OFFICE OF SPECIAL MASTERS

No. 97-643V

Filed: March 28, 2002

FRANCES DeROCHE and JAMES DeROCHE, as legal representatives of JOHN-PAUL D. DeROCHE, a minor,	*	
Petitioners,	*	
v.	*	To Be Published
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

James DeRoche, petitioner *pro se*,[1] Los Angeles, California, for petitioners.

Glenn A. MacLeod, United States Department of Justice, Washington, D.C., for respondent.

ENTITLEMENT DECISION

GOLKIEWICZ, Chief Special Master.

I. PROCEDURAL BACKGROUND

On September 25, 1997, petitioners filed a claim on behalf of their son, John-Paul D. DeRoche ("John-Paul"), under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petition for Vaccine Compensation ("Pet."), filed September 25, 1997. Based on the

[1]Mr. DeRoche is an attorney who ably represented his son's interests.

[2]The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified as

Petition and successive filings, petitioners claim that as a direct result of a Diphtheria-Pertussis-Tetanus ("DPT") vaccination administered on September 30, 1994, John-Paul suffered an acute and/or chronic encephalopathy. Pet. at 3, 5; Petitioners' Submittal of Witnesses, Exhibits, and Issues ("P. Submittal") at 5, filed March 2, 1999; Petitioners' Supplemental Pre-Hearing Memorandum ("P. Supp. Pre-Hrg Memo") at 4, 8-9, 13, submitted March 10, 1999; Petitioners' Post-Hearing Brief ("P. Post-Hrg Br.") at 1, filed May 21, 1999. Petitioners also allege that John-Paul's second DPT vaccination, administered November 29, 1994, significantly aggravated within seventy-two hours the alleged underlying encephalopathy which followed the first DPT vaccination. P. Submittal at 5; P. Supp. Pre-Hrg Memo at 4, 9-10, 13; P. Post-Hrg Br. at 1. Petitioners aver this aggravation manifested in John-Paul as "strange and eradicate [sic] behavior consisting of crossing his eyes, extending and crossing his arms in an involuntary manner," and subsequent startle responses or seizures which eventually evolved, resulting in a diagnosis of infantile spasms. Pet. at 3; P. Post-Hrg Br. at 1. In the alternative, petitioners claim that the vaccinations separately or "in tandem"[3] actually caused John-Paul's infantile spasms and subsequent mental and physical deficits, or that the DPT caused an off-Table significant aggravation of his underlying condition. Pet. at 3; P. Submittal at 5; P. Supp. Pre-Hrg Memo at 8-13; P. Post-Hrg Br. at 8, 24, 44-45.

On May 7, 1998, respondent filed a report in this matter recommending compensation be denied. Respondent's Report ("R. Rpt.") at 2, filed May 7, 1998. According to this report and subsequent filings, respondent disputes that John-Paul suffered any compensable Table or off-Table injury. R. Rpt. at 8-13; Respondent's Pre-Hearing Memorandum and Exhibit and Witness Lists ("R. Pre-Hrg Memo") at 9-10, 13, filed March 1, 1999; Respondent's Post-Hearing Memorandum ("R. Post-Hrg Memo") at 1-2, 16-36, filed May 20, 1999. Respondent presents several arguments.

First, respondent argues that the Act precludes the finding of a Table encephalopathy based on non-neurological symptoms such as those experienced by John-Paul following his first vaccination; instead, John-Paul's symptoms were "well within the range of benign and systemic post-vaccination reactions." R. Rpt. at 9; see also R. Post-Hrg Memo at 17, 19. In addition, the

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amended at 42 U.S.C.A. §§300aa-1 through -34 (West 1991 & Supp. 2001)) ("Vaccine Act" or "the Act"). References shall be to the relevant subsections of 42 U.S.C.A. §300aa.

[3]Petitioners allege that even if John-Paul's symptoms following the first vaccination do not establish a Table encephalopathy, the DPT shot

> either caused outright or contributed to a susceptibility, weakening or exacerbation of condition which rendered John-Paul more susceptible to the second DPT vaccination. After the second immunization, John-Paul manifested the onset of a seizure disorder which evidenced an underlying encephalopathy.

