

On November 1, 2013, Petitioner filed an expert report from his treating physician, Renata Engler, M.D. ECF No. 84. Respondent was ordered to file a responsive expert report by January 15, 2014. ECF No. 85. But on that date, Respondent instead filed a supplemental Rule 4(c) Report containing a motion for a ruling on the record. ECF No. 90 (“Mot.”). In it, Respondent asserted that “[P]etitioner has not shown by a preponderance of the evidence that [his vaccines] . . . caused his injuries, notwithstanding the submission of Dr. Engler’s report,” but that Respondent would not be “spend[ing] its limited resources in further defense of this case.” Mot. at 8. As such, Respondent requested that I issue a ruling on the record. *Id.*

On March 12, 2014, Petitioner responded to Respondent’s motion (ECF No. 91 (“Opp.”)) and also filed the package inserts for the hepatitis A, hepatitis B, and MMR vaccines he received. ECF No. 92. Petitioner argued that he had satisfied his burden because his treating physicians opined that his vaccinations caused his injuries. Opp. at 5-7. Petitioner also asserted that the opinion of Dr. Engler, one of his treating physicians, is particularly persuasive because Dr. Engler is “one of the foremost experts on vaccines and vaccine injuries.” *Id.* at 7. As further corroborative proof Petitioner pointed to encephalitis being a listed side effect on the hepatitis A, hepatitis B, and MMR vaccine package inserts he submitted. *Id.* at 10 (citing Exs. 38 at 6, 39 at 7, and 40 at 7).

A status conference in this matter was held on April 23, 2014, during which I ordered Petitioner to supplement Dr. Engler’s report for the purpose of addressing certain deficiencies in her initial report, such as its failure to set forth a specific theory for how the vaccines received by Mr. Gerhardt could have caused his encephalitis. In accordance with my order, Petitioner filed a supplemental report on June 23, 2014. ECF No. 94. The matter is now ripe for adjudication. *See* Vaccine Rule 20(b)(1). Based on a review of the entire record as required by the Vaccine Act (§ 300aa-13(a)(1)), I find that Petitioner is entitled to compensation.

I. Factual Background

A. Summary of Petitioner’s Medical History

The factual summary herein is derived from un rebutted materials submitted by the parties and constituting the record before me. On January 21, 2007, Petitioner (age 23) began Officers Candidate School with the United States Marine Corps in Quantico, Virginia. Ex. 1 at 3. He was in “good health and [at an] optimal fitness level.” *Id.*

As part of his initial basic training, Mr. Gerhardt received the hepatitis A and hepatitis B vaccines on January 21, 2007.³ Ex. 11 at 64. He next received the Td, MMR, meningococcal, inactivated poliovirus, and flu vaccines on January 22, 2007. *Id.* at 63-65. Soon thereafter, on January 25, 2007, Petitioner was observed to be disoriented when walking. *Id.* at 253, 257. In particular, he experienced “a sudden [loss of consciousness]⁴ while standing in formation, followed

³ Petitioner was given the Twinrix bivalent vaccine, which is a combination of the hepatitis A and B vaccines.

⁴ The exact nature of this even is unclear. Some records indicate that Petitioner did not experience a loss of consciousness but was instead not feeling well and was therefore pulled out of formation and sent to the clinic. *See* Ex.

by a reported fever, seizure like activity and alteration in cognitive skills.” Ex. 18 at 97. Petitioner presented to the medical clinic at Quantico, where he was noted to have difficulty finding words and was unable to remember his birthdate or Social Security number. Ex. 11 at 253.

Petitioner was subsequently transferred to the emergency department of Potomac Hospital, where he was admitted with the complaint of a “change in mental status.” Ex. 2 at 1, 5. Mr. Gerhardt knew his name and the then-current month and year, but he could not remember his birthdate or where he went to college. *Id.* at 5. Petitioner was then transferred to Bethesda National Naval Medical Center (“NNMC”) in Bethesda, Maryland (now part of Walter Reed National Military Medical Center). *Id.* at 16. There he was treated with acyclovir⁵ due to “high suspicion” of a herpes simplex virus infection. Ex. 3 at 12.

Not long after his transfer to NNMC, Mr. Gerhardt’s treating physicians began to suspect a relationship between his vaccinations and his illness. His diagnosis on admission to NNMC was “[u]nspecified non-arthropod-borne viral diseases of the central nervous system.” Ex. 11 at 85. The results from Mr. Gerhardt’s magnetic resonance imaging (“MRI”), electroencephalography (“EEG”), and cerebrospinal fluid (“CSF”) tests were normal, however. *Id.* at 136; *see also* Ex. 1 at 7. As a result, Mr. Gerhardt’s treating physicians (in connection with an infectious disease consultation performed on January 30, 2007) “favor[ed] post-immunization effect given [petitioner’s] . . . normal CSF analysis, MRI and EEG.” Ex. 11 at 136.

Petitioner also underwent an allergy/immunology consultation on January 30th. Ex. 11 at 136. The treating physicians who saw him at that time stated as follows:

[a]gree[d] that post-vaccination encephalitis is in the differential, however for the most part, this remains a diagnosis of exclusion. While epidemiologically, there has been little to support a definitive [sic] cause and effect vaccination/meningo-encephalitis [sic] connection, there are none-the-less scattered case reports. While the onset of symptoms (2 days)⁶ was rapid, it does not rule out entirely an autoimmune mediated process especially in a previously vaccinated patient. . . . Given the normal contrast/non-contrast MRI, [acute disseminated encephalomyelitis] and other demyelinating conditions seem[] less likely. Because of the temporal association, a Vaccine Adverse Event Report is appropriate.

Id.

