In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-342V
(to be published)

CASSIE WOLF *and* RICHARD WOLF, *on behalf of their minor child,* R.W.,	*	Special Master Corcoran
Petitioners,	*	Filed: September 15, 2016
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for Petitioners.

Amy Kokot, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION ON RECORD DISMISSING CASE[1]

On April 24, 2014, Richard and Cassie Wolf filed a petition on behalf of their child, R.W.[2], seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[3] The Wolfs sought to establish (via a "non-Table" claim) that the Diptheria Tetanus acellular Pertussis ("DTaP") and influenza ("flu") vaccines R.W. received on December 12, 2011,

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

[2] The matter as originally filed referenced R.W.'s full name. However, Vaccine Rule 16(b) provides for redaction of captions to refer only to the initials of a minor's name. Rule 16(b). Accordingly, on August 23, 2016, I ordered that the caption in this case be so revised. ECF No. 59.

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

precipitated an encephalopathy, which in turn caused language and other developmental impairments.

After the Petitioners filed two expert reports, and based upon my initial review of the case record, I proposed that the matter be decided without holding an evidentiary hearing, and the parties accepted my proposal. The parties have now filed briefs in support of their respective positions. Having completed my review of the evidentiary record and the parties' filings, I hereby **DENY** Petitioners' request for compensation, for the reasons stated below.

I. FACTUAL BACKGROUND

A. Pre-Vaccination History

R.W. was born via cesarean section on July 16, 2011. Exhibit 13 at 1618.[4] At birth, he weighed seven pounds, thirteen ounces, and his Apgar scores were eight and nine. Ex. 15 at 11. Feeding and swallowing problems were noticed early in R.W.'s life. Thus, on July 17, 2011, Mrs. Wolf met with a lactation consultant, who noted that there was "[n]o sustained sucking at the breast." *Id.* at 33. Almost two weeks later, on July 29, 2011, R.W. was examined by Ellen Springer, M.D., at Cincinnati Children's Hospital, who also documented feeding problems, coupled with suppressed lactation for Mrs. Wolf. Ex. 13 at 1, 4, 22. Mrs. Wolf and R.W. returned to Cincinnati Children's Hospital on August 15, 2011, at which time complications with breastfeeding were again observed. *Id*. at 59-61.

R.W. underwent a well-child evaluation at Hyde Park Pediatrics on August 24, 2011, at which time he was deemed normal, and received a vaccination as well (second hepatitis B). Ex. 19 at 1-2. On September 13, 2011, R.W. returned to his pediatrician for his two-month visit, and received his first DTaP, haemophilus influenzae type B ("Hib"), and rotavirus vaccines. *Id*. at 1-2. On October 13, 2011, when R.W. was three months of age, his pediatrician noted in a medical record that R.W. was projectile vomiting, but determined that he did not have pyloric stenosis. Ex. 19 at 5. At that time, R.W. received his first pneumococcal and inactivated polio vaccines. *Id.* at 1.

B. Administration of Flu Vaccine and Subsequent Medical History

R.W. returned to Hyde Park Pediatrics on December 16, 2011, for a five-month well-child examination. Ex. 2 at 1. The records from that visit note that R.W. was experiencing normal growth and development. *See id.* at 1-3. At this time, R.W. received his second DTaP, Hib, and rotavirus vaccinations, as well as his first flu vaccine. *See, id.* at 1, 10; Ex. 13 at 1690; Ex. 19 at 1. The

[4] Respondent filed no exhibits in this case, so there is no need to distinguish each side's exhibits with a prefix like "Pet'r's".

"comments" section of R.W.'s chart states that he received the flu vaccine by mistake, but "that it is most likely safe and the risks are probably the same as if given at [six] months." Ex. 2 at 1.

After the December 2011 well-child visit, there is a month-long gap in the medical records until R.W.'s next visit to the pediatrician, and there is no immediate record of R.W. having experienced any reaction to the vaccines. Petitioners have, however, attempted to fill such holes with their own testimony. Thus, Mrs. Wolf asserts (in a declaration dated April 20, 2014 (Ex. 1)) that before the December 2011 vaccinations, R.W. was "a happy and content little boy." *Id.* ¶ 3. Although R.W. had "initially experienced some feeding difficulties, those had gone away and he had met all expected developmental milestones to that point." *Id.* By the day after receiving the DTaP and flu vaccinations, however, R.W. "seemed very lethargic and had a fever and vomited," and not long after experienced "gagging and coughing with solid foods." *Id.* at ¶ 6.[5]

On January 16, 2012, Mr. Wolf took R.W. to Eastern Hills Pediatrics, reporting that R.W. had nasal congestion and a cough, which Mr. Wolf characterized as "hacking." Ex. 4 at 8. R.W. was diagnosed with an acute upper respiratory infection ("URI"). *Id.* at 9. But the records from this visit make no reference to any other problems, developmental or otherwise. *Id.* at 8-10. Records from R.W.'s subsequent six-month well-child evaluation, dated February 2, 2012, also note no abnormalities. *Id.* at 12. R.W. at this time received his second pneumococcal and inactivated polio vaccinations, as well as his third rotavirus vaccination. *Id.* at 7, 14. On March 19, 2012, R.W. received his third DTaP, Hib, and inactivated polio vaccinations. *Id.* at 7.

