In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 09-107V
Filed: September 4, 2012
Unpublished

MICHELLE BROUSSARD-PACOT, as Next Friend of COLE PACOT, a Minor,	*	
Petitioners,	*	Entitlement Denied; Seizure Disorder; Weighing Expert Testimony
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Brian R. Arnold, Brian R. Arnold & Associates, Dallas, Tx, for Petitioners.
Chrysovalantis P. Kefalas, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

GOLKIEWICZ, Special Master.

I. INTRODUCTION and PROCEDURAL BACKGROUND

Michelle Broussard-Pacot ("petitioner") filed on February 20, 2009, a Petition ("Pet.") pursuant to the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§

[1] The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). **As provided by Vaccine Rule 18(b), each party has 14 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 entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.**

300aa-10 et seq. (2006)[2] ("Act" or "Program"). The Petition seeks compensation for injuries allegedly sustained by petitioner's minor child, Cole Pacot, from immunizations administered on February 22, 2006[3] and October 18, 2006. Pet. at 1-3, ¶ I, V. Petitioner alleges that Cole's immunizations caused-in-fact his seizure disorder, as well as "developmental delay [that] is a sequel[a] of that brain injury and convulsive disorder." Petitioner's Post Hearing Memorandum ("P Memo") filed June 15, 2012 at 2. As will be discussed below, after considering the entire case record, the undersigned finds that petitioner failed to produce preponderant evidence that the vaccines were the cause or the significant aggravation of Cole's injuries.

Significant development of the case followed the filing of the Petition. In summary, petitioner obtained and filed the required medical records between April 13, 2009 and June 29, 2009. See Petitioner's Exhibits ("P Exs.") 1-23. To support her Petition, petitioner filed on October 22, 2009, the expert report of Dr. Eva Stanczak, as well as affidavits from petitioner, Michelle Broussard-Pacot, and Cole's father, Scott Pacot. P Exs. 24-26. Thereafter, respondent filed on December 22, 2009, her Rule 4(c) Report, recommending against compensating this Petition. Respondent's 4(c) Report was supported by the expert report of Dr. Russell Snyder. Respondent's Exhibit ("R Ex.") A. Thereafter, Petitioner sought and was granted multiple extensions of time to file a Supplemental Expert Report from Dr. Stanczak, as well as an expert report from a neurologist. See Orders filed Feb. 1, 2010, April 2, 2010, June 2, 2010, Aug. 18, 2010, Oct. 12, 2010, Nov. 4, 2010. On November 19, 2010 petitioner filed a Supplemental Expert Report from Dr. Stanczak. P Ex. 34. Petitioner was unable to obtain a report from a neurologist to support her Petition. See Order filed Jan. 31, 2011. Over the following year, petitioner filed additional medical literature and otherwise worked to focus the case prior to trial.

An evidentiary Hearing was conducted on December 6, 2011, to hear the testimony of Drs. Stanczak and Snyder. Fact testimony was heard from petitioner, Michelle Broussard-Pacot, and Cole's father, Scott Pacot. Thereafter, the parties filed their Post-Hearing Briefs. The record is complete and the case is ripe for decision.

II. FACTUAL HISTORY

The undersigned finds that the fact testimony did not substantially differ from the medical records; for clarity the factual history found below is taken largely from the medical records. The undersigned notes that while the parties do not dispute the factual history in this case, the parties do dispute the significance of certain facts. The medical records are extensive. Only the pertinent medical records and information are summarized below.

[2] This Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (2006) (hereinafter "Program," "Vaccine Act," or "the Act"). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

[3] The undersigned notes that while petitioner's counsel references Cole's vaccinations received on February 20, 2006, it is clear this is a typographical error and counsel is referring to Cole's vaccinations received on February 22, 2006. See Petitioner's Exhibit ("P Ex.") 16 at 4-5; P Ex. 6 at 44.

Cole Pacot was born on October 17, 2005, following a pregnancy that was "[u]nremarkable" with the exception of "twitching events." P Ex. 6 at 6. Medical City Children's Hospital records indicate that petitioner reported having "felt infant have extended periods of twitching twice" during her pregnancy. Id. Cole was delivered via elective caesarean section. Id. Cole's APGAR scores were 9 and 9.

At three days old, Cole had a "tonic-clonic[4] episode." Id. The episode was described by a pediatrician at 5:50 pm on October 19, 2005, as left sided shaky spells that were unable to be stopped for 15 minutes on and off. Id. at 10. A CT and an EEG were performed on October 19 and 20th, respectively, and nothing abnormal was detected. Id. at 41-2. The history provided in a neuro-imaging report from October 19, 2005, indicates that Cole was a "term infant with possible seizures on day 3 of life." Id. at 8. The same report indicated that phenobarbital[5] was given and a diagnosis of "R/O [rule out] Seizures" was made. Id. On October 22, 2005, Cole was given a Hepatitis B vaccination and discharged from the hospital on October 23, 2005. Id. at 2.

Cole was seen by his pediatrician on October 25, 2005. P Ex. 6 at 45. A notation of "suspect myoclonic jerks" and "will follow up w[ith] neuro[logist] from [M]ed[ical] [C]ity [Hospital]" was recorded at this visit. Id. The history also indicates the "family [was] to videotape activity and bring it to [the pediatrician]." Id.

On October 31, 2005, petitioner was seen by her doctor for an "incision check" subsequent to her caesarean section. P Ex. 4 at 3. Petitioner's doctor's records indicate that Cole "was being worked up for possible epilepsy as he has had some twitching episodes that occur mainly when he is in a deep sleep[,] but none of the physicians have been able to witness them." Id. The record further notes that "they have not been able to find anything [wrong]" with Cole and that petitioner and her husband seemed to be "coping pretty well with it all." Id.

Cole was seen again by his pediatrician on November 2, 2005, for myoclonic jerks and a well child visit. P Ex. 6 at 45. A notation was again made that "parents to try to video any abnormal movements/activity." Id. Cole was seen once again on December 9, 2005, for a "U[pper] R[espitory] I[nfection]." Id. The pediatrician's history contains no notations regarding abnormal movements or jerks. Id.

Petitioner was seen again by her physician for a post partum examination on December 13, 2005. P Ex. 4 at 2. At this visit, petitioner apparently reported that Cole "was still having unexplained seizure episodes[,] however they have been very infrequent and far apart and seem to be lessening in severity. They are hoping he will grow out of them." Id.

---

[4] Tonic-Clonic is defined as "tonicoclonic." Tonicoclonic is defined as "both tonic and clonic; said of a spasm or seizure consisting of a convulsing twisting of the muscles. Called also tonic-clonic and tonoclonic." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1936 (32nd ed. 2012).

[5] Phenobarbital is defined as "a long-lasting barbiturate, used as a sedative, hypnotic, and anticonvulsant, administered orally." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1428 (32nd ed. 2012). Phenobarbital sodium is defined as: "the monosodium salt of phenobarbital, having the actions and uses of the base; administered orally, intravenously, intramuscularly, and subcutaneously." Id.

On December 21, 2005, Cole was seen again by his pediatrician for myoclonic jerks and his two months well child visit. P Ex. 6 at 44. A notation of "Neurology, ASAP For Evaluation" was made under the heading "[m]yoclonic jerks." Id. The history further indicates that Cole received multiple vaccinations on this date, including: Pediarix,[6] Hib, and Prevnar vaccinations. Id.

Cole was seen again by his pediatrician on February 22, 2006, for his 4 month well child examination. Id. During that examination Cole received multiple vaccinations including Pediarix, Hib, and Prevnar. Id.; P Ex. 16 at 4. There is no allegation or record indicating any adverse reaction to these immunizations before March 1, 2006.