11 at 257. Other records indicate that he experienced the loss of consciousness not in formation but as he was walking down a hall. *See* Ex. 11 at 253.

⁵ Acyclovir is “a synthetic acyclic purine nucleoside with selective antiviral activity against herpes simplex virus (types 1 and 2, human herpes virus 3, Epstein-Barr virus, and cytomegalovirus) . . . used in the treatment of genital and mucocutaneous herpes virus infections in certain patients.” *Dorland’s Illustrated Medical Dictionary* (32d ed. 2012) at 24 [hereinafter *Dorland’s*].

⁶ In asserting that Mr. Gerhardt experienced the onset of his encephalitis within two days of his vaccinations, this particular medical record is contradicted by contemporaneous records indicating (as noted above) that Petitioner experienced his first symptoms on January 25, 2007 – no sooner than three days after receiving the hepatitis A and B vaccinations on January 22nd. Ex. 11 at 63-65, 253, 257.

Mr. Gerhardt thereafter underwent a neurology consultation on January 31, 2007. Ex. 11 at 140. His treating physicians concluded that Petitioner's symptoms were "not . . . neurologic in nature," and opined that "[d]ue to [Petitioner's] normal EEGs, labs, PE, and basically normal mneuropsych [sic] testing, we do not feel that [there is] . . . an organic cause for [Petitioner's] . . . mental status changes." *Id.* His diagnosis was "encephalopathy [not otherwise specified] . . . possibly related to vaccine (MMR or Td)." *Id.* at 145. Tests for herpes simplex virus, West Nile virus, St. Louis encephalitis virus, eastern equine encephalitis virus, and mononucleosis virus were negative. *Id.* at 102. On the other hand, Mr. Gerhardt's "[Chlamydo]phila pneumonia IgG was noted to be elevated," which "likely represent[ed] [a] prior infection." *Id.* But Petitioner's primary care team later noted on February 3, 2007, that the "elevated C. pneumoniae titer [was] likely insignificant given negative IgM titer." *Id.* at 153.⁷

Mr. Gerhardt was subsequently determined to be fit for duty and discharged from NNMC on February 5, 2007. Ex. 11 at 102, 144. His infectious disease physicians remained "concerned about a possible immunization reaction in light of [Petitioner's] . . . [vaccinations] that were given 4 days prior to presentation," but now seemed inclined to believe that it was "very unlikely that [Petitioner's symptoms] . . . were related to his recent immunizations." *Id.* at 102.

Shortly after his initial discharge from the NNMC, Mr. Gerhardt became ill again, and on February 27, 2007, he returned to the NNMC for a second time. During this hospital visit, Mr. Gerhardt presented or was diagnosed with a number of health issues, including, among other things, chronic/major depression, cognitive disorder, abdominal pain, post-vaccination encephalitis, anxiety disorder, polyuria, insomnia, memory lapses or loss, conversion disorder, chronic fatigue syndrome, and sleep disorders. Ex. 18 at 95-99. In the subsequent months, Mr. Gerhardt underwent physical therapy to address his bodily impairments. Ex. 4 at 1-13. Over time, he reported some improvement in his motor coordination and overall physical health. *Id.* at 1-2 and 12.

In May of 2007, Petitioner's family contacted the Vaccine Healthcare Center Network at Walter Reed Army Medical Center ("the VHC") for an evaluation, "hoping to determine if the vaccines [he] . . . received just prior to symptom onset played a role in his . . . condition." Ex. 1 at 7. As a result of his family's outreach, Mr. Gerhardt received a comprehensive evaluation at the VHC beginning in July 2007. Ex. 1 at 2; Ex. 11 at 7. Dr. Engler (Mr. Gerhardt's present expert) and Dr. Limone Collins of VHC took lead roles in the evaluation. As Dr. Engler documented at that time:

[a]cute illness and current inflammatory immune markers suggest there is an [sic] physiologic basis for this patient's disability with outstanding question of an infectious etiology versus a hypersensitivity reaction to multiple vaccines. The recent literature reports of Chlamydia infection and encephalopathy are particularly [intriguing] since this suggests a possible treatment option since definitive treatment was never provided during

⁷ IgG and IgM are medical abbreviations referring to two different classes (isotypes) of immunoglobulin: Gamma and Mu, respectively. Immunoglobulin is any of the structurally related glycoproteins that function as antibodies, and is divided into five isotypes based on structure and biologic activity. *Dorland's* at 919. "The presence of IgM antibodies is indicative of an active infection. By contrast, a response that is solely of the IgG isotype is considered to indicate a resolved infection." *Principle and Practice of Infectious Diseases* 64 (7th ed. 2010).

hospitalization. Although there was a 4-fold titer increase it remains open to question whether or not this was an [epi-phenomenon] due to broad immune activation or if this is a true acute infection.

Ex. 11 at 17.

In the ensuing months, Mr. Gerhardt's case received a great deal of scrutiny from VHC physicians. As the notes of Drs. Engler and Collins explain, "[d]ue to the unusual and complex elements of [Petitioner's] . . . case, a multidisciplinary case conference was held on 19 Oct[ober] 2007 with Allergy Immunology, psychiatry, and neuropsychology to discuss treatment options. Infectious Disease input had also been received." Ex. 1 at 8. The conferring physicians agreed on a four-part treatment plan of (1) a "30-day antibiotic course to treat chlamydia pneumoniae infection in the event the organism still harbored in the central nervous system"; (2) a 10-day trial of steroids "in the event the patient had the rare Hashimoto's Encephalopathy"; (3) a trial of intravenous immunoglobulin ("IVIG") "due to the presence of circulating immune complexes with question of a complement mediated mechanism for patient's continued systemic and cognitive symptoms"; and (4) a "trial of low dose naltrexone targeting fatigue and sleep disturbance." *Id.* at 3. Treatments (2), (3), and (4) were later "delayed" due to Petitioner's urination problems, dry eyes and mouth, and issues with sleeping. *Id.*