The records throughout the winter of 2012 reveal no particular concerns about R.W.'s development, but do reflect some worries on Mrs. Wolf's part regarding feeding issues. At R.W.'s first visit to Eastern Hills Pediatrics, he was noted to be negative for dysphagia. Ex. 4 at 8. The records from R.W.'s early February well-child visit similarly note no feeding problems. *Id.* at 12-14. But on February 17, 2012, Mrs. Wolf contacted R.W.'s former pediatrician at Hyde Park asking for a referral to address "eating issues." Ex. 2 at 7. That record does not elaborate on the precise nature of Mrs. Wolf's concerns, however. Then, on February 23, 2012, Mrs. Wolf informed an Eastern Hills pediatrician that R.W. was refusing solid foods, and that (contrary to the prior records) she had observed the problem for the past two months, or since December. Ex. 4 at 15.

[5] Petitioners have also alleged that, because of Mrs. Wolf's concerns about R.W.'s purported reaction, their pediatrician at Hyde Park Pediatrics agreed to phone the Wolfs over that weekend to check on his progress, but in so doing merely attempted to reassure them that R.W.'s reaction was normal, and otherwise dismissed their reports of R.W.'s reaction. Ex. 1 at 2 ¶ 6. They have offered phone records to corroborate this contact with their pediatrician, and have identified a call that occurred on the afternoon of December 16, 2011, made to a number matching that of the pediatrician. Ex. 11 at 1. There is no counterpart medical record of this purported call, however (although there are records of subsequent calls to this pediatrician, allowing for the inference that such calls were usually memorialized). *See, e.g.*, Ex. 2 at 7. In addition, the phone call to the pediatrician appears to have been placed the same day that R.W. was vaccinated, not the day after. The records from the December 16th visit also have a time designation of 3:30 pm – over an hour after the call to the pediatrician from that day – but say nothing about a purported reaction. *Id.* at 1, 4. There is even a chart update document from December 17, 2011, which also is silent on the concerns Mrs. Wolf claims to have expressed. Accordingly, while the Wolfs have offered unrebutted evidence of communication with their pediatrician around the time of the December vaccinations, the existing documentary record is inconclusive in memorializing what the Wolfs allege they conveyed to their pediatrician.

At this time, the records indicate, Mrs. Wolf requested a speech evaluation, but the records do not otherwise reflect any concerns at the time about R.W.'s condition or growth. *Id.*

R.W. was subsequently examined by the Interdisciplinary Feeding Team at Cincinnati Children's Hospital on April 12, 2012. Ex. 13 at 69. The narrative of his medical history included a description of eating-related symptoms that had begun prior to R.W.'s December 2011 vaccinations ("vomiting in early infancy"), as well as gagging and choking, but which the Wolfs reported had resolved by the time he was six months old, with variable but improving symptoms thereafter. *Id.* The Feeding Team's assessment concluded that R.W. was having difficulty transitioning to solid foods. *Id.* at 70. The same day, an occupational therapist evaluated R.W., observing that his "intra-oral sensation appeared to be hypersensitive to higher texture." *Id*. at 89. Speech therapy was recommended to aid with R.W.'s oral motor skills and feeding. *Id*. at 90. None of these records linked any vaccines R.W. had received to his feeding difficulties, however, nor do they reflect any recounting by the Wolfs of other developmental problems or concerns at the time.

In the following six months, the medical records reveal nothing more than a few instances in which the Wolfs took R.W. back to the pediatrician because of non-life-threatening childhood illnesses. *See, e.g.*, Ex. 4 at 18-20 (April 27, 2012 visit prompted by R.W. running high fever), and 21-23 (July 23, 2012 visit after R.W. reported vomiting and difficulty with solid foods). However, at a November 30, 2012 16 month well-visit to Eastern Hills, the record reflects that R.W. failed a verbal skill developmental test, while passing all other tests administered at the time. *Id.* at 24. R.W. also did not display any repetitive motion behaviors and was able to make eye contact with his pediatrician. *Id.* at 26. R.W. was assessed preliminarily as having a language-related development disorder. *Id.* at 27.

On December 11, 2012, R.W. (now 17 months old) had an occupational therapy evaluation with the ABC Pediatric Therapy Network. Ex. 16 at 1. The records from this evaluation memorialize Mrs. Wolf's concerns that R.W. "dislike[d] clothing textures [and] dislike[d] having [his] face touched." *Id*. R.W. was also reported to display sensitivity to bright lights, to avoid eye contact, have trouble with focus, and a tendency to become "overly excited in crowds." *Id*. at 2. Weekly occupational therapy was accordingly recommended to accompany R.W.'s ongoing speech therapy. *Id.* at 1, 5. The records from this evaluation also note R.W.'s prior speech therapy recommended after the Wolfs' initial efforts at treating his feeding problems, but that the therapy had not been intended to address any developmental problem independent from his reported feeding issues. *Id.* at 11.

