In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-885V

* *

JAMES MYERS *and* VALERIE MYERS, *as Legal Representatives of their minor grandchild*, M.M.,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Special Master Corcoran

Filed: November 17, 2016

Respondent's Motion to Dismiss; Dismissal of Petition; Vaccine Act; Denial Without Hearing.

James and Valerie Myers, pro se litigants, for Petitioners.

Ann Martin, U.S. Dep't of Justice, Washington, D.C., for Respondent.

DECISION DISMISSING CASE[1]

On November 8, 2013, James and Valerie Myers filed a petition on behalf of their minor grandchild, M.M., seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] The Petition alleges that M.M. experienced anaphylactic shock, and then developed encephalopathy with resulting developmental delays, following receipt of multiple vaccinations from November 12, 2010 to November 16, 2011. *See* Pet. at 1 (ECF No. 1). Petitioners were represented by counsel in this matter until June 2015.

After my review of the case record, and in light of the Petitioners' difficulties obtaining expert support for their causation claim, I informed the parties of my tentative view - that the matter was highly unlikely to be successful - and I invited Respondent to request dismissal of the

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

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

matter. Having completed my review of the evidentiary record and the parties' filings, I hereby **DENY** Petitioners' request for compensation, for the reasons stated below, and dismiss their claims.

I. FACTUAL BACKGROUND

M.M. was born full term, following a normal spontaneous delivery, on November 10, 2010. Ex. 3 at 4, 8. His Apgar score was nine at both one and five minutes. *Id.* at 4. M.M. was treated for a mildly elevated bilirubin level, and was then discharged home on November 12, 2010. *Id.* at 3-4, 6. M.M. received one of the vaccines at issue in this case - the Hepatitis B ("Hep B") vaccine -on November 11, 2010. Ex. 21 at 1; Ex. 2 at 3. Absolutely no adverse reaction to the vaccine is noted in the medical records in this post-birth period, however.

M.M. had his first pediatric visit with a primary care provider, Nurse Practitioner ("NP") Cathleen Jochim, on November 15, 2010, at five days of age, and he was deemed normal in health. Ex. 2 at 14. He was brought for his two-month well-child check on January 17, 2011. *Id.* at 12. At that time, Donna Myers (M.M.'s mother) brought a number of possible issues to the pediatric treater, including cold hands, a rash on the back of his head, and a lot of spitting up, but M.M.'s developmental screen and physical examination concluded that he was again normal and healthy. *Id.* M.M. received the following vaccinations at that visit: diphtheria-tetanus-acellular pertussis ("DTaP"); inactivated poliovirus ("IPV"), hemophilus influenzae type b ("Hib"), Hep B, and pneumococcal conjugate ("PCV"). *Id.*

M.M. presented for additional well-child checks throughout 2011. Ex. 2 at 9-11. At each, his examinations and developmental screenings were recorded by NP Jochim as within normal limits. *Id.* However, an "Ages and Stages" questionnaire administered by Verde Valley Parenting Partnership ("VVPP") on August 3, 2011, showed possible deficits in personal/social interaction when M.M. was nine months of age. Ex. 6 at 24, 27. M.M. received additional doses of the DTaP, IPV, Hib, PCV, and Hep B vaccines in March and June of 2011. Ex. 2 at 4, 11.

M.M.'s next pediatric visit relevant to the claims asserted herein was on November 16, 2011, when he was twelve months of age. Ex. 2 at 6. A physical examination and developmental screen again resulted in the conclusion that he was normal in overall health. *Id.* At this time, M.M. received the DTaP, measles-mumps-rubella ("MMR"), varicella, Hib, PCV, and influenza vaccines. *Id.*

As is discussed in greater detail herein, most of Petitioners' claims are based on the allegation that M.M. experienced some kind of significant reaction to the vaccines he received at his November 16th one-year-old pediatric visit. Thus, co-Petitioner James Myers alleges in a declaration filed in January 2014 that the M.M.'s behavior immediately changed once he was brought home after the November 16th vaccinations. *See* Declaration of James Myers, dated January 9, 2014 (filed as ECF No. 6-1 on January 10, 2014 (Ex. 1) at ¶11. Yet there is nothing at

all in the medical records filed in this case that record anything wrong, or even slightly out of the ordinary, with M.M. after receipt of these vaccinations. Indeed - there are no records showing that M.M. was taken to any doctor or other healthcare provider in the days, weeks, or immediate months following this visit.