In March 2008, after completing a thorough examination and review of Mr. Gerhardt's case, Drs. Engler and Collins made, among others,⁸ three final diagnoses: "1. Suspected hypersensitivity encephalopathy secondary to multiple immunizations . . . 2. Cognitive disorder [not otherwise specified] . . . 3. Chronic Fatigue Syndrome." Ex. 1 at 11. (Indeed – based upon the conclusion that Petitioner's encephalopathy and related illnesses were vaccine-related, Drs. Engler and Collins went so far as to make the legal recommendation that the matter was "eligible for referral and review by the Vaccine Injury Compensation Program since the vaccines involved are part of public health mandatory vaccines.") *Id.*

Mr. Gerhardt's diminished physical and mental condition greatly impeded his ability to continue to perform his functions with the Marine Corps. Mr. Gerhardt underwent a psychiatric evaluation in March of 2008, as a result of which Dr. George Brandt determined that Petitioner "fail[ed] to meet retention standards," and referred Petitioner to the Department of Veterans Affairs Physical Evaluation Board ("the PEB") "for final disposition." Ex. 1 at 6. Thereafter, in April 2008 the PEB began its review of Petitioner's case. *Id.* at 1-2. In connection with this review, Drs. Engler and Collins prepared an extensive summary of Petitioner's medical history. *Id.* at 1-3, 7-9. In it, they noted that Petitioner's initial diagnoses were encephalitis post-vaccination, cognitive disorder, and chronic fatigue syndrome (*Id.* at 1), and that his discharge diagnosis on February 5, 2007 was viral encephalitis. *Id.* at 7.

⁸ Petitioner actually received eleven final diagnoses in total as a result of his March 2008 examination. Petitioner was also diagnosed with: immunologic disorder NEC, polyuria, headache syndromes, persistent insomnia, anxiety disorder NOS, idiopathic urticaria, dry eye syndrome, and thyroid function test nonspecific findings. The Comprehensive Summary does not indicate, however, if the diagnoses (including the primary three referenced above) were listed in order of significance. Ex. 1 at 11-13.

In December 2008, the PEB determined that Petitioner was “[u]nfit secondary to Hypersensitivity Encephalopathy with a cognitive disorder and chronic fatigue syndrome . . . [because] the medical condition or disease does interfere significantly with [his] . . . ability to carry out the duties of his office, grade, rank, or rating.” Ex. 1 at 56. The PEB specifically noted that the VHC had:

determined that [Petitioner’s] . . . presenting encephalitis and subsequent encephalopathy and currently unfitting cognitive disorder and chronic fatigue were the sequelae of a condition classified as possibly associated with receipt of multiple immunizations . . .

Id.

On March 7, 2011, Mr. Gerhardt’s recommended disposition from the Department of Defense was changed from temporary disability to permanent disability and retirement. Ex. 32. Petitioner was determined to have, among other things, “probable hypersensitivity encephalitis secondary to vaccination” and “cognitive disorder [not otherwise specified] (status post encephalitis vaccine association).” *Id.* at 1.

B. *Analysis of Infection as Possible Cause of Petitioner’s Encephalitis and Related Illnesses*

As noted above, Mr. Gerhardt’s treating physicians gave careful consideration to whether his encephalopathy and related illnesses might have been caused by a Chlamydia infection rather than his vaccinations. Thus, in the course of evaluating Mr. Gerhardt’s condition, the VHC reviewed Petitioner’s overall medical case on September 24, 2007. Ex. 3 at 1-6. The report produced by that review specifically addressed the role this infection could have played in causing Mr. Gerhardt’s illnesses, but (after evaluation of test results and the medical record) ultimately discounted it as a factor:

[c]areful review of the patient’s medical records . . . showed a 4-fold increase in Chlamydia pneumoniae titer indicating a possible chronic infection which had never been treated with antibiotics. There have been multiple reports of Chlamydia pneumoniae encephalitis reported in the medical literature. Also it was discovered that the patient has positive thyroid autoantibodies which opens the possibility of the rare Hashimoto’s encephalitis. However, a PET scan . . . proved normal, ruling out these 2 entities.

Ex. 3 at 2.

Drs. Engler and Collins’s ultimate diagnosis similarly took into account the possibility that other causal factors precipitated Mr. Gerhardt’s illnesses – in particular, a possible pre-vaccination Chlamydia infection. But they could not conclude as such and instead noted that:

although infection during [Petitioner’s] . . . training might have played a role in the presentation of his illness, it was the consensus of the causality reviewing group that there is a possible association with the multiple immunizations (using World Health Organization

definitions for causality assessments⁹). [Petitioner's] . . . subsequent conditions may have resulted from this initial insult to his central nervous system . . . [T]his encephalopathic event, whether the result of pathogen or aberrant vaccine-associated immune activation was acute.

Ex. 1 at 13.

II. Evidence Offered by Petitioner

In support of his claim, Petitioner offered the following categories of evidence: (a) his medical records, and (b) two expert reports from Dr. Engler, one of his treating physicians.