In the next months into early 2013, R.W. received various interventions and therapies aimed at addressing his fine motor coordination, gross motor play, sensory processing, and self-stimulating behavior. *See, e.g.*, Ex. 5 at 2-11; Ex. 14 at 1-10. On February 8, 2013, the Rossetti Infant-Toddler Language scale was administered, and R.W. exhibited delays in language comprehension and expression, as well as gesturing and play. Ex. 12 at 35. By this point – over a

year after R.W. had the relevant vaccinations – treaters began to document R.W.'s developmental problems.

It was also in 2013 that certain treaters first proposed a basis for R.W.'s developmental issues. Lisa Kuan, M.D., a physician with the Division of Developmental and Behavioral Pediatrics at Cincinnati Children's Hospital, assessed R.W. on February 12, 2013. Ex. 13 at 238-42. The summary from this visit sets forth the Wolfs' recollection that their concerns about R.W.'s development began "when he had difficulty advancing his diet," prompting the feeding assessment they had obtained in April 2012, and that they remained worried thereafter about his delayed feeding and associated language development issues. *Id*. at 239. R.W. had since then exhibited delayed motor development, and petitioners reported self-stimulating behaviors (such as toe walking). *Id.* Dr. Kuan recorded R.W.'s "encounter diagnosis" as "encephalopathy, unspecified." *Id.* at 238. She did not, however, propose when the encephalopathy had occurred, or its cause. Following this assessment, Dr. Kuan diagnosed R.W. with Global Developmental Delay. Ex. 13 at 253-54. She also observed certain "[r]ed flags for Autism," and suggested the Autism Diagnostic Observation Schedule ("ADOS") evaluation for R.W. after he had a few more months of occupational and speech therapies. *Id.* at 254.

In the subsequent months, the Wolfs continued to have R.W. evaluated, and he received additional initial treatment for his developmental symptoms. Among other treaters, R.W. was seen in May 2013 by Phillip DeMio, M.D. *See generally* Ex. 20 at 1-26. Much of these records are handwritten in undecipherable script, but it appears from them that Dr. DeMio ordered certain lab tests after evaluating R.W. Petitioners next brought R.W. back to Cincinnati Children's Hospital on May 22, 2013, where he was evaluated by Rebecca Taylor, R.N. Ex. 13 at 878. Ms. Taylor's assessment concurred with those of prior treaters that R.W. showed "red flags for autism spectrum disorder," but also characterized his symptoms as "neurological in origin and therefore represent an encephalopathy." *Id*. at 881. These records, however (like those before them), provide no details as to the basis for this assessment, nor do they cite or reference any contemporaneous records that establish an encephalopathy at or near the time of the December 2011 vaccinations.

Throughout the remainder of 2013 and in 2014, R.W. continued with speech and occupational therapies. *See generall*y Ex. 12. By mid-2013, some of his feeding issues were deemed by the Wolfs to have resolved. Ex. 12 at 357.

II. EXPERT REPORTS

Only the Petitioners have offered expert reports in this case. The first, a one-page letter from Dr. DeMio, was filed on August 5, 2015. Ex. 21. Dr. DeMio (who, as noted above, treated R.W. in May 2013), opines that R.W.'s December 2011 vaccinations (in particular, the flu vaccine plus an unidentified additional vaccine) caused his "neurological and developmental abnormalities." *Id.* at 1. Dr. DeMio's letter references his 2013 evaluation of R.W., as well as "follow up labs" he ordered at the time of treatment, which he asserts established immune system

and metabolic abnormalities, but does not cite the records supporting these assertions. He also recounts a narrative of R.W.'s purported vaccine reaction consistent with that provided by Mrs. Wolf.

To explain how the vaccines actually precipitated R.W.'s symptoms, Dr. DeMio proposes that "[a]luminum adjuvants[6] and the combination of influenza with simultaneous vaccination with another vaccine can [and] do lead to a pathologic (e.g. excess) response in the body, leading to damage to the immune, neurologic, and metabolic systems, as in R.W.'s case." Ex. 21 at 1. In support of this contention, he cites a single article discussing the toxicity of aluminum adjuvants in vaccines, plus five article abstracts involving the theory that adjuvants can precipitate autoimmune/inflammatory syndromes. *Id.* at 2-19.[7] He otherwise provides no explanation for the propensity of the flu vaccine to precipitate an encephalopathy.

On February 18, 2016, Petitioners filed an opinion from Harvey Cantor, M.D., a pediatric neurologist. Ex. 22 at 1-4. Relying solely on Mrs. Wolf's statements about R.W.'s immediate post-vaccination condition, Dr. Cantor concluded that R.W. had "lethargy, fever and vomiting" within twenty-four hours of his vaccinations, which "strongly indicate that his acute Encephalopathy and his other acute symptoms, as well as his subsequent Chronic Encephalopathy/significant developmental delays, are all, quite likely, caused by the immunization(s)." *Id.* at 1-3. R.W.'s treaters identified no other possible causes for his neurologic developmental problems, such as a chromosomal abnormality. *Id.* at 3.