P. Supp. Pre-Hrg Memo at 8-9. Or stated another way, John-Paul "reacted adversely to each [DPT vaccination] in an increasingly pejorative manner." P. Supp. Pre-Hrg Memo at 11; see also P. Post-Hrg Br. at 38.

medical records fail to document any encephalopathic diagnosis or symptoms within 72 hours following either vaccination and confirm John-Paul's good health until November 1994. R. Rpt. at 9, 10; R. Post-Hrg Memo at 17-19. Further, petitioners' expert fails to support a Table injury claim as his testimony rests on symptoms and medical records which do not point to neurological events in the crucial 72 hour post-vaccinal time period. R. Post-Hrg Memo at 18-20. Moreover, even if John-Paul suffered seizures following his second vaccination, the statutory language deems seizures alone insufficient to demonstrate a Table encephalopathy. R. Rpt. at 10. Respondent also argues that "[t]o the extent that John-Paul's infantile spasms qualify as a residual seizure disorder, such an injury is no longer included as a vaccine-related injury under the *revised* Table" for purposes of a Table onset case. R. Pre-Hrg Memo at 9 (emphasis in original).

Second, respondent submits as a legal proposition that because petitioners have failed to prove an encephalopathy as defined by the "Aids and qualifications to interpretation," they cannot sustain an on-Table significant aggravation claim. R. Post-Hrg Memo at 20. In the alternative, petitioners cannot meet the four-step test for a Table significant aggravation claim set forth in Whitecotton v. Secretary of HHS, 81 F.3d 1099 (Fed. Cir. 1996). R. Pre-Hrg Memo at 10.

Third, petitioners also cannot prevail on an off-Table significant aggravation claim because of their inability to point to any medical literature supporting a causal relationship between DPT and significant aggravation. R. Pre-Hrg Memo at 9-10; R. Post-Hrg Memo at 2, 29-32. Moreover, the Institute of Medicine ("IOM") expressly rejected a causal relation between the vaccine and infantile spasms. R. Post-Hrg Memo at 30.

Finally, respondent argues that neither the medical records nor an expert opinion causally link John-Paul's infantile spasms or developmental delay to the DPT vaccine. R. Rpt. at 13. Based on the National Childhood Encephalopathy Study ("NCES"), the DPT vaccine cannot cause a chronic encephalopathy absent an initial and qualifying acute encephalopathic condition. R. Post-Hrg Memo at 27-28. Dr. Menkes, petitioners' expert, testified that John-Paul's medical history did not satisfy the NCES's criteria for inclusion in the study. R. Post-Hrg Memo at 28. In addition, "Dr. Menkes's proffered 'blood brain barrier' theory has been evaluated previously through the legal prism of Daubert's 'four guideposts' and rejected soundly." R. Post-Hrg Memo at 33. Thus, for respondent, "in the clear absence of any definitive and applicable medical or epidemiological studies, petitioners can merely speculate as to any causal relation between John-Paul's DPT vaccination and his injury." R. Post-Hrg Memo at 29.

An evidentiary hearing was held in this matter on March 20, 1999.[4] Petitioners presented factual testimony from Mrs. Frances DeRoche and Dr. Mary Doyle and expert testimony from Dr. Doyle and Dr. John Menkes; Dr. Joel Herskowitz testified on respondent's behalf. Following the hearing, the parties continued to brief the difficult legal and medical issues presented in this case.

[4]The court refers to the March 20, 1999 hearing transcript, filed in this matter on April 19, 1999, as "Tr. at #" and the May 26, 1999 closing arguments transcript, filed in this matter on June 1, 1999, as "Closings Tr. at #."

The final brief was filed on July 21, 2000. Thereafter, the parties considered settlement. However, settlement proved not possible. The case is now ripe for decision. After considering the totality of the record, the court finds petitioners failed to demonstrate by a preponderance of the evidence that John-Paul's DPT vaccinations caused or aggravated, separately or collectively, his injuries or death.[5]