A. *Petitioner's Medical Records*

Mr. Gerhardt asserts that his medical records provide “overwhelming evidence” that the vaccines he received in January 2007 caused his injuries. *See* Opp. at 8. Specifically, Petitioner pointed to his medical records from the acute phase of his illness between January 2007 and May 2007 as proof of causation. *Id.* at 6-7. Petitioner also pointed to the evaluation VHC personnel performed in July 2007, and the subsequent evaluations the PEB conducted in April 2008 and November 2008, as corroborative evidence that his vaccines caused his injuries. *Id.* at 7. Petitioner argued that these records provide proof of causation as he was consistently “diagnosed . . . with a postimmunization encephalitis and encephalopathy” by his treating physicians. *Id.*

B. *Petitioner's Expert, Dr. Engler*

In addition, Mr. Gerhardt also filed a brief expert report from Dr. Engler, his treating physician, on November 1, 2013. Ex. 36. Dr. Engler received a bachelor's degree in Biology and Humanities from Stanford University in 1971, and received her medical degree from Georgetown University School of Medicine in 1975. Ex. 37 (Dr. Engler's CV) at 1. Dr. Engler completed a two-year residency in internal medicine at NNMC in 1980. *Id.* She then completed a two-year fellowship in allergy-immunology at Walter Reed Army Medical Center in 1982. *Id.*

Dr. Engler has been a professor of medicine and pediatrics at the Uniformed Services University of the Health Sciences since 1994. *Id.* From 2001 through 2013, Dr. Engler was the director of the VHC. *Id.* Since 2013, she has been a volunteer at Walter Reed Army Medical Center in the allergy-immunology department. *Id.* She is board-certified in allergy-immunology and internal medicine, and has taught and conducted extensive research in the fields of immunology, allergology, and vaccinology. *See id.* at 3-22.

⁹ Respondent submitted the World Health Organization's (“WHO”) definitions of causation as Respondent's Exhibit A. The WHO defines a *possible* causal relationship between a vaccine and an injury as being a “clinical event with a reasonable time relationship to vaccine administration, but which could also be explained by concurrent disease or other drugs or chemicals.” Ex. A at 2. By contrast, WHO's definition of a *probable* causal relationship is a “clinical event with a reasonable time relationship to vaccine administration; is unlikely to be attributed to concurrent disease or other drugs or chemical.” *Id.*

Dr. Engler opined in her first report that Petitioner's "vaccines probably played a critical role in the development of [his] . . . severe neurologic deficits." Ex. 36 at 1. To explain her conclusion, Dr. Engler stated that "the vaccines administered contain adjuvants [sic]¹⁰ that could trigger an inflammatory/autoimmune process." *Id.* Dr. Engler further opined that "[a]lthough infection . . . might have played a role in the presentation of [Petitioner's] . . . illness, there was no direct evidence of an acute infection" at the time of vaccination, presumably based upon the test results obtained when Mr. Gerhardt first presented with symptoms of his illness after vaccination, such as the CSF test. *Id.* Dr. Engler thus argued that the lack of evidence of infection, coupled with "the presence of circulating immune complexes (C3d-binding assay)¹¹ further support[s] a likely pathogenesis of injury that involves immune inflammation rather than direct infection injury." *Id.* In Dr. Engler's view, the timing of Mr. Gerhardt's symptoms with his vaccinations, and then his subsequent hospitalization, were "consistent with the vaccines as a potential causative agent." *Id.*

Dr. Engler acknowledges but disposes of possible alternative causal factors for Mr. Gerhardt's illnesses. Thus, she noted that there was "a question about a Chlamydia pneumoniae infection" being present at the time of onset of his condition, but also observed that an unnamed infectious disease consultant concluded on January 30, 2007 that Petitioner's condition was not caused by that infection. *Id.* Dr. Engler further noted that this infectious disease consultant concluded that, in fact, Petitioner's "clinical presentation was linked to vaccine related immune inflammation." *Id.*¹²

Dr. Engler also submitted a one-page supplemental report, dated June 20, 2014, intended to address concerns I expressed about omissions in her initial report. ECF No. 94-1 (Ex. 41). In it, she explained that Mr. Gerhardt was diagnosed with encephalitis, defining the illness as an "inflammation of the brain [that] can be caused by infections . . . and in association with immune reactions to other triggers including drugs and vaccines." *Id.* at 1. Vaccines, Dr. Engler stated, can activate the immune system to induce protective responses that in some cases may be self-reactive, damaging the host's nerve tissue and causing autoimmune inflammatory diseases, such as

¹⁰ It is likely Dr. Engler meant to use the term "adjuvant," which is defined as a nonspecific stimulator of the immune response. *Dorland's* at 32.

¹¹ C3d (complement component 3) is a B-cell growth factor serum protein generated by inactivation of C3b (a constituent of the classical pathway C5 convertase). *Dorland's* at 393. An increase in the C3 levels generally can be indicative of the existence of an inflammatory illness. *Mosby's Manual of Diagnostic and Laboratory Tests* 188 (3rd ed. 2006).

¹² Dr. Engler's first report also cited the fact that that the "[Food and Drug Administration (the "FDA")] approved package inserts for both hepatitis B and tetanus vaccines describe[] a risk of encephalopathy and convulsions." Ex. 36 at 1. As exhibits attached to his filing in opposition to Respondent's motion for a ruling on the record, Petitioner included the package inserts from hepatitis A, hepatitis B, and MMR vaccines, holding them out as corroborative evidence that the vaccines he received were in fact causative. ECF No. 92. But statements contained in vaccine package inserts do not constitute reliable proof of causation, and certainly cannot be deemed admissions that the vaccines in question harmed a particular petitioner. *See Werderitsh v. Sec'y of Health & Human Servs.*, No. 99-319V, 2005 WL 3320041, at * 8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l) as saying "[a] report or information submitted by a licensed manufacturer . . . does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect"). I accordingly do not give this particular evidence much weight in my analysis.

encephalitis. *Id.* Molecular mimicry is a potential mechanism for these adverse events. *Id.* In such cases, a vaccine specifically activates cross-reactive T-cells or antibodies that initiate a process which ultimately injures the host's nerve tissues. *Id.*

Dr. Engler did not specify which of the vaccines Mr. Gerhardt received caused his encephalitis. *Id.* However, she noted that encephalitis has been “reported in association” with the hepatitis B and Tb vaccines (both of which Mr. Gerhardt received). *Id.* She concluded that “it is more probable than not that the combination of vaccines contributed significantly to the onset of the patient's illness.” *Id.* at 1-2.