Dr. Cantor proposes proinflammatory cytokine expression[8] post-vaccination as a "pathophysiological mechanism" by which the December 2011 vaccines produced R.W.'s developmental problems. Ex. 22 at 2. Specifically, he opines that production of cytokines caused by the body's response to a particular vaccine would occur in less than 72 hours, and thus consistent with Mrs. Wolf's reports of R.W.'s immediate reaction. *Id.* Dr. Cantor further notes that there is literature supporting the concept that proinflammatory cytokine production can be induced by the DTaP and Hib vaccines, which can in turn result in penetration of the blood-brain barrier

[6] An adjuvant, as the term is used in immunology, is "a non-specific stimulator of immune response." *Dorland's Illustrated Medical Dictionary* 32 (32d ed. 2012).

[7] As set forth below, while I have reviewed all articles offered in support of Petitioners' claim, I do not discuss them in detail, either because my decision does not turn on a particular article, or because the articles are offered in support of causation theories that have been exhaustively addressed, and rejected, in prior decisions involving claims similar to that asserted in this case.

[8] A cogent explanation of the purported role proinflammatory cytokines (the production of which could be encouraged by a vaccine,) would theoretically play in precipitating an autoimmune condition was set forth in *C.K. v. Sec'y of Health & Human Servs.*, 113 Fed. Cl. 757, 761 (2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014):

> A cytokine is a protein which is released almost immediately by certain cells when they come into contact with a specific antigen. When the cytokine is released it signals other cells to generate an immune response. In short, cytokines are like smoke signals which cells send out to indicate the presence of an invasion and to elicit a defensive response. . . There are, however, specific cytokines which are recognized as being either anti-inflammatory or pro-inflammatory. Pro-inflammatory cytokines can lead to fever, increased vascular permeability, and increased synovial inflammation.

sufficient to injure the central nervous system. *Id.* at 3. He also referenced literature supporting the propensity of the DTaP to cause post-immunization encephalopathy. *Id.*

III. PROCEDURAL HISTORY

As noted above, the Wolfs filed this action in April 2014, alleging that R.W.'s receipt of the DTaP and flu vaccines on December 12, 2011, caused him to develop "encephalopathy, with an aggravation of feeding problems, dysphagia, lack of coordination, and sensory and speech disturbances." Petition at 1. Between May 2, 2014, and January 21, 2015, petitioners filed medical records. Respondent filed her Rule 4(c) Report on February 23, 2015, asserting that the Wolfs were not entitled to compensation because they could not carry their burden of proof. Respondent's Rule 4(c) Report at 11 (Feb. 23, 2015).

After the Rule 4(c) Report was filed, Petitioners obtained expert testimonial support for their claim. To that end, they filed the above-referenced report from Dr. DeMio in August 2015. Shortly thereafter, the special master to whom the case had been originally assigned held a status conference, and subsequently observed that Dr. DeMio's opinion had failed to address the timing element required by the federal circuit's evidentiary test for Program claims as set forth in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005). *See* Order, dated August 21, 2015 (ECF No. 44). The special master therefore ordered the Wolfs to supplement the opinion or obtain one from another expert, *Id.*

The case was subsequently assigned to me on August 25, 2015 (ECF No. 45). Petitioners thereafter requested multiple extensions to act, and finally filed their second expert report, from Dr. Cantor, in February 2016. I then scheduled a status conference for March 15, 2016, in order to discuss with the parties my reaction to the claim. ECF No. 53. At that time, I expressed concerns about the claim's viability, observing a lack of contemporaneous record evidence supporting the conclusion that R.W. had experienced an encephalopathy. I also identified weakness in Petitioners' causation theory; the concept of attributing autism or developmental problems to a vaccine's propensity to upregulate cytokines temporarily was one that had not been successful in the past, and Dr. Cantor himself lacked the expertise necessary to reliably testify to the theory, in part because he was not himself an immunologist.[9]

In light of my concerns, I proposed ruling on the record in lieu of hearing as one possible means for resolving the case, but invited the parties to confer and determine what approach they favored. In a joint status report, dated April 15, 2016 (ECF No. 54), the parties expressed their joint view that the matter should be decided on the papers.

[9] At the time of the March 2016 status conference, I also observed that it appeared the failure of Dr. DeMio to address the third *Althen* prong remained unresolved even after Dr. Cantor's expert report. ECF No. 53 at 2. However, I acknowledge that Dr. Cantor's report does in fact (albeit briefly) maintain that the timing in which proinflammatory cytokines would be expected to be produced is consistent with Mrs. Wolf's reports of observing R.W.'s post-vaccination reaction. Ex. 22 at 2.

IV. PARTIES' RESPECTIVE ARGUMENTS

Petitioners' motion for judgment on the record was filed on May 10, 2016. ECF No. 56 ("Mot."). In it, the Wolfs emphasized the fact that Dr. DeMio was one of R.W.'s treaters (albeit one who first saw R.W. nearly seventeen months after the December 2011 vaccinations), thus rendering his opinion particularly reliable under applicable Program precedent. Mot. at 5-6, 8. They also attempted to harmonize their experts' theory with R.W.'s actual reported history of post-vaccination lethargy and fever, noting as well that the timing of these reactions was consistent with how long the cytokine expression proposed as the causal mechanism of the injury would be expected medically to occur. *Id.* at 6-7. In addition, Petitioners referenced R.W.'s dysphagia as bulwarking their contention that an encephalopathy had occurred, since that condition can be neurologic in origin. *Id.* at 7. Throughout, the Wolfs emphasized that their experts were credentialed, and that their causation theory was supported by reliable science.