On March 1, 2006, Rockville County Emergency Medical Services [EMS] was contacted and petitioner reported that Cole suffered a seizure after she awoke him that morning. P Ex. 5 at 1. EMS was dispatched to petitioner's home, examined Cole, and then transported him to Medical City Dallas Hospital's Emergency Room at petitioner's request. Id. Cole was admitted to Medical City Children's on March 1, 2006 "for tonic clonic seizures lasting approximately 5 minutes." P Ex. 6 at 141, 145. Once admitted to the ER Cole suffered another seizure. Id. at 145. He was given intravenous phenobarbital and subsequent to being admitted to pediatrics he suffered two additional seizures after being transferred to the pediatric floor. Id. Cole was again given intravenous phenobarbital and transferred to the "Pediatric Intensive Care Unit for closer observation and medical management." Id. at 147.

Cole was examined by Dr. Laham on March 1, 2006, after Dr. Owen requested his consultation. Id. at 146-47. Dr. Laham noted a "Problem List" as "[i]nclud[ing] 1. New onset seizures. 2. History of twitching type episodes from birth until approximately six weeks of age." Id. Dr. Laham further noted that Cole received a complete "neurologic workup by Dr. Owen at that time." Id.

Multiple tests were conducted after Cole's admission, including: A CT scan taken of the brain on March 1, 2006, that was normal. P Ex. 6 at 187. A hematology report showed normal levels, with the exception of a high platelet count. Id. at 166. A body fluid analysis [CSF] of cerebrospinal fluid indicated a high protein count. Id. at 170. Cole's ammonia, lactic acid, and creatinine levels were found to be low. Id. at 171. A urine chemistry analysis indicated "a normal pattern of organic acids." Id. at 175. The impression from an x-ray of Cole's chest was "hazy interstitial hazy may indicate elements of edema, microatelectasis, and/or microaspiration. No lumbar consolidation." Id. at 186.

Dr. Michelle Papo examined Cole on March 2, 2006, in the PICU her impression was "[n]ew onset seizures, etiology unknown." P Ex. 6 at 163.

Cole was discharged by Dr. Laham on March 3, 2006, after having no further sezures for 36 hours. Id. at 141. Cole's diagnosis upon discharge was "[n]ew onset seizures." Id. Cole's

[6] Pediarix "is a combination product containing DTaP, hepatitis B, and inactivated polio vaccines." See Pediarix Vaccine: Questions and Answers at http://www.cdc.gov/vaccines/vpd-vac/combo-vaccines/pediarix/faqs-hcp-pediarix.htm (last visited July 11, 2012).

family was instructed to follow-up with neurologist Dr. Owen's office and Cole was prescribed phenobarbital to be given twice daily. Id.

Cole was examined by Dr. Owen on March 31, 2006, at Dallas Pediatric Neurology Associates, after Cole experienced another seizure during the night of March 30, 2006. P Ex. 13 at 8. The seizure Cole suffered on March 30, 2006, was the first Cole had experienced since his seizures suffered on March 1, 2006. Id. Dr. Owen indicated that Cole was 5 ½ months old and suffered from seizures with an unknown etiology. Id. Dr. Owen further indicated that there was "no concern about [Cole's] development" and that the "[f]amily was worried about next shots since [the March 1, 2006] seizures were 6 days after shots." Id. Dr. Owen recommended that further vaccinations be held off until Cole's seizures were "well controlled." Id. However, Dr. Owens impression was that "seizures 6 day[s] after shots **doesn't** strongly implicate shots." Id. (emphasis added).

Cole was seen by his pediatrician on April 25, 2006, for his 6 month well-child examination, his seizures, and a feeding problem. P Ex. 6 at 43-44. The pediatrician's records indicate that Cole was being followed by Dr. Owen, but that petitioner desired a second opinion from another neurologist. Id. Cole's pediatrician's records further document that immunizations were held off because of "seizures [at] [n]eurologist's request." Id.

On May 4, 2006, Cole was seen by a new neurologist, Dr. Anthony Riela, for a "second opinion concerning seizures." P Ex. 11 at 31. Dr. Riela noted that Cole's "neurological history begins in 3/06 . . . .[when Cole] had his first seizure." Id. Dr. Riela observed Cole have a seizure lasting two minutes after Cole awoke "from a nap that consisted of generalized tonic-clonic activity followed by post-ictal sleep." Id. An EEG was performed and was normal. Id. Dr. Riela's impression was "multiple generalized tonic clonic seizures in an otherwise normal infant despite phenobarbital treatment." Id. Dr. Reila planned with Cole's parents to admit him to the hospital the following day to "have his seizures reassessed." Id. Cole was admitted to the hospital the following day for "uncontrolled seizures" and a two day EEG was preformed. P Ex. 6 at 89, 98, 101, 109. Dr. Reila's impression of the EEG was "[a]bnormal" and he felt the EEG "support[ed] the diagnosis of seizures." Id. at 109.

Cole was seen by his pediatrician on May 23, 2006, for gastroesophageal reflux. P Ex. 6 at 43. During that visit Cole's pediatrician noted that he was behind on his vaccinations and further indicated that Cole's neurologist did **not** believe Cole's seizures were related to his vaccinations received at four months. Id. (emphasis added). It was noted that the vaccinations would be held off to determine whether Cole's new anti-seizure medication was effective. Id.

Cole saw a new pediatrician, Dr. Susan Smart, on July 26, 2006, for his nine month well-child visit. P Ex. 8 at 6, 8. Dr. Smart noted Cole had experienced no seizures for two months and was a well-child with seizures. P Ex. 8 at 6, 8. Petitioner testified that Cole suffered a seizure while sleeping on October 7, 2006. P Ex. 25 at 6; Transcript of December 6, 2011 Hearing at 15 ("Tr. at _"). On October 18, 2006, Dr. Smart saw Cole for his 12 month well-child visit during which he received a Pediarix vaccination. P Ex. 8 at 6, 7.

On October 28, 2006, petitioner called EMS. P Ex. 10 at 2. When EMS arrived Cole was still "actively seizing" and petitioner indicated he had been seizing for 25 minutes. Id. Cole's seizing "ceased" three minutes after the arrival of EMS and he was transported to Children's Medical Center. Id. A post-admission examination indicates that Cole had suffered a tonic-clonic seizure lasting 30 minutes and was transported to the ER, however he was not seen at the ER and went home. P Ex. 6 at 51; see also Tr. at 16-20. Cole suffered additional shorter seizures that same date and was admitted to the hospital to control his seizures. Id. at 51-52. Cole was admitted to the hospital with a temperature of 99.8 degrees Fahrenheit. Id. at 52. The medical records note Cole had recently received immunizations with no accompanying fever. Id. at 51. Cole received the following medications: Topomax, Pyridoxine, folinic acid, Clonazepam, and Foshenytoin at the hospital. Id. at 49. Cole was discharged on October 29, 2006, once he returned to "baseline," his final diagnosis was serial seizures with status epilepticus[7]." Id. at 51.

Cole was examined by Dr. Smart on October 30, 2006. P Ex. 8 at 4. Dr. Smart recorded that Cole suffered eight seizures on October 28, 2006. Dr. Smart reported Cole's mood "changed," his "eyes look droopy," and "at times [he] will start screaming." Id. Dr. Smart's assessment was that Cole suffered a "seizure – post vaccination" and planned to report the event to the Vaccine Adverse Events Reporting System ("VAERS"). Id.

On November 10, 2006, a VAERS report was submitted by Dr. Burton's, Cole's prior pediatrician, office noting Cole's February 22, 2006, vaccinations and his March 1, 2006, seizures.[8] P Ex. 15 at 2.