III. Respondent's Contentions

Respondent's arguments against an entitlement award are wholly contained in her two Rule 4(c) Reports. The thrust of Respondent's overall position is that Petitioner has not provided preponderant evidence that his vaccines caused him neurological injuries. *See* Respondent's Report at 12; Mot. at 6. Respondent asserts that Petitioner's treating physicians never “definitively stated that [P]etitioner's symptoms were, more likely than not, caused in fact by his receipt of vaccines Rather, the[ir] ultimate conclusion . . . was that there was a possible – not probable – connection between [P]etitioner's symptoms and his vaccinations.” Respondent's Report at 13.

Respondent's supplemental Rule 4(c) Report and accompanying motion sets forth Respondent's reaction to Dr. Engler's opinion. Respondent asserted that the opinion is insufficient to support Petitioner's claim (Mot. at 6) because Dr. Engler “does not elaborate as to which vaccines petitioner received, if any, contain adjuvants, nor does she articulate a viable theory of inflammatory/autoimmune response caused generally by adjuvants or specifically by the vaccines here.” *Id.* Further, “Dr. Engler likewise fails to discuss a mechanism as to how [the] proposed immune inflammation resulted in encephalopathy in this case,” and fails to demonstrate how the timing of the onset of Petitioner's symptoms was appropriate. *Id.* Simply stated, Respondent maintained that Dr. Engler relies primarily on the temporal relationship between Petitioner's vaccinations and the onset of his illnesses to opine that a relationship existed between the two. *Id.* at 7. Respondent also argued that “there is no evidence to support [Dr. Engler's] . . . position that an immune response can be triggered within twenty-four hours from exposure to vaccine antigens.” *Id.*

In addition, Respondent disagreed with Dr. Engler's view that Petitioner's records do “not support an infectious etiology for . . . [his] encephalitis.” *Id.* Rather, Respondent claimed that Petitioner's elevated Chlamydia pneumonia titers suggest “a potential alternate cause.” *Id.*

IV. Legal Standards Governing Program Entitlement Claims

To receive compensation under the 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, or (2) that his illnesses were actually caused by a vaccine (a category of claim often generically referred to as a “non-Table injury”). *See* §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); 300aa-14(a), as amended by 42 C.F.R. § 100.3; 300aa-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).¹³

The Vaccine Act requires a petitioner to establish his entitlement to a Program award by a preponderance of the evidence. § 300aa-13(a)(1). This means that a petitioner must demonstrate that it is “more likely than not” that the vaccine at issue caused his injury. *Moberly*, 592 F.3d at 1322 n.2. 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). In determining the persuasiveness of the evidence, the special master must assess “the record as a whole” and may not find that a petitioner has established an entitlement to compensation based solely on his own claims “unsubstantiated by medical records or by medical opinion.” § 13(a)(1).

Petitioner does not allege a Table injury in this case, and I do not find support in the record in any event that would allow a compensation award on such grounds.¹⁴ Petitioners such as Mr. Gerhardt attempting to establish a non-Table injury must typically satisfy (by a preponderance of the evidence) the three prongs set forth by the Federal Circuit in the *Althen* decision: (1) a medical theory causally connecting the vaccination to the injury (*i.e.*, that the vaccine “can cause” the injury); (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury (*i.e.*, that in this case the vaccine “did cause” the injury); and (3) a proximate temporal relationship between the vaccination and the injury. *Althen*, 418 F.3d at 1279. A petitioner who successfully does so has carried his burden – at which point the burden shifts to the Respondent to demonstrate by preponderant evidence that the petitioner’s injury is “due to factors *unrelated* to the administration of the vaccine.” § 300aa-13(a)(1)(B) (emphasis added). And where, as is the case here, a petitioner alleges that his receipt of a number of vaccines caused his illnesses, the failure to identify or single out one of the vaccines as the predominating factor in his alleged injury is not fatal to the claim, so long as all of the vaccines in question are covered under the Vaccine Act. *Doe/74 v. Sec’y of Health & Human Servs.*, No. ____V, 2010 WL 2788239, at *9 (Fed. Cl. Spec. Mstr. June 28, 2010).

¹³ 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 decisions 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).

¹⁴ There is a Table injury specified for the MMR vaccine where a petitioner establishes he experienced encephalitis with onset occurring within five to fifteen days after vaccination. 42 C.F.R. § 100.3(a)(III)(B). Petitioner has not alleged, however, such a claim, nor has he attempted to prove that his illnesses were specifically the result of the MMR vaccination he received – and even if he had, the medical records establish that Mr. Gerhardt’s first symptoms occurred three days after his last vaccinations, which would be too soon to meet the requirements for this Table injury.