Respondent's opposition to the Wolfs' claim was filed on June 14, 2016. ECF No. 57 ("Opp."). Respondent stressed that both expert opinions– singularly and taken together – failed to establish a reliable and persuasive theory for how the vaccines R.W. received caused his developmental symptoms. Opp. at 12-14. In particular, she attacked the notion that Dr. DeMio's status as a treater warranted much weight, while challenging Dr. Cantor's qualifications to provide an opinion on the immunological effects of the vaccines R.W. had received. *Id.* at 13. She also questioned whether the facts showed anything more than a temporal association between vaccination and R.W.'s developmental problems, maintaining that this was at bottom the primary rationale for their opinions. *Id.* at 15. And she asserted that the third *Althen* prong had still not been addressed with sufficient preponderant proof. *Id.* at 16.

Petitioners' reply was filed on June 23, 2016. ECF No. 58 ("Reply"). The Wolfs stressed the Cincinnati Children's encephalopathy diagnosis as a reasonable and reliable basis for their experts' opinions, along with R.W.'s dysphagia. Reply at 2-4. They also pointed out that the experts did not solely rely on Mrs. Wolf's recitation of R.W.'s post-vaccination condition, noting at the same time that her fact statements fill a gap in the record rather than contradict it. *Id.* at 4-5. And they distinguished other cases in which petitioners claiming an encephalopathy were found unable to support the contention with evidence, pointing to the record as distinct in this case and therefore calling for a different result. Finally, they reiterated their previous arguments about the medically acceptable nature of the timing between the vaccinations and the purported encephalopathy. *Id.* at 9.

V. 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).[10] In this case, Petitioners do not assert a Table claim.

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 (which is the kind of claim asserted in this matter), a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

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

[10] 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).

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

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

medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony.

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

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

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

must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

In determining whether a particular expert's testimony was reliable or credible, I may consider whether the expert offers an opinion that exceeds his training or competence. *Walton v. Sec'y of Health & Human Servs.*, No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While (in keeping with the liberality with which evidence offered in Vaccine Program cases is treated) I have considered all of the testimony of the experts offered by Petitioners in this case, I may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See e.g., King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications).

D. Consideration of Medical Literature

Petitioners' experts filed some medical and scientific literature in this case, including articles offered in support of their causation theories. *See generally* Exs. 21 and 24-30. I have reviewed all of the medical literature submitted in this case, although my decision does not discuss each filed article in detail. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted). This is due to the fact (as expanded upon below) that the theories for which they are offered have been addressed at length in prior decisions – but in no cases have petitioners previously succeeded in meeting their burden of proof with respect to such theories.

E. Determination to Resolve Case Without Hearing.

Here, the litigants have accepted my proposal to decide entitlement based on written submissions and evidentiary filings. 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.

VI. ANALYSIS

After careful review of the expert reports, medical records, and the arguments of both sides, I conclude that Petitioners have not established preponderant evidence in favor of their claim. My decision is rooted in both the facts of this case as well as applicable decisions in previously-litigated matters, involving causation theories highly similar to the present.

First, the record evidence does not support Petitioners' principal allegation: that R.W. experienced an encephalopathy after his December 2011 vaccinations. The term "encephalopathy" is very broad. *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"). Because this is a causation-in-fact case, I am not applying the "very restrictive" definition of encephalopathy utilized in Table cases (where causation is presumed after relevant factual predicates are established).[11] *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).

But even though the Wolfs need not satisfy the narrow Table definition of the term, they still have the burden of demonstrating the existence of objective evidence of a reaction to a vaccine suggestive of an encephalopathy. Here, there is no evidence in the record that this occurred: no medical records documenting a reaction, minimal independent evidence corroborating the Petitioners' assertions of R.W.'s 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. Rather, the record merely suggests that R.W. experienced a URI approximately a

[11] According to the qualifications and aids to interpretation ("QAI") applied to vaccine Table claims, a vaccinee is considered to have suffered a Table encephalopathy if he or she manifests an injury encompassed in the definition of an "acute" encephalopathy within the appropriate time period, and then a "chronic" encephalopathy is present for more than six months after the immunization. 42 C.F.R. § 100.3(b)(2) (emphasis added). In accordance with the QAI, an acute encephalopathy must be sufficiently serve to require hospitalization (regardless of whether the vaccinee is actually hospitalized). 42 C.F.R. § 100.3(b)(2)(i). For a child less than 18 months of age who did not experience an associated seizure event, an acute encephalopathy is deemed to be present if there is a "significantly decreased level of consciousness" that persists for at least 24 hours. 42 C.F.R. § 100.3(b)(2)(i)(A). Children less than 18 months of age presenting after a seizure are considered to have an acute encephalopathy if they have experienced a "significantly decreased level of consciousness" that persists beyond 24 hours and cannot be attributed to the seizure or medication. Id. The referenced phrase "significant decreased level of consciousness" must be evidenced by the presence of at least one of the following clinical signs for at least a 24-hour period: "(1) [d]ecreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) [d]ecreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things)." 42 C.F.R. § 100.3(b)(2)(i)(D).