On December 4, 2006, Dr. Smart's records indicate that she spoke to petitioner, discussed the Vaccine Program, and agreed to write an affidavit. P Ex. 8 at 3. On December 28, 2006, Dr. Smart prepared a one page letter discussing Cole's seizures. P Ex. 9 at 1. Dr. Smart addressed the letter "To Whom It May Concern" and referenced a VAERS report number. Id. Dr. Smart provided a history of Cole's immunizations on February 22, 2006 and October 18, 2006, as well as his hospital admission for seizures on March 1, 2006, and October 28, 2006, and indicated that she found that "[t]he timing of both hospitalizations soon after the administration of the Pediarix vaccine is too coincidental." Id. Dr. Smart further indicated that she felt that the "vaccine may play a role in Cole's development of uncontrolled seizures" and that she was "reluctant" to administer additional "vaccinations due to the severity of Cole's seizure disorder." Id. Dr. Smart went on to detail the stress and heartache Cole's condition had placed on the family, as well as their "enormous" medical expenses, and indicated she felt "we should do everything in our power to help this family." Id.

[7] Status Epilepticus is defined as "1. a continuous series of generalized tonic-clonic seizures without return to consciousness, a life-threatening emergency. 2. any prolonged series of similar seizures without return to full consciousness between them; the two major types are convulsive s[tatus] epilepticus which is life threatening, and non-convulsive s[tatus] epilepticus." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1767 (32nd ed. 2012).

[8] The undersigned notes that while Dr. Burton references Cole's vaccinations received on February 20, 2006, P Ex. 15 at 2, it is clear this is a typographical error and Dr. Burton is referring to Cole's vaccinations received on February 22, 2006. See P Ex. 16 at 4-5; P Ex. 6 at 44.

Cole suffered further intermittent seizures thereafter. Cole's father, Scott Pacot, testified on December 6, 2011, that Cole had remained seizure free for the previous two years, although he suffers from developmental delays which his father testified Cole's doctors attribute to his seizures. Tr. at 51-52.

The undersigned notes that there is no disagreement between the parties regarding the facts, although the parties do disagree regarding the significance of petitioner's pre-natal twitching and "jerks" Cole experienced immediately subsequent to his birth and whether or not these events were the onset of Cole seizure disorder. Ultimately, the undersigned finds it is not necessary to resolve whether or not these events were part of Cole seizure disorder as the undersigned finds that in either event Cole's vaccinations were neither the substantial cause nor the significant aggravation of his injury as discussed below.

III. LEGAL STANDARD

In Vaccine Act cases, causation can be established either through the statutorily prescribed presumption of causation or by proving causation in-fact. For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions, which create a rebuttable presumption that the vaccine caused the injury or condition if they are found to occur within a prescribed time period. §14(a); 42 C.F.R. § 100.3. Petitioner has conceded her initially pled Table encephalopathy case fails for lack of a factual predicate supported by the medical records. P Memo at 6. The undersigned concurs, and so finds. Thus, petitioner must prove that the vaccination in-fact caused Cole's injury, a so-called "off-Table" case.

According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[9] To demonstrate entitlement to compensation in a causation in-fact case, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused or significantly aggravated the injury alleged. See, e.g., Bunting v. Sec'y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec'y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec'y of Dept. of Health & Human Servs., 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992); see also §§11(c)(1)(C)(ii)(I) and (II). To prevail, petitioner must produce "preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." Pafford v. Sec'y of Health and Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999)). The vaccination "must be a 'substantial factor'" in bringing about the injury, but "it need not be the sole factor or even the predominant factor." Id. at 1357 (quoting Shyface, 165 F.3d at 1352-53).

[9] A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 371-72 (1970)(Harlan, J. concurring)(quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

In Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit explained that petitioner's burden is to produce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury."

The evidence relating to these three prongs "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355. Petitioner must provide a "reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly v. Sec'y of Dept. of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2005); Broekelschen v. Sec'y of the Dept. of Health & Human Servs., 618 F.3d 1339, 1350 (Fed. Cir. 2010), reh'g en banc denied (Dec. 8, 2010). Petitioners do not satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")); Hodges v. Sec'y of the Dept. of Health & Human Servs., 9 F.3d 958, 960 (Fed. Cir. 1993). Also, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

Petitioners must support their proposed causation theory with a "sound and reliable medical or scientific explanation." Knudsen v. Sec'y of the Dept. of Health & Human Servs., 35 F. 3d 543, 548 (Fed. Cir. 1994).[10] As the Federal Circuit reiterated:

[10] The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "Daubert is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Sec'y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). See also Cedillo v. Sec'y of Dept. of Health & Human Servs., 617 F.3d 1328, 1338-39 (Fed. Cir. 2010)(approving the use of the Daubert factors in examining the reliability of expert testimony); Moberly v. Sec'y of Dept. of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010)(citing Daubert; approving of the use of the Daubert factors in determining expert reliability). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. In other words, the "testimony must be supported by appropriate validation – i.e., 'good grounds,' based on what is known." Id. Factors relevant to that determination may include, but are not limited to:

> Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication;

> Although Althen and Capizzano make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. See Daubert, 509 U.S. at 593-97, 113 S.Ct. 2786 (noting that one factor in assessing the reliability of expert testimony is whether the theory espoused enjoys general acceptance within a relevant scientific community). . . . Althen makes clear that a claimant's theory of causation must be supported by a "reputable medical or scientific explanation." 418 F.3d at 1278.

Andreu v. Sec'y of Dept. of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); see also Grant, 956 F.2d at 1148 ("A reputable or scientific explanation must support this logical sequence of cause and effect."). The Federal Circuit further explained in Andreu:

> The assessment of whether a proffered theory of causation is "reputable" can involve assessment of the relevant scientific data. Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard . . .

> whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995)(Kozinski, J.), on remand from, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 593. However, the Supreme Court has provided guidance to the lower courts in determining the reliability of a novel proposition:

> [S]ubmission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. (citation omitted). The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1280 (Fed. Cir. 2005)("the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."); see also, Gall v. Sec'y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

Andreu, 569 F.3d at 1380 (citing Bunting, 931 F.2d 867, 873 (Fed. Cir. 1991)). Proving causation in-fact by proving the Althen standards requires preponderant proof of each of the three prongs. de Bazan v. Sec'y of the Dept. of Health & Human Servs., 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); Moberly, 592 F.3d at 1315, 1322; Caves v. Sec'y of the Dept. of Health & Human Servs., 100 Fed. Cl. 119, 132 (Fed. Cl. 2011) aff'd per curiam, No. 2011-5108, slip op. (Fed. Cir. Feb. 14, 2012).

In this case, petitioner alleges that Cole's vaccinations "caused in fact" his injuries, however, petitioner argues "[i]n the alternative" that Cole's vaccinations caused him to suffer "an aggravation of a pre-existing condition." P Memo at 19. As explained by my colleague to demonstrate a significant aggravation claim petitioner must still establish the Althen causation factors, but must also establish the factors identified in Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099 (Fed. Cir. 1996). Raybuck v. Sec'y of Health & Human Servs., No. 06-846V, 2010 WL 4860778, at *12 (Fed. Cl. Spec. Mstr. Nov. 9, 2010).

> Thus, Petitioners must show (1) the person's condition before administration of the vaccine; (2) the person's current condition (or condition following vaccination); (3) whether the person's current condition constitutes "significant aggravation" of the person's condition before vaccination; (4) a medical theory causally connecting such a significantly worsened condition to the vaccination; (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation; and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Id., citing Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (Fed. Cl. 2009).

A finding that petitioners established their *prima facie* burden does not end the inquiry. The Act provides that a petitioner may not receive compensation "if the court finds by a preponderance of the evidence on the record as a whole 'that the illness, disability, injury, condition, or death described in the petition is due to **factors unrelated to the administration of the vaccine** described in the petition.'" Knudsen, 35 F.3d at 547 (citing §13(a)(1)(B))(emphasis in original); Walther v. Sec'y of the Dept. of Health and Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) ("[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a prima facie case.").