II. FACTUAL BACKGROUND[6]

Mr. and Mrs. DeRoche are John-Paul's legal adoptive parents. Pet. at 1. John-Paul was born on July 23, 1994, following an emergency Cesarean section performed as a result of an induced labor that failed to progress; he suffered fetal distress and his head was not descending well. P. Ex. 1 at 2, 3, 4, 5, 11, 12, 15; P. Supp. Ex. 1 at 3, 5. John-Paul was "limp on presentation [with] no resp[iratory] effort noted" and a heart rate less than 60. P. Ex. 1 at 15. He required intubation and cardiac pulmonary resuscitation for 20 seconds whereupon John-Paul's heart rate increased, medical personnel discontinued compressions, and he began spontaneous respirations. P. Ex. 1 at 15. He responded well to additional stimuli and offered a lusty cry. P. Ex. 1 at 15. John-Paul's Apgar scores at 1, 5, and 10 minutes were 2, 9, and 9 respectively.[7] P. Ex. 1 at 5, 11. Following the

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[5]Sadly, John-Paul died in early 2001 following a massive seizure. See Letter to the court from Mr. DeRoche, dated December 6, 2001, filed by leave of the special master on January 30, 2002. The DeRoches notified the court of their son's death subsequent to the close of the record in this case and the court's initial drafting of the final entitlement decision. John-Paul's death in 2001 automatically converted petitioners' claim to a death case. The court may award a petitioner the statutory death benefit of $250,000 upon a showing by a preponderance of the evidence either that the death was a "sequela" of an underlying Table injury or that the vaccine actually caused the death. See, e.g., Shyface v. Secretary of HHS, 165 F.3d 1344 (Fed. Cir. 1999); Hossack v. Secretary of HHS, 32 Fed. Cl. 769 (1995); Greway v. Secretary of HHS, No. 90-2028V, 1995 WL 631871 (Fed. Cl. Spec. Mstr. Oct. 12, 1995). See also §11(c)(1)(C)(ii)(I), §14(a)(I)(E), and §15(a)(2). Due to the nature of the issues presented, the court's Table and off-Table analyses in this case are the same notwithstanding John-Paul's untimely passing.

[6]Citations to "P. Ex. 1-5" are from petitioners' Evidentiary Notebook filed with the petition on September 25, 1997. Citations to "P. Supp. Ex. 1-10" are taken from Petitioners' First Supplemental Filing of Documents (exhibits 1-9), filed December 8, 1997, and Petitioners' Second Supplemental Filing of Documents (exhibit 10), submitted February 26, 1998. Because Petitioners' Fourth Supplemental Filing of Documents, filed March 18, 1999, does not contain separate exhibits, it will be referenced by page numbers as "P. Fourth Supp. Ex. at #." Duplicate filings have not been cited. All other petitioners' exhibits will be cited as "P. Ex." followed by the exhibit number or letter and the relevant page numbers.

[7]The Operation Report dated July 23, 1994, states:

> Upon entering the uterine cavity a fair amount of bloody amniotic fluid, probably indicative of abruption was seen. Healthy male infant was then delivered in cephalic

delivery, John-Paul was transferred to the nursery in stable condition and subsequently discharged the same day with no apparent negative effects from his post-natal resuscitation. P. Ex. 1 at 7, 14, 15; P. Supp. Ex. 1 at 8; but see P. Supp. Ex. 1 at 1 (indicating a discharge date of July 25, 1994).

John-Paul was a healthy and normally developing child for the first two months of life. Declaration of Frances DeRoche ("Decl. F. DeRoche") at 1, filed July 21, 1998; Tr. at 81-83. At his first month appointment with Dr. Apau, he was smiling and his HEENT[8] and neurologic exams were within normal limits. P. Ex. 2 at 19. Developmentally, he was meeting both his first and some second month milestones, such as lifting and holding his head halfway briefly, focusing on and following a rattle with his eyes, sitting supported with his head erect and bobbing, smiling socially when stimulated, and recessing his activity when spoken to. P. Ex. 2 at 34. Mrs. DeRoche averred that "to [her] knowledge, the pediatrician at this visit found [John-Paul] to be developing normally and hitting his milestones." Decl. F. DeRoche at 2; see also Tr. at 81-82. The contemporaneous records from the appointment support this. He received his first hepatitis B vaccination at this time and suffered no apparent reaction. P. Ex. 2 at 19.

At John-Paul's two month well-baby appointment on September 30, 1994, his examination appeared within normal limits and his pediatrician noted no problems or concerns. P. Ex. 2 at 20. Developmentally, his Kansas Infant Development Screen chart ("KIDS")[9] revealed he visually

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> presentation, suctioned, cord clamped and cut, and the baby was given to the Neonatal Team. The baby was crying upon delivery with fair muscle tone, and in our opinion Apgar scores should be corrected at one minute and not at 2.