Temporally, the next medical record relevant to Petitioners' claims is from May 9, 2012, at which time Mr. Myers and his daughter, M.M.'s mother (with the assistance of a Family Support Specialist from the VVPP), completed the 18- Month Ages & Stages Questionnaire. Ex. 21 at 101-14. The results of the questionnaire were deemed to reveal potential delays in M.M.'s communication and social-emotional development, and M.M. was therefore referred to the Arizona Early Intervention Program ("AZEIP"). *Id.* at 107, 117. It was in May of 2012 when Ms. Myers and her daughter are documented to have expressed concerns about M.M.'s speech and overall development – including the possibility that he was autistic. Ex. 2 at 81. M.M.'s mother also noted that she had considered him "fine" until he had received the vaccinations mentioned above at his twelve-month pediatric visit. *Id.* But the records from May 2012 make no mention of anyone observing any other kind of reaction to these vaccines.

AZEIP performed an evaluation of M.M. on May 29, 2012, and determined that he was eligible for the state early intervention program. Ex. 2 at 43-47; Ex. 21 at 115, 117-19. The developmental team specifically concluded that M.M. demonstrated age appropriate abilities in motor, cognitive and adaptive skills, but that he exhibited significant delays in the areas of communication and social-emotional development. Ex. 2 at 46. The history section of AZEIP's evaluation recorded Petitioners and M.M.'s mother as again stating that his developmental problems began after his twelve-month-old vaccinations, but did not relate any symptoms of any other noticeable physical reaction to these vaccines.

M.M. continued to receive pediatric care for the remainder of 2012, as well as speech therapy from AZEIP. Ex. 2 at 78. By 2013, Petitioners (who took over M.M.'s care in order to alleviate the burden imposed on his mother) began to explore a variety of treatments for M.M.s' developmental problems, including taking M.M. to a practitioner of naturopathic medicine. Ex. 21 at 143-51. That individual performed a hair analysis that purported to find that M.M. had potentially toxic levels of various metals in his body. *Id.* at 147-50; Ex. 13 at 7; and Ex. 2 at 67. But this practitioner closed her practice, and the Myers brought these concerns (and in particular, that the vaccines M.M. had received might have played a role in his developmental problems) on April 29, 2013, to a toxicologist, Daniel Brooks, M.D. Ex. 2 at 19-22; Ex. 21 at 156-59. Dr. Brooks, however, rejected the naturopath's proposal that hair testing was an appropriate measure of whether a child in fact had metal poisoning at all, expressing the view that he had "no concerns" that there was in fact any relationship between M.M.'s problems and vaccines or metal toxicity. Ex. 2 at 21; Ex. 21 at 158.

Records generated over the next eighteen months or so reflect that M.M. was treated by several naturopathic providers and a homeopathic physician with various therapies, including

supplements and chelation therapy.[3] *See generally* Exs. 9, 11, 12. As Petitioners explored such treatments, they began to more specifically recall a temporal relationship between the onset of M.M.'s developmental problems and his November 2011 vaccinations. *See, e.g.,* Ex. 9 at 35; Ex. 13 at 97. They also increasingly insisted that pediatric treaters consider whether M.M. suffered from various illnesses and multi-systemic problems. Ex. 13 at 45- 95, 238. In particular, Mr. Myers "want[ed] a doctor to look at the vaccine record and say there is a possible medical reason for his illness." *Id.* at 89. Indeed, Mr. Myers informed a pediatrician that a naturopath to whom M.M. had been taken had diagnosed M.M. with encephalopathy (*Id.* at 66) – although there is no evidence from the record of either a medical doctor making that diagnosis, or that it was ever considered in the months immediately following the November 2011 vaccines.[4]

Many efforts were made, at Petitioners' urging, in the following months to attempt to identify some unspecified illness in M.M. that could possibly be linked to his developmental problems and/or the November 2011 vaccines he had received. By February 2014, M.M.'s pediatrician, Wendy T. Tuccille, M.D., determined that she could no longer treat M.M., largely due to Petitioners' unwillingness to accept her recommendations for appropriate therapies, coupled with their insistence that M.M. receive treatments that Dr. Tuccille did not consider medically acceptable, such as hyperbaric oxygen treatments.[5] Ex. 21 at 375.

On April 8, 2014 (and well after the filing of this case), M.M. saw Martha Grout, M.D., M.D., a medical doctor and homeopathic physician, for an initial evaluation. Ex. 12 at 11. Although Dr. Grout did not prepare a formal expert opinion in this case[6], certain litigation-related statements and correspondence she did prepare have been referenced by Petitioners in support of her claim, and so some discussion of her treatment of M.M. is required.