The case law permits petitioners to rely upon a variety of different kinds of proof in attempting to substantiate a Program claim. For example, as the Federal Circuit has noted, contemporaneous medical records “warrant consideration as trustworthy evidence.” *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). The Federal Circuit added that “[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” *Id.*

Petitioners may be awarded Program compensation based on “medical records or . . . medical opinion.” See § 300aa-13(a)(1); *Althen*, 418 F.3d at 1279-80. Although expert testimony may be helpful in making an entitlement ruling, there are no “hard and fast *per se* scientific or medical rules” for finding causation under the Vaccine Act. *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners may therefore satisfy their burden with circumstantial evidence (*Althen*, 418 F.3d at 1280) which includes the opinions of treating physicians. *Moberly*, 592 F.3d at 1325 (holding that “treating physician evidence . . . [can] support[] the claim of causation”); see also *Carter v. Sec’y of Health & Human Servs.*, No. 04-1500V, 2007 WL 415185, at *21 n. 25 (Fed. Cl. Spec. Mstr. Jan. 19, 2007). A special master may determine that a petitioner has carried his or her burden of proof sufficient to receive a Program award even where his or her claim is not supported by conclusive medical literature, epidemiological studies, and/or general acceptance in the scientific or medical communities. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

V. Analysis

A. Overview of Evidence

There is a discrepancy in this case between the breadth of evidence reflected by Mr. Gerhardt’s treatment history (which would typically be used to establish the “did cause” *Althen* prong two) and Dr. Engler’s comparatively sparse expert reports (which would typically be offered to satisfy the “can cause” *Althen* prong one). Respondent argues that Petitioner has not presented sufficient preponderant proof to establish that the vaccines he received “can cause” the kinds of encephalitis-oriented injuries¹⁵ he suffered to satisfy the first *Althen* prong. In particular, Respondent suggested that Dr. Engler’s opinion is insufficient because it “fails to discuss a mechanism as to how proposed immune inflammation resulted in encephalopathy in this case.” Mot. at 6.

Dr. Engler’s initial report provided only a cursory explanation as to how the vaccinations Mr. Gerhardt received could injure an individual by causing encephalitis, and did not lay out in detail the reasoning behind the explanation that he provided. Dr. Engler appeared to embrace in part a theory that adjuvants in the vaccines might result in the kinds of injuries experienced here,

¹⁵ Although Petitioner characterized his injury in his petition as non-specific “neurological injuries” (see Petition at 1), Petitioner’s treating physicians described his condition more precisely as encephalopathy/encephalitis. See, e.g., Ex. 32 at 1.

although she provided no medical literature that would explain the mechanism by which such substances could trigger an autoimmune response. Ex. 36 at 1. Dr. Engler does suggest that test results performed around the time of onset of Mr. Gerhardt's illness – and in particular the existence of “circulating immune complexes” discovered as a result of such tests – permit the inference that immune inflammation rather than an infection was the cause of Mr. Gerhardt's encephalitis. *Id.*

The supplemental report filed at my request in June, though also brief, added some needed heft to the first report. Dr. Engler explained the process by which a vaccine could activate the immune system causing an autoimmune inflammatory disease. Ex. 41 at 1. She also opined that immune system responses could be more severe in certain susceptible individuals, and that encephalitis has “been reported” in association with the receipt of tetanus-containing vaccines and the hepatitis B vaccine. *Id.* And she provided a more detailed explanation of other possible mechanisms by which the vaccines might have caused an autoimmune response leading to Mr. Gerhardt's encephalitis and related illnesses, such as molecular mimicry. *Id.*

Overall, Dr. Engler's reports do not provide much detail in theorizing how Petitioner's vaccinations could have caused onset of his encephalitis and related injuries in the short timeframe at issue. *See* Respondent's Mot. at 6-8. Besides being facially sparse, the reports are not supported by any medical literature that would put flesh on the “bones” of their assertions. Nevertheless, I find that the two expert reports, taken together, set forth enough of a theory to explain how Mr. Gerhardt's vaccination could have harmed him to constitute sufficiently reliable evidence satisfying the first prong of *Althen*.

It is true that petitioners in the Vaccine Program cannot prevail simply by establishing the mere “possibility” that a vaccine injured them. *See Bast v. Sec'y of Health & Human Servs.*, --- Fed.Cl. ---, 2014 WL 3719188, at *18 (2014) (“[t]he preponderance of the evidence standard requires more than proof of a mere possibility”). But at the same time, a petitioner need not prove to a scientific degree of certainty that the vaccine at issue could theoretically harm an individual. *See Knudsen*, 35 F.3d at 549 (“requir[ing] identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program”). Rather – given the Program's goal of awarding damages to “vaccine-injured persons quickly, easily, and with certainty and generosity,” *Rooks v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344) – the preponderance standard is a bit more forgiving, even to expert reports (like the ones at issue in this case) that are not accompanied by substantial corroborative proof from the medical or scientific community. *See Andreu*, 569 F.3d at 1379 (“a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery”) (citations omitted).

I therefore do not discount Dr. Engler's opinions simply because they are concise. Dr. Engler has advanced a theory of causation in this case. Her supplemental report did not merely repeat statements contained in her first report but rather expanded on earlier statements just enough to respond to my concerns. I also take note that Dr. Engler's credentials (and demonstrated experience with vaccine-related injuries as former VHC director) are excellent, making her well-qualified to opine as to the matters disputed in this case.

If the above were not enough, Dr. Engler's dual role as both Mr. Gerhardt's expert and one of his primary treating physicians provides me additional grounds for considering her opinions probative. Treating physicians' views as to the relationship between a petitioner's vaccination and his subsequent injuries are of course usually most probative of the second *Althen* prong – that the vaccine in question “did cause” the petitioner's injuries – because those doctors are uniquely positioned to determine whether “a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1280. But the same evidence considered with respect to one *Althen* prong can be applied to another. *Capizzano*, 440 F.3d at 1326; *see also Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 145 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012) (although there is an “analytical demarcation” between the analysis of *Althen* prongs one and two evidence, a treating physician's “statement that a vaccine did in fact cause an injury presupposes that the vaccine is capable of causing that injury”).