P. Supp. Ex. 1 at 10. This report corrected John-Paul's Apgars to 6 and 9. P. Supp. Ex. 1 at 10.

[8]"HEENT" is an acronym for "head, eyes, ears, nose and throat."

[9]The Kansas Infant Development Screen chart lists on a vertical axis those milestones a child is expected to meet at a specific month or months of age; the corresponding horizontal axis lists in chronological order the child's actual age (in months) on examination. See Tr. at 11; P. Ex. 2 at 34. In practice, a physician marks on the chart at each month of age, ideally contemporaneously with the well-baby appointments, which milestones the child is actually achieving. A completed chart would then indicate to a reviewer whether the child was meeting the milestones as expected for his age, meeting milestones above and beyond what is anticipated for children of his chronological age, or regressing in his developmental milestones at a certain chronological age by now failing to achieve milestones he had met previously. Unfortunately, the chart is quite confusing and the undersigned, counsel, and the experts spent considerable time deciphering the practical usage of the chart, its completion date, and its internal inconsistencies. See Tr. at 53-54, 121-23, 165-69, 184, 185, 201, 204-06. Dr. Herskowitz attested he had never before seen a KIDS chart. Tr. at 184, 206. Dr. Mary Doyle, John-Paul's treating pediatrician, testified that she could not be sure when she recorded some of the negative responses, indicated by hash or minus marks. Tr. at 53-54 ("I can't tell when the minus marks were made . . . it's difficult for me to reconstruct when I would have put the minus

tracked moving persons and achieved three month milestones such as cooing and chuckling, following moving objects with his eyes on all planes, searching for sounds with his eyes, holding a rattle, and keeping his head held at a 45º angle while prone. P. Ex. 2 at 34; Tr. at 53. However, he also no longer smiled socially when stimulated nor lifted his head halfway while prone. P. Ex. 2 at 34. He also failed to sit supported. P. Ex. 2 at 34. Nevertheless, John-Paul received his first DPT vaccination at this visit in combination with a Hib vaccination. P. Ex. 2 at 20; P. Ex. 5 at 86.

That evening, around 7:00-8:00 p.m., John-Paul awoke and suffered from inconsolable crying, high-pitched or shrill screaming, and stiffening for a period of 10-15 minutes. P. Ex. A ("Declaration of Philomena Grabowski") at 1-2, filed September 25, 1997; Tr. at 85. His inconsolable behavior caused his babysitter, his maternal grandmother Philomena Grabowski, so much concern that he was in severe pain that she placed a 911 call at 7:50 p.m.; paramedics arrived on the scene shortly thereafter to find John-Paul "crying in [his] grandmother's arms."[10] P. Supp. Ex. 6 at 98-99; see also P. Ex. A at 2; Tr. at 85. Mrs. Grabowski told the paramedics that she became alarmed by John-Paul's coughing up mucous. P. Supp. Ex. 6 at 99; Tr. at 85. She also averred "[t]he paramedics stated that the red color and the shrill cry indicated to them that he was in pain, but the absence of blue also indicated to them that he was receiving oxygen." P. Ex. A at 2; see also Tr. at 87. The paramedics' examination revealed no apparent problems; John-Paul was mildly ill, but alert, breathing normally and clearly, with no vomiting or mucous concerns. P. Supp. Ex. 6 at 99. His grandmother administered Tylenol in their presence. P. Ex. A at 2; Tr. at 87. The paramedics waited for John-Paul to calm down, reassured his grandmother, then left without further treatment or recommendations for hospitalization. P. Ex. A at 2; P. Supp. Ex. 6 at 99; Tr. at 87. When Mr. and Mrs. DeRoche returned home from dinner, John-Paul was asleep. Decl. F. DeRoche at 2. In the days following, Mrs. DeRoche "did not notice any immediate reaction." Decl. F. DeRoche at 2. Since John-Paul's episode did not last three hours or involve a fever or convulsions, she dismissed it as "one of those unfortunate side effects of the shot." Tr. at 87.