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[3] Chelation therapy involves injecting a patient with a chelating agent (such as a synthetic solution ethylene-diaminetetra-acetic acid, or EDTA) which binds to heavy metals to remove them from the body. *Dorland's Medical Dictionary*, 1912 (32nd ed. 2012).

[4] Eventually (and perhaps due to Mr. Myers's persistence in the belief that M.M.'s problems were more global than an idiopathic ASD), some of M.M.'s treaters recorded in his history "encephalopathy, unspecified" – but without providing corroboration or explanation for the inclusion of the diagnosis. Ex. 13 at 60-63.

[5] Hyperbaric oxygen therapy (which is used to treat a variety of conditions) involves breathing pure oxygen in a pressurized room or body-sized tube. *Tests and Procedures: Hyperbaric Oxygen Therapy*, Mayo Clinic (Nov. 25, 2014), http://www.mayoclinic.org/tests-procedures/hyperbaric-oxygen-therapy/basics/risks/prc-20019167?B p=1. (last visited Oct. 31, 2016). When an individual is placed in a hyperbaric oxygen therapy chamber, air pressure is increased to three times higher than normal, permitting the lungs to gather more oxygen than would be possible at normal air pressure. *Id.* The individual's blood then carries this oxygen throughout the body, which purportedly helps fight infection and promotes healing. *Id.* However, medical science has not confirmed that hyperbaric oxygen therapy is an effective autism treatment. *Id.* Moreover, although hyperbaric oxygen therapy is generally a safe procedure, it does involve risks, including the possibility of lung collapse, middle ear injuries, and seizures. *Id.*

[6] Had Dr. Grout been offered as a causation expert, her lack of qualifications on immunology would only have been but one factor negatively impacting her credibility. Dr. Grout is reported to have had her medical license in Florida revoked, after a homeopathic treatment she oversaw for an eighteen month-old's eye illness resulted in the child's death. A. Ault, "Homeopathy Doc Gives Up License after Toddler's Death," Medscape Medical News, October 16, 2015, http://www.medscape.com/viewarticle/852778 (last visited October 25, 2016).

Dr. Grout's history (written two and one-half years after vaccination) stated that immediately after the November 2011 vaccinations, M.M. "became very lethargic, lay pretty much limp in bed," and that physical changes in his movement were evident the very next day. Ex. 12 at 11. She proposed that "the multitude of vaccines which [M.M.] was given simply overwhelmed his defense system." *Id.* at 13. Dr. Grout continued to treat M.M. after April 2014, as Petitioners extended their efforts to address M.M.'s physical and developmental problems in nontraditional ways.

There is some other post-filing evidence in M.M.'s medical records pertaining to his claim. On December 16, 2015, M.M. presented to a neurologist, Melanie Burgos-Alarcio, M.D., of Phoenix Neurology & Sleep. Ex. 21 at 531. Dr. Burgos-Alarcio recorded M.M.'s treatment history as it was relayed to her by Mr. Myers, reporting that M.M. had a "history of severe vaccine reactions," and that specialists had expressed concerns about immune-mediated syndromes, mitochondrial dysfunction, or other metabolic disorders. *Id.* at 532. Under the "allergies" section of the past history notes, Dr. Burgos-Alarcio recorded "Vaccines (multiple): anaphylaxis." *Id.* Nothing in these more recent records, however, establishes the basis for this statement, or why it is an appropriate assertion despite the lack of any prior evidence (as discussed above) corroborating an anaphylactic reaction to any vaccine M.M. has ever received.

II. Procedural History and Parties' Arguments

As noted above, Petitioners (originally represented by counsel) initiated this action in November 2013. For the next twelve months, the Myers filed medical records in the matter, with a statement of completion on November 7, 2014 (ECF No. 26). By this date, Petitioners had still not filed a formal expert report, although they had filed a "narrative report" from Dr. Grout in October 2014. ECF No. 23 (Ex. 14, filed as ECF No. 23-1). Special Master Hamilton-Fieldman (to whom the case was originally assigned) subsequently held a status conference and ordered the Petitioners to obtain an additional expert report, given the extent to which they seemed to be alleging that M.M. had suffered some kind of developmental problem, likely akin to autism. Order, dated December 10, 2014 (ECF No. 27). Not long thereafter, the matter was transferred to me.