The question of a factor unrelated is not present in this case. Petitioner's case is measured against the above standards.

IV. DISCUSSION

Where "medical evidence [is] not definitive," the special master may rely heavily on expert medical testimony. Broekelschen v. Sec'y of the Dept. of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010). Expert medical testimony is particularly important in off-Table injury cases because "[t]he special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories." Id. (citing Lampe v.

Sec'y of the Dept. of Health & Human Servs., 219 F.3d 1357, 1361 (Fed. Cir. 2000)). "Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases." Moberly, 592 F.3d at 1325-26 (holding special masters "are entitled – indeed, expected – to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting the evidence"). However, in weighing the expert testimony, the special master may not "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." Andreu v. Sec'y of the Dept. of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009). This case is not about the credibility of the experts - but it is a case of qualifications, persuasiveness and reliability of the experts. On that score, respondent prevailed by a wide margin.

In this case, the undersigned relies heavily on the testimony of Dr. Snyder to resolve the underlying key issue of whether Cole's vaccinations were the cause in-fact of his seizure disorder or the significant-aggravation of a pre-existing seizure disorder. As discussed in detail below, petitioner's expert, Dr. Stanczak, was unable to provide a reliable medical theory connecting Cole's vaccines to his seizure disorder. Furthermore, respondent's expert, Dr. Snyder, persuasively rebutted every component of Dr. Stanczak's theory of vaccine causation. Given the opportunity, Dr. Stanczak declined to comment on Dr. Snyder's report, Tr. at 86, and deferred to a pediatric neurologist, such as Dr. Snyder, for the diagnosis, treatment, and etiology of seizure disorders. Id. at 90. Dr. Snyder convincingly explained why it was exceedingly unlikely that the vaccine was the cause of Cole's seizure disorder. Dr. Snyder's testimony simply outmatched that of Dr. Stanczak. Dr. Snyder, as an active pediatric neurologist who has examined thousands of patients with seizure disorders, offered coherent, cogent, and reliable testimony. As discussed below, Dr. Stanczak's testimony by contrast, was inconsistent, illogical, not supported by the medical records or any reliable scientific or medical evidence. Further, her testimony was not predicated upon any expertise in neurology, or pediatric neurology. Unfortunately for petitioner, Dr. Stanczak proved to be an ineffective expert witness. In contrast, Dr. Snyder was highly persuasive.

a. Experts

i. Petitioner: Dr. Cheryl Stanczak

Cheryl Stanczak, D.O, expert for the petitioner, is a practicing pediatrician at Mountain View Pediatrics in Marion, VA, although she also practices in offices located in other states. Tr. at 58. Dr. Stanczak sees patients for general pediatric needs and also special needs. Id. at 59. Dr. Stanczak is also the Owner and President of Osteopathic Consultative Services of Appalachia. P Ex. 40 at 2. Previously, Dr. Stanczak has held numerous academic positions as a clinical instructor and adjunct professor in the area of pediatrics, primarily at the University of Texas. Tr. at 60-61. Dr. Stanczak has served as the Chair of the Department of Pediatrics at the Edward Via Virginia College of Osteopathic Medicine. P Ex. 40 at 2; Tr. at 59.

Dr. Stanczak holds a Doctor of Osteopathy[11] from the Texas Young College of Osteopathic Medicine. P Ex. 40 at 1; Tr. at 60. Dr. Stanczak completed her pediatric internship and residency at Children's Medical Center in Dallas, Texas. P Ex. 40 at 1; Tr. at 60. Dr. Stanczak is board certified by the American Board of Osteopathic Pediatrics. P Ex. 40 at 1. Dr. Stanczak has presented lectures, held many professional memberships, including leadership positions within these memberships, and has been the recipient of multiple awards throughout her professional career. P Ex. 40 at 2-5.

Dr. Stanczak testified as an expert in pediatrics and osteopathic medicine without objection. Tr. at 62-63.

ii. Respondent: Dr. Russell D. Snyder

Respondent presented the expert testimony of Russell D. Snyder, M.D. Presently, Dr. Snyder is an Emeritus Professor of Neurology at the University of New Mexico School of Medicine. R Ex. B at 2. Dr. Snyder sees clinic patients two days a week. Tr. at 123-24. Dr. Synder has been with the University of New Mexico School of Medicine since 1967 and served as an associate professor, assistant professor, and professor of pediatrics and neurology. R Ex. B at 1- 2. Dr. Synder has also served as the University's Director of the Division of Pediatric Neurology and the Director of Neuromuscular Clinic. Id.

Dr. Synder received a Doctor of Medicine from the University of Pennsylvania. He completed his internship at Bryn Mawr Hospital, and his completed residency in the areas of general practice, pediatrics, and as a special fellow in pediatric neurology at the University of Colorado. R Ex. B at 1. Dr. Snyder is board certified in pediatrics, neurology, and neurology with a special competence in child neurology. Id. at 2.

Dr. Snyder has served on the editorial boards of the following publications: Journal of Child Neurology, Neurology, and Neurological Therapeutics: Principles and Practice. R Ex. B at 4. Dr. Snyder currently sits on the editorial boards of the journals of Pediatric Neurology and Current Pediatric Reviews. Id. Additionally, Dr. Snyder has published extensively in his areas of professional expertise throughout his career. Id. at 5-16. Dr. Snyder has also held multiple professional memberships, including leadership positions within these memberships. Id. at 2-4.

Dr. Snyder has treated thousands of patients with seizure disorders and epilepsy during his career. Tr. at 124-25. He has also "train[ed] medical students in the treatment and diagnosis of seizure disorder." Id. at 124. Dr. Snyder testified as an expert in pediatric neurology and in general pediatrics without objection. Id. at 125-26.

b. Expert Testimony Concerning Causation

[11] Osteopathy is defined as "a system of therapy founded by Andrew Taylor Still (1828-1917), based on the theory that the body can make its own remedies against disease and other toxic conditions when it is in normal structural relationship and has favorable environmental conditions and adequate nutrition. It uses generally accepted physical, medicinal, and surgical methods of diagnosis and therapy, while placing chief emphasis on maintenance of normal body mechanics and on manipulative methods of detecting and correcting faulty structure." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1347 (32nd ed. 2012).

i. Althen Prong One: Petitioner was unable to provide a reputable medical or scientific explanation of how the DTaP vaccine can cause or significantly aggravate Cole's seizure disorder

The first prong of Althen requires preponderant evidence of a "medical theory causally connecting the vaccination and the injury." This requirement has been referred to as the "can cause" prong: can the vaccine cause the alleged injury. Pafford v. Sec'y of the Dept. of Health & Human Servs., No. 01-165V, 2004 WL 1717359 (Fed. Cl. Spec. Mstr. 2004), aff'd 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). To meet the first prong of Althen, petitioner "must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly, 592 F.3d at 1322 (citing Knudsen, 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Broekelschen, 618 F.3d 1339, 1345 (Fed. Cir. 2010). Petitioner's proof cannot merely establish a "plausible" or "possible" causal link between the vaccine and the injury; the proof must meet the statutory standard of preponderance. Moberly, 592 F.3d at 1322; see also Caves, 100 Fed. Cl. at 132, 144.