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marks. . . . [A]s best I can recall I put in the hash marks at a later date as kind of a graphic, you know, reminder that he kind of lost these things and then regained them again at a later date."). In addition, to the court and the experts, parts of the chart seemed internally inconsistent. Tr. at 187, 204-06. For instance, the chart states that at two months, John-Paul failed to smile socially when stimulated (a two-month milestone), but he still cooed and chuckled (a three-month milestone). P. Ex. 2 at 34. At two months, John-Paul could not repeatedly lift his head halfway while prone (a two-month milestone), but he could, while in that position, sustain holding his head at a 45 degree angle (a three-month milestone). P. Ex. 2 at 34. In any event, the chart, despite these questions, provided the experts with valuable information regarding John-Paul's developmental status. The court relies on the chart, mindful of the discrepancies and questions surrounding its completion.

[10]Mrs. DeRoche testified that the crying episode had to have lasted longer than 10-15 minutes since John-Paul was still crying when the paramedics arrived and the local fire station was 10 minutes away from the house. Tr. at 86, 92-93.

John-Paul was next seen by his treating physician on October 27, 1994, at his third month well-baby examination. Other than suffering from an upper respiratory infection, the physician reported no unusual vaccine reactions or health and developmental concerns. P. Ex. 2 at 21. John-Paul received his oral polio and hepatitis B vaccinations at this time. P. Ex. 2 at 21. Although not stated in the medical records, Mrs. DeRoche avers that "[a]t the end of the third month, John-Paul was not hitting the third month milestones. We were not alarmed; people were always telling me that children develop at their own pace." Decl. F. DeRoche at 3. The KIDS chart reveals that at three months John-Paul achieved some four and five month milestones, but also regressed in some two and three month milestones. P. Ex. 2 at 34; Tr. at 53-54. For instance, John-Paul acquired four month milestones such as laughing aloud, putting toys to his mouth, and lifting his head and chest up while prone. P. Ex. 2 at 34. He also met five month milestones such as bringing hands to midline (finger play) and no head lag when pulled to sit. P. Ex. 2 at 34. However, he no longer cooed and chuckled nor visually tracked a moving person. P. Ex. 2 at 34. In addition, he still did not progress in lifting his head halfway while prone, sitting supported, smiling socially, or rolling prone to supine (or reverse). P. Ex. 2 at 34. By the end of October, following a plane ride with her son to Boston during which John-Paul was uncharacteristically quiet for an infant, Mrs. DeRoche noticed that John-Paul was not vocalizing as much as he had before the first vaccination. Decl. F. DeRoche at 2; Tr. at 88, 89.

Despite the events surrounding John-Paul's first vaccination and his KIDS chart evaluations, his mother reported that he was developing normally until 4 months of age. P. Supp. Ex. 9 at 142; P. Supp. Ex. 10 at 1; but see Decl. F. DeRoche at 3 ("At the end of the third month, John-Paul was not hitting the third month milestones. We were not alarmed; people were always telling me that children develop at their own pace."). At his four month well-baby examination on November 29, 1994, John-Paul's treating pediatrician, Mary Doyle, M.D., described him on exam as alert, meaning "he was functioning like he should function for a four-month old," with appropriate height, weight, and head circumference for his age. Tr. at 13; see also Tr. at 18; P. Ex. 2 at 22. However, she also noted the following concerns: an asymmetrical or flat head with left ear displacement (with a plan to rule out craniosynostosis or premature closing of the skull sutures), poor head control and head lag, gross motor delay, and per the mother's stated concerns, a failure to vocalize as much as he had before although he continued to respond to noise and voices.[11] P. Ex. 2 at 22; Decl. F. DeRoche at 3; Tr. at 59. John-Paul's examination was otherwise within normal limits. P. Ex. 2 at 22; Tr. at 14. Dr. Doyle attributed John-Paul's head lag to a neck muscle problem. Tr. at 30, 92. The pediatrician

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[11]Dr. Doyle testified that by "head lag" she meant that she

> expect[ed] a four-month old[,] . . . when [she] pull[ed] them to sit[,] . . . that they can hold their head in the plane of their body, their shoulders and then as you pull them up forward, they should be able to come up with you and he was not able to do that.