In the next two months, Petitioners endeavored to obtain the supplemental report, filing a second report/statement from Dr. Grout on February 23, 2015 (Ex. 17, filed as ECF No. 33-1). Later in May of that same year, Respondent filed her Rule 4(c) Report, setting forth her position that the matter was not appropriate for compensation. ECF No. 38. In June 2015, the Myers's attorney withdrew from the matter, and they proceeded as *pro se* litigants from that point onward. After granting the unopposed motion to withdraw, I held a status conference in the case, ordering Petitioners to consider obtaining another expert report, in order to firm up their causation argument more effectively or persuasively linking the relevant vaccines to M.M.'s condition, and report back on their determination by the end of August. *See* Order, dated July 15, 2015 (ECF No. 50).

Petitioners were granted additional time in which to obtain a supplemental expert report (*see* Order, dated September 25, 2015 (ECF No. 54), but when they failed to provide substantive details on their progress in finalizing such a report, I set a deadline in February 2016 for its filing. Order, dated November 30, 2015 (ECF No. 56). But that deadline was also missed, and after a status conference, and based on my review of the file, I determined it was appropriate to permit Respondent to move for dismissal of the Petitioners' claims entirely. *See* Order, dated March 22, 2016 (ECF No. 59). After some delay in setting a briefing schedule, I eventually ordered Respondent's motion to be filed on or before August 30, 2016. Order, dated July 19, 2016 (ECF No. 62). Respondent met the deadline, and the motion was served on August 29, 2016. ECF. No. 63 ("Motion").

Respondent's Motion was the sole pleading filed in response to my July 19th Order – Petitioners never responded in writing to the motion, despite being provided a deadline of September 30, 2016 to do so, nor did they move for additional time to act. Accordingly, Respondent's motion is effectively unopposed. Based on a review of the medical records, Respondent maintains that Petitioners cannot establish a Table claim for anaphylaxis – whether on the basis of the Hep B vaccine M.M. received at birth, or the DTaP or MMR vaccines received in 2011. Motion at 19-20, 23-24. She also argues that the record does not support Petitioners' allegation that M.M. experienced a Table encephalopathy after any of the November 2011 vaccinations. *Id.* at 21-23. Finally, she asserts that Petitioners cannot satisfy by preponderant evidence any of the causation prongs established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) required to prove a "non-Table" claim. *Id.* at 24-25.

Although Petitioners did not formally oppose Respondent's motion, I will note the contents of those record items they have offered (beyond the pieces of treating history already discussed) relevant to deciding the motion, outside of the medical records already mentioned. First are the two statements prepared by Dr. Grout. Her initial statement was filed in October 2014. *See generally* Ex. 14. In it, Dr. Grout provides a narrative recounting of M.M.'s medical history, summarizing events in his treatment history both before and after the November 2011 vaccinations, based on Petitioners' own statements. *Id.* at 1-2. She also sets forth the nature of some of her own tests on M.M., including efforts to measure metals in his body. *Id.* at 3. Ultimately, Dr. Grout's first statement suggests the possibility that M.M. suffered from some sort of metabolic disorder that in her view may have played a role in his developmental problems, but otherwise offers only a conclusory opinion that the vaccines he received in November 2011 triggered his developmental problems. *Id.* at 4.

Dr. Grout's next statement was filed after this matter had been transferred to me. *See* Ex. 17. It largely seems to have been intended to attack the notion that M.M. was autistic. *Id.* at 1. But as with her prior statement, Dr. Grout does little to opine as to the causal propensity of any of the vaccines M.M. received in November 2011, instead again making conclusory statements about their capacity to cause neurologic injury resulting in developmental problems, and largely relying

on the temporal association between the vaccination and the timing of M.M.'s developmental problems. *Id.* at 3 ("[*p*]*ost hoc* is not necessarily *propter hoc,*" although "the temporal sequence is hard to ignore in this case"). Indeed – Dr. Grout expressly acknowledges the limits of her opinion. *Id.* ("[w]ithout actually doing a brain biopsy it would be impossible to make a pathologic diagnosis of encephalitis"; "[t]here is considerable controversy as to "the cause" of autism").

Second are several submissions provided by Petitioners. Mr. Myers's Declaration from January 2014 avers that within twenty-four hours of the first Hep B vaccination on November 11, 2010, M.M. exhibited problems related to vaccination, including jaundice, projectile vomit, and cold, purple extremities. Ex. 1 at ¶ 3. He also developed a "blistering, purple rash on the back of his head" which eventually cleared. *Id.* at ¶¶5-6. Then, on November 16, 2011, when M.M. was brought home from the physician's office after receiving his twelve-month vaccinations, he became "lethargic and limp," blankly staring and soon unable to make eye contact. *Id.* at ¶ 11. Mr. Myers avers that M.M.'s next evaluation did not occur until about six months later on May 9, 2012, by which time he "had drastically changed from a neurologic standpoint." *Id.* at ¶ 12.