month after the December 2011 vaccinations. No contemporaneous records indicate that any treater at that time linked the vaccinations to the illness, and then the medical record suggests no other health problems for several months thereafter. This leaves only Mrs. Wolf's statements about R.W.'s reaction, which are by themselves insufficient evidence to base a factual determination that R.W. experienced a vaccine-induced encephalopathy. Section 13(a)(1); *see also Murphy v. Sec'y of Health & Human Servs.*, No. 05-1063V, 2016 WL 3034047, at *31-33 (Fed. Cl. Spec. Mstr. Apr. 25, 2016) (no evidence of immediate reaction to vaccination sufficient to find encephalopathy in non-Table case), *mot. for review den'd*, No. 05-1063V (Fed. Cl. Aug. 15, 2016).

The Wolfs cite to medical records (in particular, Dr. Kuan's notes from the Cincinnati Children's Hospital) in which R.W.'s developmental problems appear to be blamed on some kind of encephalopathy (of admittedly unknown origin, moreover), but these have far less probative value than Petitioners assume. Those records do not explain the basis for the treater's assertions, nor do any of the treaters link the time immediately after vaccination with their conclusion, by referencing elements from R.W.'s prior medical history to explain their suppositions. Such assertions may also have been based not upon a physician's analysis, but instead on medical histories provided by the Wolfs. This kind of long-after-the-fact treater view is very thin evidence of a real encephalopathy, let alone one that could have precipitated developmental problems if not autism outright, and I need not accept it or give it weight simply because it came from a treater. *See 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").

Petitioners further point to the dysphagia diagnoses made of R.W. in April 2012, citing this as indirect proof of an underlying neurologic condition. But such facts also do not merit significant weight under the circumstances. First (and as with the overbroad definition of encephalopathy), the fact that dysphagia can have a neurologic basis cannot be leveraged to mean that evidence of dysphagia *proves* the existence of an encephalopathy, since it too reflects a neurologic condition. Rather, Petitioners would need to offer some scientific or medical literature suggesting dysphagia is either a direct product of encephalopathy, and/or that it is associated with developmental problems or autism (further underscoring the connection Petitioners wish for me to draw). But these are points neither expert has taken up, let alone the concept that a vaccine could itself cause, or be associated with, dysphagia.

Second, Petitioners' argument is contrary to the record evidence. R.W.'s feeding issues were evident to the Wolfs before his December 2011 vaccinations, and they continued to be observed before treaters first began to suggest, in the fall of 2012, that R.W. might have autism or some other developmental problem. Evidence of a preexisting condition relevant to a claimed injury can undermine a petitioner's argument that a vaccine caused that condition. *Shalala v. Whitecotton*, 514 U.S. 268, 274-75(1995) (Vaccine Act claimant who demonstrates she experienced symptoms of injury after receipt of vaccination does not succeed in her claim if the evidence fails to indicate that she had no symptoms of injury before her vaccination). Accordingly,

if feeding issues related to R.W.'s dysphagia predated his vaccinations, I cannot conclude that the feeding issues were themselves the product of the same neurologic injury that is alleged to have been caused by those vaccinations, or that they were a precursor to it.

Besides the above deficiencies in Petitioners' proof, Petitioners' causation theory is itself highly problematic, given its similarity to theories that have routinely been rejected in other Program cases. Dr. Cantor's theory proposes that proinflammatory cytokine expression induced by the December 2011 vaccines caused R.W.'s developmental problems, and cites literature supporting his opinion. Ex. 22 at 2; *see also* Y. Kashiwagi, *et al., Production of Inflammatory Cytokines in Response to Diptheria-Pertussis-Tetanus (DPT), Haemophilus Influenzae Type b (Hib), and 7-Valent Pneumococcal (PCV7) Vaccines*, 10:3 Human Vaccines and Immunotherapics 677-85 (2013) (Filed as Ex. 24)[hereinafter, "Kashiwagi"].

Other program petitioners have made arguments similar to that advanced in this case about the alleged harm that expression of proinflammatory cytokines (the production of which can be encouraged by vaccines) can have in producing a variety of injuries. *See, e.g., Godfrey v. Sec'y of Health & Human Servs.*, No. 10-565V, 2015 WL 10710961 (Fed. Cl. Spec. Mstr. Oct. 27, 2015) (HPV vaccine alleged to cause juvenile ankylosing spondylitis), *mot. for review den'd,* No. 10-565V, slip op. (Fed. Cl. May 25, 2016); *Cozart v. Sec'y of Health & Human Servs.,* No. 00-590V, 2015 WL 6746499 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (hepatitis B, DTaP, and Hib vaccines alleged to have caused infant's death). In such cases, experts have cited some of the same literature offered by the Wolfs's experts here, like Kashiwagi. *Cozart*, 2015 WL 6746499, at *6-8 (discussing Kashiwagi in detail).[12]