Dr. Stanczak opined Cole's vaccines were the cause in-fact of his seizure disorder or alternatively that his vaccines significantly aggravated a pre-existing seizure disorder. Tr. at 85-7.[12] Dr. Stanczak further testified it was her opinion that the DTaP component of the Pediarix vaccine that was responsible for Cole's condition. Id. at 85. To support this opinion Dr. Stanczak testified, when asked the significance of Cole vaccines in relation to his seizures, that "the more vaccines [Cole] received, that particular one [Pediarix] in general, the worse his seizures became." Tr. at 68. Dr. Stanczak testified that Cole might have had a type of "hypersensitivity" response to his vaccinations called an Arthus reaction.[13] Dr. Stanczak averred that "an Arthus reaction []can take days to months to weeks to actually have any kind of reaction on a human that's having that reaction." Id. at 71. Dr. Stanczak opined that "[t]he more you are exposed to a certain foreign protein, the more likely you are to have a bad reaction, and that reaction can occur never, or it can occur three weeks later, or it can occur months later." Id. at 72. Dr. Stanczak further testified that people have

[12] The undersigned notes that Dr. Stanczak's opinion regarding whether or not Cole's vaccinations caused an aggravation of a pre-existing condition has wavered throughout the course of this claim. Dr. Stanczak's initial report contemplated that the vaccines aggravated Cole's pre-existing condition. P Ex. 24 at 3. However, Dr. Stanczak made it unequivocally clear in her second report this case is not a significant aggravation claim, as Cole did not suffer a pre-existing condition. P Ex. 34 at 1-5. Ultimately, Dr. Stanczak simply stated "yes" to counsel's question on whether she believed Cole could have suffered a significant aggravation of his condition. Tr. at 86. Dr. Stanczak did not expand on this answer.

[13] An Arthus reaction is defined as "the development of an inflammatory lesion, with induration, erythema, edema, hemorrhage, and necrosis, a **few hours** after intradermal injection of antigen into a previously sensitized animal producing precipitating antibody; it is classed as a type III hypersensitivity reaction in the Gell and Coombs classification of immune responses. The lesion results from the precipitation of antigen-antibody complexes, which causes complement activation and the release of complement fragments that are chemotactic for neutrophils; large numbers of neutrophils infiltrate the site and cause tissue destruction by release of lysosomal enzymes. Called also Arthus phenomenon." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1598 (32nd ed. 2012) (emphasis added).

> . . . antigen-antibody complexes, and this is, in fact, how vaccines work anyway. We are injected with something that could make us sick, and our body reacts to it, causing these antibody antigen complexes. And when you take a little bit of that vaccine over time, you develop the ability to not have those complexes make you sick.

Id. at 77. Dr. Stanczak averred that in some people "these complexes bond[] to blood vessels on the inside, and as a result causes inflammation. It can block the blood vessels. . . . cause vasculitis . . . [a]nd as a result, it causes decreased oxygenation because your vessels are clogged." Id. Dr. Stanczak indicated that this can result in the incapability for "organs to get oxygenated." Id. Dr. Stanczak testified that based on the length of time between Cole's vaccinations and his post-vaccination seizures she believed Cole could have experienced an Arthus reaction subsequent to his vaccinations. Id. at 72-73, 81. Dr. Stanczak summarized her theory as follows:

> This child did not have any documented scientific evidence of seizures until after he had immunizations, because he had an EEG in the newborn nursery that was normal. He had another EEG that was normal, and the rest of them were abnormal, after he received two sets of vaccinations. My theory was and still is that if you have enough inflammation from an Arthus reaction or some kind of hypersensitivity reaction to one of the foreign proteins in the vaccines, that you can develop enough hypoxia and enough inflammation to have seizures.

Tr. at 82. Unfortunately for petitioner, Dr. Stanczak was unable to provide any reliable evidence to support her theory. The literature filed by petitioner to support Dr. Stanczak's theory either discussed the DTP vaccine, or did not speak to her theory of causation at all.[14] Id. at 69-70. Cole did not receive the DTP vaccine; he received the Pediarix immunization which includes the

[14] See P Ex. 28, Rosalia C. Silvestri-Hobson, Abnormal Neonatal EEG, http://emedicine.medscape.com/article/1139692-overview (Nov. 25, 2008) (Dr. Stanczak failed to indicate how this article supported her theory of vaccine causation in this case.); P Ex 28, Pediarix Prescribing Information at 16 (Dr. Stanczak relies, in her expert reports, on the package insert for support as it indicates that "seizures without fever were noted to occur after the administration of Pediarix. No seizures without fever were noted to occur in patients who received the same vaccine components, only in separate injections, at the same visit." P Ex. 24 at 3; Ex 35 at 2. However, Dr. Stanczak fails to explain how this information supports vaccine causation in this case. As explained by Dr. Snyder studies performed for the package insert are safety studies and "those studies had no control groups that they could be compared to for just seizure frequency during that period of time." Tr. at 145); P Ex. 35, Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines, 67-9 (1991) (Discusses studies of infantile spasms following pertussis vaccines. In particular the Millichap study which Dr. Stanczak relies upon in her second report, P Ex. 34 at 2, and testimony Tr. at 72-5, found that "the time interval from immunization to onset of spasms was from 6.5 hours to 5 days" and listed "delayed cellular hypersensitivity reaction" as a "postulated mechanism for pertussis-related seizures." The undersigned notes, as discussed below, this excerpt from the 1991 IOM report and the Millichap study discussed within the IOM report pertain to the whole cell pertussis vaccination and not the acellular pertussis vaccine which was contained in the Pediarix immunizations received by Cole.).

DTaP vaccine. Dr. Stanczak conceded these are two different vaccinations — the DTP contains pertussis, the DTaP does not — and agreed "that studies of the pertussis vaccine should [not] be applied to the acellular pertussis vaccine."[15] Id. at 70. Dr. Stanczak indicated on cross-examination that she does not know of any studies that support "that an acellular pertussis vaccine can cause an Arthus reaction or continued Arthus reaction." Id. at 107.

Further there is simply no evidence in the record that Cole suffered an Arthus reaction, aside from Dr. Stanczak's testimony that he "could" have suffered this type of inflammatory reaction. Dr. Stanczak herself conceded testing was not performed to identify if Cole suffered any generalized inflammation post vaccination, nor does it appear from the records that an Arthus reaction was even contemplated by his treating medical care providers. Tr. at 79. Dr. Stanczak's testimony on this issue was extremely confusing. She stated that inflammation in the blood vessels was the precipitator of harm. Id. at 77. But there was no evidence of inflammation. Id. at 78. When asked what evidence exists of the Arthus reaction she reasoned backwards that the seizure following immunization which **could** be caused by an Arthus reaction is the evidence of the Arthus reaction. Id. at 80. But she conceded that there is no evidence in the record to support this theory. Id. When asked if she was giving an opinion that more probably than not that the Arthus reaction explains the seizures following immunization, Dr. Stanczak responded:

> It would be extremely difficult to prove, but I think that in theory, I think that could very likely happen. I would say yes, that's probably what happened.

Id. at 81. However, after giving this opinion, Dr. Stanczak was forced to concede yet a second time that there is no documented evidence of an Arthus reaction. Id. Dr. Synder agrees. Tr. at 143-44. (Dr. Snyder indicates Dr. Stanczak's theory is not biologically possible as an Arthus reaction occurs "within hours of immunization."). Her testimony on this issue was most unconvincing. Dr. Stanczak's theory is neither supported by the medical records nor the literature.

On cross-examination Dr. Stanczak testified "for me the temporal issue is important. He had some activity in the newborn nursery which was documented by the clinical personnel and by a physician. And then he received his immunizations, this occurred again . . . . To me that's significant for this child having some sort of environmental change that could have possibly made his seizures worse, more violent." Tr. at 99. The Federal Circuit has rejected this very formulation of evidence. In Moberly, the Federal Circuit characterized the essence of the evidence before the special master as follows:

> [The vaccinee] was healthy before she received her second DPT vaccination; she suffered seizures within 36 hours of receiving the vaccine; DPT is capable of causing seizures and permanent brain damage; and no alternative cause of her condition has been identified.

[15] Acellular pertussis and is less virulent than the previously administered pertussis vaccine, as explained by Dr. Snyder : "acellular pertussis has many of the toxic elements removed, and it is thought to be much safer than the previous form of the pertussis which was not acellular. The previous form had many dirty components to it." Tr. at 151.