In July 2016, Petitioners filed a number of documentary materials in support of their claim on disk, after failing to do so earlier despite my order.[7] Included in these materials was a "Revised Statement" from Mr. Myers that expanded on his earlier declaration. *See generally* Ex. 22 ("Revised Statement"). This is an eight-page unsigned declaration that includes some additional details about the nature of M.M.'s purported vaccine reactions, and also attempts to explain the basis for Petitioners' assertions that M.M. experienced a Table anaphylactic injury – both when he received the Hep B vaccine at birth, and then a year later after the DTaP and MMR vaccinations. *Id.* It includes no record citations, however, corroborating its assertions.

In addition, Petitioners have offered a pleading-like response that seems to anticipate Respondent's motion. *See generally* Ex. 23. This document purports to offer record citations supporting Petitioners' allegations – although the temporally-earliest record evidence cited to is from January 17, 2011, which states parental concerns of cold hands, spitting up and a head rash, the remaining citations all reference treatment of M.M. long after the November 2011 vaccination time. *See, e.g., Id.* at pages 7-31.

[7] Following a status conference held on March 21, 2016, Petitioners were ordered to file the documents that were sent to the court in paper in disc format by April 8, 2016. *See* Scheduling Order filed on March 22, 2016 (ECF No. 59). Petitioners missed that deadline, however, and so on April 19, 2016, I issued a show cause order requiring the Petitioners to file the documents on disc immediately. *See* Order filed April, 19, 2016 (ECF No. 60). Again, Petitioners failed to follow my order, however, and I issued an additional order stating that if the disc was not filed by July 15, 2016, I would dismiss the case for failure to prosecute. *See* Order filed June 30, 2016 (ECF No. 61). The compact disc was finally received by clerk's office on July 18, 2016.

III. APPLICABLE LEGAL STANDARDS

A. Claimant's Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8] In this case, the Petitioners assert Table and non-Table claims.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the

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

type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

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

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions

among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dep't of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

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

B. Law Governing Analysis of Fact Testimony

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical

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

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

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

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has

listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Determination to Resolve Case without Hearing

The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via an evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous special master decisions on the papers in lieu of hearing). It is particularly appropriate to decide a matter on the papers if the underlying claim presents arguments that have repeatedly been rejected, or if it is self-evident from the filed evidence (including expert reports) that there is no need to hear oral testimony to decide the case. In *Hooker,* for example, petitioners alleged that certain thimerosal-containing vaccines that their minor son received caused him to experience developmental regression that resulted in an ASD diagnosis. The claim was resolved on the papers and without a hearing, given the wealth of relevant contrary holdings. *Hooker,* 2016 WL 3456435, at *39-40.

IV. ANALYSIS

I. Petitioners Cannot Establish by Preponderant Evidence Their Table Claims.

A. Anaphylaxis Table Claims

Petitioners allege variably that some or all of the vaccines M.M. received - either the Hep B at birth in 2010, or the DTaP and MMR a year later - caused anaphylaxis or anaphylactic shock. Of the several vaccines in question, anaphylaxis is listed on the Vaccine Injury Table as a covered condition for all three of these particular vaccines. 42 C.F.R. § 100.3(a). They are therefore the only possible bases for a Table claim herein involving the injury of anaphylaxis.

Anaphylaxis is defined in the "Qualifications and Aids to Interpretation" ("QAI") section of the Table to be "an acute, severe, and potentially lethal systemic allergic reaction" that begins "minutes to a few hours after exposure." 42 C.F.R. § 100.3(b)(1). Indeed, as the Table specifically establishes, and consistent with the requirement that the reaction be "acute," the time period for

the first symptom or manifestation of onset of anaphylaxis for any vaccine for which anaphylaxis is a covered condition is four hours or less – regardless of the vaccine. 42 C.F.R. § 100.3(a). Table claims alleging anaphylaxis that are not supported by preponderant evidence of a reaction having occurred in that narrow time window are routinely dismissed. *See, e.g., Waterman v. Sec'y of Health & Human Servs.*, No. 13-960V, 2015 WL 4481244, at *4-5 (Fed. Cl. Spec. Mstr. June 30, 2015) (twelve hours between vaccination and reaction resulting in death too long to establish Table claim of anaphylactic injury), *mot. for rev. den'd*, 123 Fed. Cl. 564 (2015); *La Londe v. Sec'y of Health & Human Servs.*, No. 06-435V, 2012 WL 5351164, at *10 (Fed. Cl. Spec. Mstr. Sept. 28, 2012) (onset of anaphylactic reaction five hours after receipt of DTaP vaccine too long outside of defined period to support Table claim), *mot. for review den'd,* 110 Fed. Cl. 184 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *Betancourt v. Sec'y of Health & Human Servs.*, No. 04-458V, 2007 WL 4820969, at *20 (Fed. Cl. Spec. Mstr. Dec. 10, 2007) (dismissing Table claim of anaphylactic injury too long after MMR vaccine).