Yet the theory has been found unpersuasive time and again. *See, e.g., Godfrey*, 2015 WL 10710961, at *10-14 (theory that vaccine could promote cytokine upregulation was insufficient to establish injury in question, especially since injury had known genetic cause that was present, and no reliable scientific evidence supported proposition that cytokine upregulation was pathogenic); *Cozart*, 2015 WL 6746499, at *6-8 (denying motion for reconsideration of dismissal decision; theory that cytokine expression in brains of children suffering from sudden infant death syndrome was causal ignored more recent studies showing that cytokine expression was an indicator of stress rather than cause); *but see Koehn v. Sec'y of Health & Human Servs.,* 773 F.3d 1239 (Fed. Cir. 2014) (special master erred in rejecting causation theory involving alleged harm of vaccine-induced proinflammatory cytokines on grounds that theory lacked reliable scientific support, but

[12] As noted above, I do not discuss in detail all of the articles submitted by Petitioners in this case, although they are not voluminous in nature, because (as a whole) their findings do not "move the needle" as to whether Petitioners carried their burden in this case. Thus, even if I had found (which I do not) that Petitioners' theory satisfied the first *Althen* prong, the evidentiary record would not evince that *in this case* the theory played out in practice, given the total lack of proof of any reaction by R.W. to the December vaccinations. I note in passing, however, that most of the articles offered are facially unhelpful to Petitioners' case. Exhibits 26 and 27, for example, involve the live form of bordatella pertussis vaccine distinguishable from the acellular form that R.W. received, while another (Exhibit 28) discusses acute necrotizing encephalopathy, an illness R.W. never has been found to have and which the record does not suggest at all he ever had.

correctly determined that purported timing of alleged cytokine upregulation process lacked scientific basis, and therefore claim was properly dismissed).

Indeed (and more importantly), the cytokine expression theory linking vaccination to autism was addressed in the primary Omnibus Autism Proceeding ("OAP")[13] decisions, but rejected. *See, e.g., Snyder v. Sec'y of Dep't of Health & Human Servs.*, No. 01-162V, 2009 WL 332044, at *101 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (evidence did not establish whether inflammation observed in brains of autistic subjects was cause or effect of autism), *aff'd*, 88 Fed. Cl. 706 (2009). Post-OAP efforts by petitioners to retool the theory have not been successful either. *See, e.g., Fester v. Sec'y of Health & Human Servs.,* No. 10-243V, 2016 WL 1745436, at *23-24 (Fed. Cl. Spec. Mstr. Apr. 7, 2016 (rejecting theory that brain inflammation (as evidenced by high cytokine levels) played a causal or contributory role in the development of autism, in part given that it borrowed heavily from similar theory previously rejected in OAP cases). Accordingly, even if portions of Dr. Cantor's opinion about the association between vaccines and proinflammatory cytokine production has some reliable basis, there is insufficient support for the contention that cytokine upregulation is *itself* causal of autism or similar developmental problems.[14]

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[13] 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.

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 contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

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

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

Ultimately a total of 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.

[14] The record similarly does not support Dr. Cantor's proposition that cytokine proliferation even actually occurred in R.W.'s case. Not only are there no available testing results for R.W. contemporaneous with his vaccinations that would demonstrate subsequent cytokine proliferation, but also the medical records themselves record only that he experienced a URI approximately a month later, and do not otherwise paint a picture of a child suffering from harmful amounts of inflammation (Mrs. Wolf's claims otherwise notwithstanding) in any way that a treater would have deemed medically significant.

Dr. DeMio's proposed mechanism - that aluminum present in a vaccine as an adjuvant can prompt an immunologic reaction sufficient to cause a neurologic injury presenting as autism - has similarly been rejected, at least to date, as an insufficiently reliable basis for a causation theory. The concept that the extremely small amounts of metals found in different vaccines could be toxic, or could otherwise somehow stimulate a child's immune system in a pathogenic fashion, was rejected soundly by the OAP test case decisions, all of which involved developmental injuries akin to what R.W. has experienced. *See, e.g., Dwyer v. Sec'y of Health & Human Servs.,* No. 03-1202V, 2010 WL 892250, at *108 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (rejecting proposition that mercury in thimerosal-containing vaccines could be toxic to susceptible children and play a causal role in the development of autism). Since then, petitioners have shifted to identifying aluminum as the culprit rather than mercury, but their theories continue to fail. *See, e.g., Bushnell v. Sec'y of Health & Human Servs*., No. 02-1648V, 2015 WL 4099824, at *19 (Fed. Cl. Spec. Mstr. June 12, 2015) (rejecting theory that vaccines may have contained either mercury or aluminum in sufficient amounts to be neurotoxic, and thereby precipitate regressive encephalopathy manifesting as autism); *Fresco v. Sec'y of Health & Human Servs*., No. 06-469V, 2013 WL 364723, at *25 (Fed. Cl. Spec. Mstr. Jan. 7, 2013) (petitioners failed to offer reliable evidence that aluminum adjuvants could cause autism).[15]

More broadly, the claim that any vaccine could play a role in causing an ASD, or 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). No Program claimant has yet succeeded in establishing a non-Table claim that any vaccine has the potential to cause autistic-like developmental problems, let alone autism.[16] Thus, even if I were to credit the lesser contention that a vaccine might promote cytokine