Moberly, 592 F.3d at 1323.

The Circuit affirmed the special master's denial of compensation based upon the insufficiency of this proof, noting, as did the special master, that the "problem with that evidence is that it amounts at most to a showing of temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury." Id. That formulation of proof proffered by petitioner in this case – a literal temporal relationship, plausible connection between vaccines and seizures, and absence of other causes – is the same considered and rejected in Moberly, and accordingly must likewise be rejected by the undersigned.

In addition, even if petitioner's formulation of proof was sufficient — which it is not — petitioner's evidence lacks reliability and thus is rejected. See id. at 1324 ("the special master is entitled to require some indicia of reliability to support the assertion of the expert witness"). While Dr. Stanczak is a qualified pediatrician, her testimony on vaccine causation was very weak, was not supported by the record or medical literature, and was conclusively rebutted by Dr. Snyder's cogent testimony. Dr. Snyder has extensive experience with pediatric neurology, he has treated thousands of patients with seizures disorder, is familiar with vaccine injuries and his testimony exhibited that vast knowledge and experience.

Dr. Snyder testified that it was his opinion based on a review of the record in this case, the testimony presented, and his own expertise that Cole's vaccinations on February 22, 2006, and October 18, 2006, did not cause him to suffer a seizure disorder. Tr. at 127. Dr. Snyder testified that Dr. Stanczak's theory of causation involving an Arthus reaction was not biologically plausible. Tr. at 143. Dr. Snyder explained "[t]he Arthus reaction tends to be a local reaction. You produce an abscess in an animal model, and it tends to occur within hours of immunization, not days later, when it occurs in immunization. . . . It also has lab tests. . . ." Id. at 144.

Dr. Snyder opined that Cole suffered seizures prior to his immunizations in utero and then for six weeks subsequent to his birth as described in the medical records.[16] Id. at 127-136. Dr. Snyder testified that it was his opinion that Cole's seizure disorder was possibly caused by a pyridoxine dependency. Id. at 139-140. More significantly, Dr. Snyder testified there is no evidence that vaccines cause epilepsy, nor is it "generally accepted in the medical literature that acellular-pertussis containing vaccines cause afebrile seizures. Id. at 142. Dr. Snyder further testified if he was Cole's physician he would recommend that Cole complete his vaccination schedule, because vaccinations "are safe" and Cole's seizures were caused by other reasons. Id. at 143.

[16] While it appears from the medical records that Cole's treating physicians diagnosed and treated Cole for seizures prior to his immunizations, the undersigned does not find it necessary to resolve whether or not these events were part of Cole's seizure disorder, because regardless, the undersigned finds that petitioner has not demonstrated that Cole's vaccinations caused or significantly aggravated his seizure disorder.

As previously stated, "[w]eighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases." Moberly, 592 F.3d at 1325. The undersigned finds that petitioner's expert, Dr. Stanczak, while a knowledgeable pediatrician, was not able to put forth a persuasive and reliable medical theory causally connecting Cole's vaccinations to his seizure disorder. The Federal Circuit has made it clear that the proposed theory of causation must be shown to be "at work" in the case presented. Id. at 1324; see also Broekelschen, 618 F.3d 1339, 1345 ("[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to petitioner's case."). As in Moberly, even assuming that Dr. Stanczak's theory of an Arthus reaction causing seizures was found reliable, Dr. Stanczak made no showing that the "proposed mechanism was at work" in Cole's case. Moberly, 592 F.3d at 1325. That is, Dr. Stanczak was unable to substantiate her proposed medical theory for the vaccines causing an Arthus Reaction or inflammation, or the Arthus reaction or inflammation causing Cole's seizures. In addition to petitioner's defective proof, Dr. Snyder persuasively testified, based on his expertise that an Arthus reaction "occurs within hours of immunization, not days later." Tr. at 144, 146. Nothing in the record supports an Arthus reaction or any inflammatory response to the vaccinations. As in Moberly, there is no evidence in this case "suggesting" that the Arthus reaction theory applied to Cole's case, and therefore it must be rejected as unproven.

In conclusion, based upon the above testimony, the medical records, and other evidence submitted, the undersigned finds that petitioner has failed to meet her *prima facie* burden of providing a "medical theory causally connecting the vaccination and the injury." Dr. Stanczak's theory of an Arthus reaction causing seizures was not established to any degree of reliability and was effectively rebutted by Dr. Snyder's persuasive testimony. Further, there was no evidence showing that the theory of an Arthus reaction "was at work" in Cole. Moberly, 592 F.3d at 1324. Accordingly, it is found that petitioner failed to meet by preponderant evidence Prong I of Althen.

Since petitioner has failed prong I of Althen, the discussion of prong II is not necessary since finding that the vaccine could not cause the injury, it follows that the vaccine did not cause the injury. See Moberly, 592 F.3d at 1322; Broekelschen, 618 F.3d at 1345-46 ("causation is relative to the injury," and the theory must pertain specifically to the petitioner's case). However, the undersigned will briefly discuss how petitioner has also failed Althen prong II and prong III.

ii. Althen Prong Two: Petitioner is unable to prove that Cole's vaccinations caused or significantly aggravated his seizure disorder

The second prong of Althen requires preponderant evidence of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." This prong is sometimes referred to as the "did cause" test: in petitioner's case, did the vaccine cause the alleged injury. Pafford v. Sec'y of the Dept. of Health & Human Servs., No. 01-165V, 2004 WL 1717359 (Fed. Cl. Spec. Mstr. 2004); see also Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("Because causation is relative to the injury, a petitioner

must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case…"). Petitioner must show that the vaccine was the "but for" cause, or in other words, "the vaccine was the 'reason for the injury.'" Pafford v. Sec'y of the Dept. of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006).

Applying Dr. Stanczak's theory specifically to Cole's clinical presentation, as previously discussed one sees Cole's medical records are devoid of signs of an Arthus reaction or inflammation to support Dr. Stanczak's theory. Specifically, as Dr. Stanczak agreed on cross-examination, typically evidence of an Arthus reaction is supported by inflammation at the injection site. Tr. at 107. In this case there is no record of an Arthus reaction or injection site inflammation noted in Cole's post-vaccination records, id. at 107, nor is there any indication that Cole's treating physicians suspected a possible Arthus reaction as Dr. Stanczak conceded. Id. at 79 ("I did not see it anywhere."). In addition, as discussed in the Althen Prong I analysis above, in rebuttal to Dr. Stanczak's testimony, Dr. Snyder opined that if an Arthus reaction were to have occurred post vaccination it would occur "within hours of immunization, not days later." Id. In this instant case, Cole's seizures post-vaccination occurred more than week after his October 2006 and February 2006 vaccinations.

It is also important to note that the fact that the opinion letter of Cole's treating doctor, Dr. Smart, is offered as important and highly relevant evidence, but it is not determinative evidence. As discussed above, Dr. Smart's December 28, 2006, "To Whom It May Concern" letter provided a history of Cole's immunizations on February 22, 2006, and October 18, 2006, as well as his hospital admission for seizures on March 1, 2006 and October 28, 2006, and indicated that she found that "[t]he timing of both hospitalizations soon after the administration of the Pediarix vaccine is too coincidental." P Ex. 9 at 1. Dr. Smart further indicated that she felt that the "vaccine may play a role in Cole's development of uncontrolled seizures" and that she was "reluctant" to administer additional "vaccinations due to the severity of Cole's seizure disorder." Id. Dr. Smart went on to detail the stress and heartache Cole's condition had placed on the family, as well as their "enormous" medical expenses, and indicated she felt "we should do everything in our power to help this family." Id.