The medical record in this case robustly establishes that Mr. Gerhardt's treating physicians (including Dr. Engler) concluded that his vaccinations caused his encephalitis and related illnesses. They reached this conclusion, moreover, only after giving the matter considerable thought and rigorous analysis, weighing their diagnoses and discarding those that testing did not support. The opinions of treating physicians are generally considered “compelling” (although not binding) in establishing a Program claim. *See, e.g., Zatushni v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 612, 623-24 (2006); *Capizzano*, 440 F.3d at 1326 (“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’”). And special masters have ruled in favor of petitioners despite the fact that the evidence is less robust with respect to one (or more) of the three *Althen* prongs than the other prong(s). *See, e.g., Myer v. Sec'y of Health & Human Servs.*, No. 06-148, 2011 WL 3664358, at *11 (Fed. Cl. Spec. Mstr. July 28, 2011) (citations omitted) (strong evidence under *Althen* prong two may overcome weaker evidence under prongs one and three). Here, the strength and comprehensiveness of the evidence from Mr. Gerhardt's treatment history is enough to supplement a less exhaustive expert report offered in support of *Althen* prong one – especially where, as here, the expert who penned the report was also one of the Petitioner's primary treating physicians. *See* § 300aa-13(b)(1)(B)); *Capizzano*, 440 F.3d at 1320, 1326.

As a backdrop to all of the above, I also take note that Respondent has made no effort to rebut Petitioner's expert report by providing a report of her own, preferring instead to raise questions about the adequacy of proof offered by Petitioner overall. In some cases (such as where the overall record was sparse, or acutely deficient in a specific regard), this approach to defending against a Program claim might be sufficient to carry the day. But Respondent's failure in this case (which features extensive and undisputed medical records) to attempt to rebut Dr. Engler's opinions with an expert of her own is a compelling omission. *Lankford v. Sec'y of Health & Human Servs.*, 37 Fed. Cl. 723, 726 (Fed. Cl. 1996) (citing *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979 (Fed. Cir. 1993) (“a special master is not free to disregard testimony asserting that a vaccine-caused encephalopathy occurred where that testimony (i) is presented by a qualified medical specialist, (ii) reflects a reasoned evaluation of undisputed facts, and (iii) stands uncontradicted by any opposing medical opinion”).

B. *Application of Evidence to Althen Causation Prongs*

Based on all of the above, I find that Petitioner has provided sufficient evidence to carry his burden of establishing that it was “more likely than not” that the vaccines he received in January 2007 caused the encephalitis and related injuries that he subsequently experienced.

With respect to the first *Althen* prong, Petitioner offered a medical theory demonstrating that the vaccines he received could have caused his encephalitis and related illnesses. The thin nature of Dr. Engler’s expert report (which has not been fully remedied by supplementation) is strengthened by the fairly comprehensive evidence from Mr. Gerhardt’s medical records that his treating physicians (which included his expert as well as other practitioners at Walter Reed experienced with vaccine-related illnesses) deduced a relationship between the vaccines he received and his illnesses. I thus find that Mr. Gerhardt has provided just enough evidence to satisfy this first prong of his overall causation burden.

The evidence offered in support of the second prong is considerably stronger. Although the mere temporal association between vaccination and illness, in the absence of any other evidence, is insufficient proof of causality (*Moberly*, 592 F.3d at 1323), the record here reveals that the treating physicians’ conclusions were amply tested and supported. For more than a year after Mr. Gerhardt’s vaccinations, Petitioner’s treating physicians personally examined Petitioner and his clinical course, considered whether his vaccinations were causative, and in the end concluded that his illnesses were likely vaccine-caused. *See supra* pp. 4-7. Corroborating the theory sketched out by the sequence of Petitioner’s illness is the report that Drs. Engler and Collins completed with the input of their colleagues in April 2008 for Petitioner’s PEB submission. Ex. 1 at 3, 7-10. They, along with several other physicians,¹⁶ including an infectious disease consultant, conducted a thorough and extensive examination of Petitioner’s medical records, and carefully examined Petitioner’s then-current state. *See id.* at 5-6.

Notably, Dr. Engler and her colleagues specifically considered whether Petitioner’s vaccinations could have caused his injuries. *See id.* at 7. The first of ten differential diagnoses they made was “[s]uspect hypersensitivity encephalopathy secondary to multiple immunizations.” *Id.* at 11. Drs. Engler and Collins thereupon documented that “it was the consensus of the causality reviewing group that there is a possible association with the multiple immunizations” Petitioner had received and his illnesses. They did not reach this determination in a conclusory fashion, moreover. For example, the treating physicians initially speculated that Petitioner’s Chlamydia infection “might have played a role in the presentation of his illness” (*Id.* at 8), but they tested and subsequently disregarded that hypothesis. After observing Petitioner’s elevated Chlamydia IgG titers (which would suggest a resolved infection) without a corresponding rise in his IgM titers (which would have, by contrast, suggested a still-active infection) (*see supra* note 7), and then reviewing the results of a PET scan of Mr. Gerhardt’s brain, the physicians ruled out a Chlamydia

¹⁶ Drs. Engler and Collins and their colleagues convened a “multidisciplinary case conference” on October 19, 2007. The conference was composed of Drs. Engler and Collins and members from the psychiatry and neuropsychology departments. The conference also received the input of an infectious disease “consultant.” *See* Ex. 36 at 1. It is unclear from the record, however, the total number of participating physicians.

infection as the cause of Mr. Gerhardt's illnesses. *See* Ex. 3 at 2; Ex. 11 at 153. Petitioner was also tested for the presence of numerous other infectious entities capable of causing neurological issues, such as West Nile virus, Epstein-Barr virus, St. Louis encephalitis virus, Eastern equine encephalitis virus, and mononucleosis virus. All such tests were negative, lending strength to the diagnosis of vaccine-caused encephalitis.