Here, the contemporaneous records contradict Petitioners' personal, after-the-fact testimonial assertions about anaphylaxis. Records both from M.M.'s birth in 2010, as well as his 2011 well-child visit, show no evidence of any severe injury or reaction within the required four-hour window. Nor have Petitioners offered any third-party corroborative evidence of anaphylaxis. The only record support that can be mustered at all for Petitioners' Table claims herein are the statements in Dr. Burgos-Alarcio's 2015 notations, but the contemporaneous records do not corroborate them, and it is more likely she relied on erroneous statements about M.M.'s medical history in so stating. Accordingly, Petitioners' anaphylaxis Table claims are unsupported by preponderant evidence and warrant dismissal.

B. Encephalopathy Table Claim

Petitioners next assert that the 2011 vaccines M.M. received caused him to experience a Table encephalopathy. Only the DTaP and MMR vaccines can be the basis for such a claim, and M.M. unquestionably received both in November 2011. 42 C.F.R. § 100.3(a). Because causation is presumed after the Table's factual predicates are established, the definition of encephalopathy that the Table adopts has been deemed, appropriately, "very restrictive." *Dixon v. Sec'y of Health & Human Servs.*, No. 01-605V, 2003 WL 23218020, at *4 (Fed. Cl. Spec. Mstr. Nov. 25, 2003), *mot. for review den'd*, 61 Fed. Cl. 1 (2004).

According to the QAIs, a vaccinee is considered to have suffered a Table encephalopathy if he or she manifests an injury encompassed in the definition of an "acute" encephalopathy within the appropriate time period, *and then* a "chronic" encephalopathy is present for more than six months after the immunization. 42 C.F.R. § 100.3(b)(2). An acute encephalopathy must be sufficiently severe to require hospitalization (regardless of whether the vaccinee is actually hospitalized). 42 C.F.R. § 100.3(b)(2)(i). For a child less than 18 months of age who did not experience an associated seizure event, an acute encephalopathy is deemed to be present if there is a "significantly decreased level of consciousness" that persists for at least 24 hours. 42 C.F.R. §

100.3(b)(2)(i)(A). Children less than 18 months of age presenting after a seizure are considered to have an acute encephalopathy if they have experienced a "significantly decreased level of consciousness" that persists beyond 24 hours and cannot be attributed to the seizure or medication. Id. The referenced phrase "significantly decreased level of consciousness" must be evidenced by the presence of at least one of the following clinical signs for at least a 24-hour period: "(1) [d]ecreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) [d]ecreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things)." 42 C.F.R. § 100.3(b)(2)(i)(D).

As with Petitioners' anaphylaxis claims, however, the Table encephalopathy claim is unsupported by record evidence that would establish either an immediate acute reaction or a following chronic condition. There is no evidence from the time period immediately following the November 2011 vaccinations that M.M. experienced any kind of neurologic injury – no test results, no treater opinions, and no evidence that Petitioners or any other of M.M.'s caregivers sought treatment for him. All that remains are Petitioners' after-the-fact allegations of what they observed – none of which are reflected or reconciled with the medical record, and therefore that (as other Program decisions counsel) cannot be given equal weight to those same records. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law").

The same goes for later treater opinions, which occurred long after the 2011 vaccinations, and/or are based primarily on M.M.'s recounted history as provided by the Petitioners rather than independent analysis. They are not entitled to deference simply because they come from a treater. *Nuttall v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 821, 832 (2015) ("[t]he reasoning underlying the finding that opinions of treating physicians should be given particular weight does not apply when . . . the treating physician only saw the patient after the injury and based his opinion on the same evidence as relied upon by the retained experts"). This Table claim thus also warrants dismissal.

II. Petitioners' Non-Table Claim is not Supported by Preponderant Evidence.

A. M.M. Did not Experience an Encephalopathy.

Petitioners' causation claim still fails even if it is not confined to the admittedly narrow definition of encephalopathy embraced by the Table, but instead analyzed in light of the broader sense of the term as applicable to non-Table claims. *See, e.g., Miller v. Sec'y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093, at *23 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (quoting Respondent's expert in that matter as defining encephalopathy to mean generally that "there's something wrong with the brain").