[15] Indeed, as I recently observed in *Morris v. Sec'y of Health & Human Servs*., No. 12-415V, 2016 WL 3022141, at *12 (Fed. Cl. Spec. Mstr. Apr. 1, 2016), "no special masters have ever found [aluminum adjuvant causal] theories to be persuasive" in any context in which the theory has been advanced. *See also Rowan v. Sec'y of Health & Human Servs.*, No. 10–272V, 2014 WL 7465661, at *12 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (denying entitlement to Petitioner who claimed the aluminum adjuvant in the HPV vaccine caused her headaches, migraines, and chronic fatigue syndrome), *mot. for review den'd*, 2015 WL 3562409 (Fed. Cl. May 18, 2015).

[16] For purposes of comparison, it is instructive to consider the facts of two rare cases where petitioners successfully established (or settled) Table claim encephalopathies (where, as noted above, the standards for establishing an encephalopathy are more strict) resulting in ASD symptoms. In *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), and then within 48 hours developed a high fever that became low-grade over the next several days, along with inconsolable crying, sleeplessness, and significant, noticeable motor problems that worsened over the next several days. 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 by preponderant evidence that the vaccinated child experienced a seizure followed by loss of consciousness shortly after receipt of pertussis-containing vaccine; the severe reaction lasted for more than 24 hours, with resulting demonstrable significant changes in behavior. But the special master responsible for that decision (former Chief Special Master

expression sufficient to instigate an autoimmune reaction, or that some kind of adjuvant could in theory prompt a pathologic and/or autoimmune response, there is insufficient support for the greater proposition that such a reaction could (except in extremely rare cases, that would be evident from the strong evidence of a reaction) lead to an ASD or similar developmental problem.

In addition, the expert reports offered by Petitioners have their own deficiencies independent of the theories they espouse. Both experts rely heavily on the Wolfs's recitation of the medical history instead of objective record evidence from the time of vaccination – and such evidence is lacking in this case in any event. *Burns*, 3 F.3d at 417 (proper for special master to reject expert opinion based on facts not substantiated by the record). Petitioners' second expert, Dr. Cantor, is not an immunologist, and thus lacks the personal or professional expertise to offer a reliable opinion on the propensities of adjuvants. Dr. DeMio for his part offers only a conclusory opinion that provides little in the way of reliable science in support. The fact that he was one of R.W.'s subsequent treaters does not aid Petitioners – he did not treat R.W. around the time of the vaccinations, but over a year later, and he offers no detailed explanation of a medical records interpretation to support his opinion. *Nuttall*, 122 Fed. Cl. at 832. And neither expert has sufficient expertise to persuasively establish how the vaccines at issue would affect a child from an immunologic standpoint.

Given all of the above, I cannot conclude that Petitioners have offered sufficient preponderant evidence to meet their overall burden as set forth by the Federal Circuit in *Althen.* The theory that the vaccines R.W. received could have caused an encephalopathic reaction, later producing neurologic injury sufficient to manifest as autism or other developmental problems, is unreliable, lacking in critical scientific support or offered from experts that possess the background necessary to offer a persuasive opinion. The evidence of R.W.'s actual medical history, furthermore, does not at all support the conclusion that he ever experienced an encephalopathy sufficient to cause neurologic injury – and certainly not an injury that was not evident until months after the vaccination.

This also underscores Petitioner's failure to establish the third *Althen* prong as well, regarding the timeframe in which the purported reaction producing the encephalopathy would be expected to, and did, occur. Dr. Cantor proposes that the cytokine upregulation would be underway "in less than 72 hours," (Ex. 22 at 2), but the medical record reveals a gap of one month between the date of vaccination and R.W.'s next pediatric visit – at which he was diagnosed with merely a

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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.

Even though the Wolfs do not advance a Table claim, and therefore did not need to establish an encephalopathy in accordance with the Table definition, these cases demonstrate the degree of severity that might reasonably accompany a reaction to vaccination sufficient to produce developmental change in a child – a far cry from what occurred here.

URI, and at which time no other symptoms that might corroborate the purported reaction are evident. Even if I credit Mrs. Wolf's factual assertions about an observed reaction the same day of the vaccination (which would be more consistent with Dr. Cantor's anticipated timing), it remains the fact that the record does not evince an ongoing reaction of sufficient length and strength to connect the vaccination with R.W.'s developmental problems, none of which were even hinted at before late February of 2012, when treatment for his feeding issues was first explored and speech therapy was considered. This is too long of a lapse of time, given the nature of the reaction proposed by Petitioners.

CONCLUSION

The factual record does not support the Wolfs's contention that the DTaP or flu vaccines had any connection to R.M.'s subsequent ASD/developmental symptoms, nor have the Petitioners established that the vaccines *could* cause autism or something resembling it. There is no more than a temporal relationship between vaccination and his language/developmental problems – not nearly enough to satisfy the Act's otherwise-lenient preponderance evidentiary standard. This is not a close case. Petitioners have not established entitlement to a damages award.[17]

IT IS SO ORDERED.

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

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