In summary, Petitioner's case was reviewed by multiple physicians, including Dr. Engler, an allergist-immunologist and then-Director of the VHC (making her especially qualified to consider the role a vaccination might play in an individual's subsequent health). Petitioner's treating physicians were well aware that the onset of Petitioner's condition occurred shortly after he received multiple vaccinations, but the record does not show that the treating physicians relied solely on the temporal connection between vaccination and injury as the basis for their conclusions. Their opinions were also not based on a "simplistic elimination of other potential causes of the injury." *Moberly*, 592 F.3d at 1323. Their careful consideration of Petitioner's medical condition and history provides ample reason for me to find their opinions reliable and persuasive. *Walther*, 485 F.3d at 1151; *see also Myer v. Sec'y of Health & Human Servs.*, No. 06-148V, 2011 WL 3664358, at *10-11 (Fed. Cl. Spec. Mstr. July 28, 2011).

I find as well that the third *Althen* prong is satisfied. It 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.* To satisfy this *Althen* prong, 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." *de Bazan*, 539 F.3d at 1352.

The explanation for what is a medically acceptable timeframe must coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *de Bazan*, 539 F.3d at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (Fed. Cl. 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), *motion for review denied* (Fed. Cl. Dec. 3, 2013), *appeal docketed* (Fed. Cir. 2014).

Because Petitioner's treating physicians considered the vaccines to be causative, they necessarily concluded that his injuries manifested within a medically acceptable period. Dr. Engler's expert reports underscore this conclusion. Exs. 36 and 41. I thus find that *Althen* prong three is also satisfied.

C. *Respondent Has Not Demonstrated an Alternative Cause for Petitioner's Illnesses*

Having determined that Mr. Gerhardt provided sufficient preponderant evidence that his vaccinations caused him to suffer encephalitis and related illnesses, the burden shifts to Respondent to establish (also by the same preponderance of the evidence standard) that Petitioner's injuries are

due to “factors unrelated” to the vaccines.¹⁷ *C.K. v. Sec’y of Health & Human Servs.*, 113 Fed. Cl. 757, 766 (2013) (citing *Knudsen*, 35 F.3d at 547); *Deribeaux v. Sec’y of Health & Human Servs.*, 105 Fed. Cl. 583, 587 (2012), *aff’d*, 717 F.3d 1363 (Fed. Cir. 2013); *see also Knudsen*, 35 F.3d at 547; 42 U.S.C. § 300aa–13(a)(1)(B). Respondent can meet her burden by relying on evidence derived from the same record that a Petitioner draws upon to carry his initial burden.¹⁸

Here, Respondent failed to offer record proof sufficient to establish the existence of a cause of Petitioner’s illnesses unrelated to the vaccinations that he received. At most, she suggests that Petitioner’s Chlamydia infection, which may have been present at the time of vaccination, “is a potential alternate cause.” Respondent’s Mot. at 7. As noted above, there is in the record evidence of such an infection, identified around the time Mr. Gerhardt first sought medical treatment after his vaccinations. Moreover, Petitioner’s treating physicians did at one time consider that infection as potentially causative (*see* Ex. 1 at 3, 15; Ex. 11 at 150), and initially prescribed antibiotics for Petitioner to combat the infection. Ex. 1 at 8. But they ultimately abandoned the hypothesis that his neurological complications and other symptoms were caused by a Chlamydia infection, based upon the tests they subsequently performed. *See* Ex. 3 at 2 (noting that a PET scan ruled out the possibility of Chlamydia-caused encephalitis). Because Petitioner’s treating physicians themselves explicitly rejected Respondent’s theory of causation, and because Respondent provides no other evidence or arguments that would cast doubt on the treating physicians’ diagnoses and determinations, Respondent has not met her burden of establishing an alternative cause for Petitioner’s encephalitis and related illnesses.

¹⁷ Although the law pertaining to Respondent’s burden does not come into play because I find that Petitioner carried his initial burden, I reference it here because one of Respondent’s articulated arguments in opposing an entitlement award is that Mr. Gerhardt appears to have suffered from a contemporaneous, or even preexisting, Chlamydia infection. *See, e.g.*, Mot. at 7.

¹⁸ For instance, in *Rupert v. Sec’y of Health & Human Servs.*, No. 10-160V, 2014 WL 78526, at *1 (Fed. Cl. Spec. Mstr. Feb. 3, 2014), Petitioner argued receipt of the influenza vaccine caused his Guillain-Barré syndrome (“GBS”), whereas Respondent asserted that Petitioner’s upper respiratory tract infection, which he developed after his influenza vaccination was the primary cause. Notably, the treating physicians in *Rupert* had unequivocally stated that the likely cause of Petitioner’s GBS was his upper respiratory tract infection. *Id.* at 2-3, 14-15. Further, they affirmatively stated that his influenza vaccination did not cause his GBS. *Id.* at 3, 15. Accordingly, the special master found that Respondent had proven a cause of Petitioner’s GBS unrelated to his influenza vaccination. *Id.* at 1.

CONCLUSION

For the reasons discussed above, I find that Petitioner is entitled to compensation because he has met his statutory burden of providing preponderant evidence that his vaccinations more likely than not caused his encephalitis and related illnesses. In order to guide the parties through the damages phase of the action, a separate damages order will issue.

IT IS SO ORDERED.

/s/Brian H. Corcoran

Brian H. Corcoran

Special Master