To establish that M.M. experienced a post-vaccination encephalopathy, Petitioners have the burden of demonstrating the existence of *some* objective evidence of a neurologic reaction by M.M. to a vaccine suggestive of an encephalopathy. Here, however, there is no evidence in the record that this occurred: no medical records documenting a reaction, minimal independent evidence corroborating Mr. Myers's claims of a severe reaction to the vaccines, and no evidence of a treater making the diagnosis of a vaccine-induced encephalopathy at or around the time of the vaccinations. There are also no test results that would indirectly suggest a brain injury - cerebral spinal fluid tests showing inflammation, for example, or the results of a magnetic resonance imaging test. *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461 at *36 (Fed. Cl. Spec. Mstr. July 22, 2015) (inflammation of the brain can be demonstrated by the presence of inflammatory cells in cerebral spinal fluid or the brain or based on inflammation observed on MRI). Again, Petitioners rely heavily on their own statements about what they observed – statements that are not corroborated by contemporaneous proof, and which also were largely made after this case was filed, further diminishing their reliability. *Swick v. Sec'y of Health & Human Servs.*, No. 13-526V, 2016 WL 370010 at *3 (Fed. Cl. Spec. Mstr. Jan. 7, 2016) ("testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate").

B. Petitioners Cannot Satisfy the *Althen* Prongs.

Putting aside the above, it is equally, but more globally, evident that Petitioners cannot establish any of the *Althen* prongs by a preponderance. First, they have never offered a sufficient expert opinion establishing that any of the vaccines M.M. received in November 2011 "can cause" any form of developmental regression. The two statements offered from Dr. Grout evince why I (as well as Special Master Hamilton-Fieldman before me) ordered the Myerses to obtain a true expert report – neither provide a reliable opinion on causation. Even ignoring the fact that Dr. Grout generally lacks the experience or credentials necessary to testify about either the possible causes of developmental problems, or the role vaccines could play in such circumstances, her two statements do nothing to advance a reliable causation theory – a scientifically-supported, credible explanation for how vaccines like those received by M.M. in November 2011 might theoretically result in some kind of encephalopathic reaction, or other neurologic injury that could eventually produce a developmental problem. *Sullivan v. Sec'y of Health & Human Servs.*, No. 10-398V, 2015 WL 1404957 at *15 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) ("Rather, as with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases").

Second, Petitioners cannot establish, based upon the filed record, preponderant proof that M.M. did in fact suffer a neurologic injury as a result of his twelve-month-old pediatric visit vaccinations. Other than Mr. Myers's testimony, nothing at all in the record indicates that M.M. did experience a reaction to those vaccines, and nothing suggests any treater who cared for M.M. in the days and months immediately thereafter suspected a relationship between vaccines and his

subsequent developmental problems. Mr. Myers's own statements about a reaction are themselves uncorroborated by the record, and seemingly-confirming statements thereafter from treaters who saw M.M. long after the fact appear to have been wholly based on the narrative provided by Mr. Myers or his wife. The very fact that M.M. did not (based on the filed records) even see a treater for approximately five months after the November 2011 vaccinations undermines the claim that M.M. did suffer an abrupt and noticeable change in this period – for, as Vaccine Program case law recognizes, were that the case there would usually be records confirming it, given that the health of a young child was at stake. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (presumption that contemporaneous records are usually more probative than after-the-fact witness statements "is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions").

Finally, the temporal relationship between the onset of M.M.'s developmental issues and the vaccines he received has not been shown to be medically acceptable. Mr. Myers purports that M.M. experienced an immediate reaction that was noticeable the day of the November 16, 2011 vaccinations. But no expert theory has been provided that would support an immunologic reaction occurring that quickly – let alone one that would percolate for months thereafter, without any intervening indication of an ongoing reaction, and until concerns about M.M.'s development were officially brought to the attention of treaters in May 2012, as the records reveal. Thus, Petitioners have not demonstrated that the time period from vaccination to reaction and/or onset of injury was reasonable and anticipatable from a medical/scientific standpoint.

C. Vaccine Act Claims Alleging Developmental Problems Post-Vaccination are Rarely Successful

My reaction to Petitioners' claim is reasonably informed by past and recent decisions of other special masters. When faced with the theory that a vaccine precipitated an encephalopathy leading to developmental problems – whether or not those problems ultimately manifested as autism or simply developmental regression – they have uniformly found that the theory was wanting. The lack of success of similar claims provides a benchmark against which the very limited evidence offered in this case can be measured.