The Federal Circuit has noted the importance of treating physicians in vaccine cases. In Andreu v. Sec'y of the Dept. of Health & Human Servs., the Federal Circuit reaffirmed that the testimony of treating physicians is "quite probative" **"[i]f a claimant satisfies the first and third prongs of the Althen standard"** because "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." Andreu, 569 F.3d 1367, 1375 (emphasis added) (quoting Capizzano v. Sec'y of the Dept. of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006)(remanding decision to special master to reevaluate the second prong of Althen concerning the opinions of the treating physicians who concluded that the vaccine was the cause of the petitioner's injury)). In this case, petitioner failed to establish either the first or third prongs of Althen. In addition, the Court of Federal Claims has cautioned against reflexively accepting the statements of treating doctors because "there is nothing in Andreu that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted." Snyder v. Sec'y of the Dept. of Health & Human Servs., 88 Fed. Cl. 706, 746 n. 67 (Fed. Cl. 2009). As found above under the Althen prong one analysis, petitioner failed

to prove by preponderant evidence a reliable medical theory of how the vaccinations could cause Cole's seizures. Dr. Smart's opinion letter and other medical record notes, in essence, amount to the observation of a literal temporal relationship between the vaccines and the post-vaccinations seizures as "too coincidental." P Ex. 9 at 1. There is no discussion of how the vaccine could cause the seizures or did cause Cole's seizure disorder. This reasoning, in isolation, has been consistently and repeatedly rejected by the Federal Circuit. E.g., Moberly, 592 F.3d at 1323 ("As this court has stated, 'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'") (citing Althen, 418 F.3d at 1278)).

Additionally, Cole's treating neurologists indicated that they did not ascribe to the theory that Cole's vaccinations played a likely role in his seizures. Dr. Owen indicated that Cole suffered from seizures with an unknown etiology and noted his opinion that Cole's "seizures 6 day[s] after [the February 22, 2006] shots doesn't strongly implicate shots." P Ex. 13 at 8. While Dr. Owen recommended that further vaccinations be held off until Cole's seizures were "well controlled," such recommendation does not speak to causation, but as seen in numerous other cases, is a precautionary measure. P Ex. 13 at 8. Dr. Reila's impression after his first consultation on Cole was "multiple generalized tonic clonic seizures in an otherwise normal infant despite phenobarbital treatment." P Ex. 11 at 31. And while petitioner testified that Dr. Reila indicated "it was a possibility" [that the vaccines caused his seizure disorder] he recommended Cole continue to be vaccinated. Tr. at 31. There is nothing in Dr. Reila's records ascribing a causative role to the immunizations.

The clinical evidence does not support Dr. Smart or Dr. Stanczak's opinion, no medical literature supports their opinions and their opinions were persuasively rebutted by testimony of Dr. Snyder a pediatric neurologist, as well as the medical records of petitioner's treating pediatric neurologist Dr. Owen. In these circumstances, there exist good reasons to not rely on the treating pediatrician, Dr. Smart, or petitioner's expert pediatrician, Dr. Stanczak.

Accordingly, the undersigned finds that petitioner failed to provide preponderant evidence that the vaccines did cause or significantly aggravate Cole's seizures and thus failed to meet Althen's prong two.

iii. Althen Prong Three: Petitioner was unable to establish the injury or the significant aggravation of the injury occurred within a time frame that comports with petitioner's medical theory of causation

The third prong of Althen is "showing of a proximate temporal relationship between the vaccination and injury." The Circuit explained that meeting this prong "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation in-fact." de Bazan v. Sec'y of the Dept. of Health & Human Servs., 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); see also Althen, 418 F.3d at 1278; Pafford, 451 F.3d 1352, 1358.

The petitioner has the burden of proof. While petitioner was able to show a literal temporal association, the petitioner offered no evidence of a **medically-accepted** temporal relationship between the vaccination and the alleged injury. Pafford, 451 F.3d at 1358; see also de Bazan, 539 F.3d at 1352. Dr. Stanczak testified that

> for me the temporal issue is important. He had some activity in the newborn nursery which was documented by the clinical personnel and by a physician. And then he received his immunizations, this occurred again . . . . To me that's significant for this child having some sort of environmental change that could have possibly made his seizures worse, more violent.

Tr. at 99. Dr. Snyder, however, testified against a medically accepted temporal relationship, opining

> I'm sure they [the vaccinations] didn't implicate it [the seizure disorder] because of the interval between the immunization and the seizure, which with one of the immunizations was eight days and with another one, was ten days, and that's long for any sort of problem from the immunization.

Tr. at 141. When asked directly if eight days, the period of time between Cole's February 22, 2006 vaccinations and his March 1, 2006 seizures, would "be a medically appropriate temporal association between an acellular pertussis vaccination and the onset of seizures" Dr. Snyder opined, "[n]o. When it occurs it is usually much shorter." Tr. at 145-46. Dr. Synder elaborated "if there was a neurotoxin in the immunization, it would manifest immediately. If there was an allergic reaction, those also occur very quickly. Even the Arthus reaction is within hours of immunization." Id. Likewise, Dr. Snyder testified that the periods of ten and eight days (the periods of time between Cole's vaccinations on February 22, 2006 and October 18, 2006 and his post-vaccination seizures on March 1, 2006 and October 28, 2006) is too long a timeframe to support a significant aggravation. Id. at 147.

Further, Dr. Stanczak conceded on cross-examination that there is nothing in the submitted medical literature or any literature that she is aware of that indicated an acellular pertussis vaccination can cause a seizure eight to ten days after vaccinations.[17] Id. at 104. Dr. Stanczak also agreed that Dr. Owens, one of Cole's treating neurologists "did not find the temporal association particularly important." Id. at 106.

The undersigned notes that Dr. Stanczak's testimony on the onset of Cole's seizures was incredibly confusing. Initially, Dr. Stanczak testified that Cole's seizure on March 1, 2006,

[17] In fact the literature submitted by Dr. Stanczak indicates that "seizures occurred within 48 hours of temporally related pertussis-containing vaccines." Tr. at 104. While the undersigned recognizes that studies pertaining to pertussis-containing are not applicable to acelluar pertussis vaccinations, this is a significantly shorter period of time than the eight to ten days Dr. Stanczak testifies to as temporally appropriate in this case.

seven days[18] after Cole's February 22, 2006 vaccinations, "was a first evidence of seizure activity that was witnessed by the parents." Tr. at 67. Dr. Stanczak then testified that the May 2006 seizures recorded on EEG was "the first medical documentation of seizure activity." Id. Later, Dr. Stanczak agrees she testified that Cole's first seizure occurred on March 1, 2006, indicating that was "the first time it is medically, clinically documented with scientific evidence." Tr. at 110. When the undersigned pointed out that this was inconsistent with her report she indicated "[t]hat's my mistake I read my notes wrong, because the first medical documentation was in May." Id. at 111. Despite the lack of medical documentation, i.e. an EEG, Dr. Stanczak then opines that "more probably than not, it was a seizure that was seen on March 1[, 2006]." The undersigned pointed out to Dr. Stanczak that she had testified that the events Cole experienced prior to the February 22, 2006 immunizations were not seizures, despite having been only clinically documented like the March 1, 2006 event. Id. at 112-13. In follow-up the undersigned inquired "why is the March 1[, 2006] one a seizure?" Id. at 113. Dr. Stanczak changed her position again, indicating "I'm not sure I said that . . . there was no medical documentation of any seizure activity until May." Id. At this point Dr. Stanczak changes her testimony and dismisses the March 1, 2006, event as a seizure agreeing that she "was mistaken on that," id. at 114, and explaining that she would not recognize a seizure until there was scientific evidence of seizure activity; clinical evidence and documentation was not sufficient in her opinion to support a seizure diagnosis. Tr. at 113-16.

