption regarding onset, A.M.’s condition would *still* not fit the *timeframe* discussed in the medical literature submitted in this case (*see* pp. 24-25, above.) This would preclude any finding of a proximate temporal relationship between the vaccination and the injury, as required under *Althen* Prong 3.

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<sup>31</sup> To clarify, Petitioners have failed to show that A.M.’s condition was either *initially caused* by his vaccinations, or was *aggravated* in any way by his vaccinations.

***E. This is ultimately not a close case***

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” 418 F.3d at 1280. Accordingly, I note that this case, overall, is *not* a close case. For all the reasons set forth above, I found that Dr. Souayah’s theory was *not at all* persuasive, while Respondent’s expert was *far* more persuasive.<sup>32</sup>

## XII

### CONCLUSION

The record of this case demonstrates plainly that A.M. and his family have been through a tragic ordeal. I had the opportunity, during the first evidentiary hearing in New York City, to meet and observe A.M.’s parents. I have also studied the records describing A.M.’s medical history, and the efforts of his family in caring for him. Based upon those experiences, the great dedication of A.M.’s family to his welfare is readily apparent to me.

I do not doubt that A.M.’s parents are sincere in their belief that his MMR vaccine played a role in causing A.M.’s condition, and I find it unfortunate that my ruling in this case means that the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to the families of *all* developmentally disabled children, regardless of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their children, and all are deserving of sympathy and admiration.

However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of “causation-in-fact” evidence, to a listed vaccine. In this case, the evidence

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<sup>32</sup> I note also that Petitioners ended their reply brief with an argument that “Respondent has not met her burden to prove an alternative cause or factor unrelated.” (ECF 153, p. 14.) Petitioners, however, are mistaken in this assertion with regard to the *law*. In this case, I have firmly concluded that Petitioners have never met *their* burden of demonstrating that it is “more probable than not” that A.M.’s MMR vaccination played any role in causing his neurological disorder. Therefore, the burden *never shifted* to Respondent to demonstrate an “alternative cause” for A.M.’s disorder. *See, e.g., DeBazan v. HHS*, 539 F.3d 1347, 1352-53 (Fed. Cir. 2008) (emphasizing that “it is clearly the petitioner’s burden to prove that the vaccine was a cause-in-fact of her injuries,” and specifically holding that the burden shifts to the government “once the petitioner has established a prima facie case for entitlement to compensation and thus met her burden to prove causation-in-fact.”)

advanced by the Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on A.M.'s behalf.<sup>33</sup>

s/ George L. Hastings, Jr.  
George L. Hastings, Jr.  
Special Master

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<sup>33</sup> In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.