Six to seven years have passed since the primary Omnibus Autism Proceeding ("OAP")[9] decisions. In that time, the claim that any vaccine could play a role in causing an ASD, or

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

developmental symptoms similar to an ASD, finds no support in prior Program decisions. *See generally Valle v. Sec'y of Health & Human Servs.*, No. 02-220V, 2016 WL 2604782, at *3-4 (Fed. Cl. Spec. Mstr. Apr. 13, 2016) (identifying 14 cases involving the claim that a vaccine caused autism that have been dismissed after hearing since 2012, plus eight decided against the petitioner without holding a hearing); *R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review den'd.*, 127 Fed. Cl. 136 (2016); *R.K. v. Sec'y of Health & Human Servs.*, No. 03-0632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Sept, 28, 2015), *mot. for review den'd*, 125 Fed. Cl. 57 (2016), *appeal docketed*, No. 16-1609 (Fed. Cir. Feb. 23, 2016). No Program claimant has yet succeeded in establishing a non-Table claim that any vaccine has the potential to cause autism-like developmental problems, let alone autism. This is despite the fact that claimants have tried, again and again, to alter previously-rejected theories in the hopes of prevailing.

The concept that a vaccine could precipitate an encephalopathy, which in turn could cause a child to either develop autism or some lesser kind of regressive developmental problem, has been similarly litigated repeatedly, without success. *See, e.g.*, *Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603, at *4-5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) (petitioners failed to demonstrate that DTaP vaccine caused or significantly aggravated underlying mitochondrial disease resulting in ASD); *Miller v. Sec'y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (petitioners failed to demonstrate that several childhood vaccines caused encephalopathy or aggravated underlying mitochondrial disease/dysfunction); *Lehner*, 2015 WL 5443461 (petitioners failed to demonstrate that flu vaccine caused autoimmune encephalitis).[10]

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

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

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

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

[10] Only in a few rare circumstances have petitioners succeeded on such a theory, but their singular facts underscore why they did not suffer the same fate. For purposes of comparison, it is instructive to consider the facts of two such cases (which, although they involved Table claims, are nevertheless instructive for the kind of facts necessary to prove the kind of severe, post-vaccination encephalopathy that would trigger a severe neurologic change in a child). In

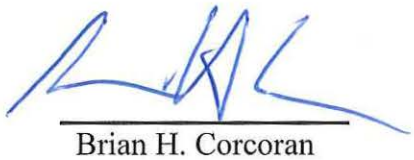
The aforementioned cases do not bind my determination herein. But it is appropriate to take into account the number of times highly similar causation theories involving a post-vaccination developmental injury – whether autism or regression – have been asserted and rejected. Nothing in the facts of this case suggests a different outcome is appropriate.

CONCLUSION

Based upon the foregoing, the factual record does not support the Myers's contentions that M.M. experienced any reaction at all to the vaccines he received, or that those vaccines had anything to do with his developmental problems (whether or not they are properly diagnosed as autism). The Myers have demonstrated true passion and concern for M.M., for which they are to be commended, but the evidence does not support their claim. This is not a close case. It is appropriate to dismiss the matter now.[11]

For the reasons stated above, this claim is DISMISSED.

IT IS SO ORDERED.



Brian H. Corcoran
Special Master

Poling v. Sec'y of Health & Human Servs., No. 02-1466V, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. Apr. 10, 2008), for example, the child in question (who was later diagnosed with mitochondrial disease that allegedly made her susceptible to adverse effects of vaccination) had received several vaccinations (not including the flu vaccine). Within 48 hours, the child developed a high fever that became low-grade over the next several days, along with inconsolable crying, sleeplessness, and significant, noticeable motor problems that worsened over the next several days. Respondent settled that case before a trial was held.

In *Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), some petitioners met the Table criteria for an "acute encephalopathy" following vaccination by establishing with preponderant evidence that the vaccinated child experienced a seizure followed by loss of consciousness shortly after receipt of a pertussis-containing vaccine; the severe reaction lasted for more than 24 hours, with immediately-resulting and demonstrable significant changes in behavior. But the special master responsible for that decision (former Chief Special Master Vowell) explicitly noted in her decision that petitioners would not have been able to establish entitlement under their non-Table claim, because their expert presented a causation opinion that she found "absurd and biologically impossible." *Wright*, 2015 WL 6665600, at *2.

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