Dr. Stanczak then testifies that Cole's first "medically documented" seizure was not the March 1, 2006, clinically noted seizure, but was instead the May 5, 2006, recorded seizure, because in her opinion "unless you have a positive EEG, I think you can't say [Cole had] a seizure disorder." Tr. at 116. Amazingly, Dr. Stanczak maintained that the February 22, 2006, vaccination was temporally associated with the May 2006, seizures which occurred more than two months following the immunizations. Id. at 115-16. Dr. Stanczak's testimony on this point was so dubious and obviously unreliable, it undermined the totality of her testimony and was a stark exhibition of her lack of knowledge in the field of neurology. This even further protracted onset of two months is not supported by any evidence other than the ipse dixit of Dr. Stanczak. The undersigned further notes that Dr. Stanczak agreed however that she would defer to a pediatric neurologist the "treatment of seizure disorders," the "diagnosis of seizure disorders," and "etiology of seizure disorders." Tr. at 90. Dr. Snyder, a pediatric neurologist, testified that an EEG is not necessary to diagnosis a seizure disorder, that "the clinical statement that diagnoses the seizure" as "the standard medical practice," Id. at 132, and that, as supported by the medical literature, an EEG is often unable to pick-up a seizure. Id. at 137-38 citing R Ex F, Brunquell et al, Prediction of outcome based on clinical seizure type in newborn infants, 140 The Journal of Pediatrics, Vol. 6, 707 (June 2002).

The record is devoid of reliable evidence from petitioner of an appropriate medical timeframe for the onset of Cole's seizures. Accordingly, based upon Dr. Snyder's cogent testimony and the absence of reliable testimony from Dr. Stanczak concerning the medically-accepted temporal relationship between the vaccine and the injury, the undersigned is unable to

[18] The undersigned notes that during the course of the hearing the parties and their experts referred to the period of time between Cole's February 22, 2006 vaccinations and March 1, 2006 seizure as eight days; Dr. Owen categorized this same period of time as six days, P Ex. 13 at 8; the undersigned calculates it as seven days, which excludes March 1, 2006.

find petitioner proffered preponderant evidence concerning the medically appropriate timeframe connecting Cole's vaccinations with the onset of his seizure disorder or the significant aggravation of his condition. Petitioner failed to prove prong three of Althen.

c. Petitioner's Arguments

The undersigned has reviewed petitioner's post-hearing briefs and does not find petitioner's arguments persuasive. For example, petitioner argues in her post-hearing brief that Dr. Stanczak's testimony and expert reports discussing the medical records and literature, "ties it all up and scientifically and affirmatively show, with medical certainty, that there is a causal nexus between Cole injuries and the vaccine he received." P Memo at 18. The undersigned disagrees. As an initial mater, the undersigned points out that it is not necessary that petitioner prove her case to a degree of medical certainty. Petitioner must provide a "reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly, 592 F.3d at 1322; Broekelschen, 618 F.3d at 1350. However, as discussed above petitioner has wholly failed to satisfy the Althen three prong test and offered no convincing evidence that Cole's seizures and sequelae were more likely than not caused by his vaccinations or significantly aggravated by his vaccinations. In summary, as discussed above:

- Dr. Stanczak's theory of causation was not supported by the medical record, the medical community, or the scientific literature;
- Dr. Stanczak *conceded* that neither the medical literature nor the medical community supports the proposition that the acellular pertussis vaccine can cause afebrile seizures;
- Dr. Stanczak's theory that Cole suffered an Arthus reaction leading to his seizures is not supported by any evidence in the record;
- Cole's post-vaccination seizures did not have a medically acceptable temporal relationship to his vaccinations (Dr. Snyder a pediatric neurologist persuasively testified that the period of time between Cole vaccinations and his seizures was too short to implicate the vaccinations as a potential cause.); and
- Dr. Stanczak's testimony that an Arthus reaction would explain the delay in time between Cole's vaccinations and subsequent seizures was persuasively rebutted by Dr. Snyder's testimony that an Arthus reaction occurs within hours and not days of vaccination.

The undersigned agrees with respondent, petitioner's theory was "unreliable, fit the facts like a square peg in a round hole, and the time frame was medically unacceptable and unsupported by reliable medical evidence." R Memo at 21. In the final analysis, petitioner's case fails for lack of any reliable support — the clinical evidence, the medical literature, the treating neurologists, and the ineffective and unpersuasive testimony from Dr. Stanczak fail to support petitioner's claim.

Lastly, petitioner argues "that Cole at a minimum, suffered an aggravation of a pre-existing condition as a result of his [February and October 2006] vaccines." P Memo at 19. Petitioner argues that the undersigned should analyze petitioner's significant aggravation claim under the standard set forth in the Whitecotten decision. Id. at 19-20. However, the Whitecotten case involves the significant aggravation of a Table Injury. Petitioner has conceded she cannot

demonstrate a Table Claim. P Memo at 6. As previously discussed, the Court of Federal Claims in Loving provided a framework for considering significant aggravation claims in off-Table claims blending the tests in Whitecotten and Althen.

> Petitioners must show (1) the person's condition before administration of the vaccine; (2) the person's current condition (or condition following vaccination); (3) whether the person's current condition constitutes "significant aggravation" of the person's condition before vaccination; (4) a medical theory causally connecting such a significantly worsened condition to the vaccination; (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation; and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Raybuck, 2010 WL 4860778, at *12 citing Loving, 86 Fed. Cl. 135, 144. The undersigned has discussed above at length why petitioner has not demonstrated the Althen factors in relation to either Cole's vaccinations and injury, or alternatively Cole's vaccinations and the significant aggravation of his injury. Accordingly, since petitioner has failed to establish prongs 4-6 of the Loving test (the Althen factors) it is not necessary to discuss the first 3 Loving prongs. However, assuming petitioner did suffer a seizure disorder prior to his February and October 2006 vaccinations, the undersigned finds that petitioner has not established that Cole's condition was significantly aggravated by his vaccinations. While petitioner testified that Cole did not develop as quickly as her other children, and that subsequent to his October 28 seizures Cole had difficulty crawling for a "week or two," this testimony does not constitute reliable medical evidence that his vaccinations significantly aggravated a pre-existing seizure disorder. See Tr. at 164-65; § 13(a) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."). Further, as Dr. Snyder explained: "aggravation has to do with a long-term course of events" and there is no evidence regarding Cole's "milestones being lost at the time of immunizations" or a decline in functioning." Tr. at 155-56. Dr. Snyder testified as a treating pediatric neurologist who has treated thousands of patients with seizure disorders that Cole's clinical history is "consistent with neonatal seizures who often have unfavorable outcomes" and that there are "no signs of aggravation" and as a treater if he examined Cole he would have no reason to believe that Cole's vaccinations altered the course of his condition. Id. at 148. Dr. Stanczak provided no meaningful testimony on the issue of significant aggravation. Petitioners' claim of significant aggravation was not developed or substantiated. As stated earlier, Dr. Stanczak stating conflicting positions regarding the issue of aggravation in her two expert reports. P Ex. 24 at 3 ("The argument may be made that repeated exposure to the vaccine caused a gradual, cumulative aggravation of the preexisting seizure disorder.); P Ex. 34 at 4("In summary since there is no scientific evidence of a preexisting seizure disorder, the can be no argument for 'aggravation' of a condition that cannot be proven to have ever existed."). At most, this claim appears to be counsel's effort to make any conceivable argument on behalf of his client, which is understandable. However, medical support for the claim is severely lacking and Dr. Snyder's convincing testimony forecloses even the consideration of significant aggravation. Accordingly, any claim for significant aggravation is rejected.

IV. CONCLUSION

In conclusion, based on the record as a whole, and as discussed above, the undersigned finds that petitioner has failed to meet her burden of proof and entitlement is **denied**. The Clerk of Court shall enter judgment accordingly.

IT IS SO ORDERED

s/Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master