Tr. at 14-15. Because of this lack of head control, Dr. Doyle diagnosed John-Paul with gross motor delay. Tr. at 19. This is distinguishable from fine motor delay, which involves the small muscles, and personal/social or language delays which John-Paul did not exhibit. Tr. at 19-20.

also wrote, under the "Shot reaction?" section, "cried for 10-15 min after 4 hr." P. Ex. 2 at 22. This notation references the previous DPT vaccination given on September 30, 1994. Tr. at 24-25, 60. Mrs. DeRoche confirms that she "discussed with his pediatrician the episode which occurred on September 30 . . . [and] was told that, unfortunately, pain resulting in crying was a side effect of the vaccination."[12] P. Ex. B ("Affidavit of Frances DeRoche") at 2, filed September 25, 1997; see also Decl. F. DeRoche at 3; Tr. at 92. His KIDS chart noted his failure to meet or otherwise regain a number of one to four month milestones. P. Ex. 2 at 34. Again, despite the stated concerns, John-Paul received his second DPT vaccination in combination with a Hib. P. Ex. 2 at 22. By the time John-Paul arrived home from his appointment, he was asleep. Tr. at 93. John-Paul exhibited no unusual behavior throughout the afternoon. Tr. at 93.

Several hours later, on the same day of the second DPT vaccination at approximately 7:00 p.m., the DeRoches witnessed John-Paul exhibiting erratic behavior consisting of crossing of the eyes with involuntary extensions and crossing of his arms and legs.[13] P. Ex. 2 at 23; P. Ex. B at 2;

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[12]Dr. Doyle did not recall Mrs. DeRoche mentioning that paramedics were called to the house on September 30, 1994. Tr. at 60. To the best of the pediatrician's recollection, her notes reflect the extent of the discussion with Mrs. DeRoche regarding John-Paul's reaction to his previous DPT inoculation. Tr. at 59-60.

[13]Dr. O. Carter Snead's Ambulatory Neurological Notes dated February 2, 1995, from his January 12, 1995 visit with John-Paul, describe the post-November 29th events as follows:

> [H]e received this immunization in the morning . . . [and] on the same day the child developed crossing of the eyes which lasted for approximately several seconds and short lasting episodes of stiffening of upper extremities. The parents recalled that John has been having approximately ten to twelve similar spells per day which lasted for approximately one week. The parents also noticed that John did not have any such movement during sleep stage. According to the parents, John was not ill at that time. After a week, John stopped with the stiffening of the upper extremities but continues to have occasional eye crossing, so for this reason, John was seen by an ophthalmologist who diagnosed him with far sidedness and a stigmatism. The parents noticed that John occasionally still has eye crossing and sometimes eyes fluttering.

P. Supp. Ex. 10 at 1. A later evaluation from August 6, 1995, provides a similar description:

> In November 1994, he developed paroxysms of bilateral upper extremity extension with crossing over the eyes. Each episode lasted 1 to 2 seconds, and this occurred 10 to 20 times over 5 days. It then resolved and has not returned. The onset of these episodes was within 12 hours of a DPT vaccination.

P. Ex. 5 at 86.

Decl. F. DeRoche at 3. The movements were very subtle and unnoticeable by morning. Tr. at 94. The DeRoches compared their son's behavior with adverse reaction descriptions contained in a post-vaccination handout but did not find that their observations coincided with the pamphlet's list of reactions to monitor. P. Ex. B at 2. John-Paul's behavior continued for three days, unaccompanied by crying or other alarming activity. P. Ex. 2 at 23; Decl. F. DeRoche at 3; Tr. at 95. Although he remained fussy over those few days, Mrs. DeRoche did not feel he suffered a "drastic" change in his behavior. Tr. at 95. Prior to these events, "John-Paul had never exhibited any sign of seizures in any form whatsoever." Decl. F. DeRoche at 3. Although Mrs. DeRoche spoke with Dr. Doyle on November 30, 1994, to receive the results of John-Paul's x-rays to rule out craniosynostosis (which were normal), neither the medical records nor Dr. Doyle's testimony support that Mrs. DeRoche mentioned during this conversation either of John-Paul's post-vaccinal episodes or her review of the vaccine-adverse reaction handout. Tr. at 25, 62; P. Fourth Supp. Ex. at 184, 185. Nevertheless, the pediatrician and the DeRoches arranged for a December 2nd appointment to discuss further the ramifications of Dr. Doyle's November 29th findings and the x-ray results.

John-Paul was examined on December 2, 1994, by Doctors Mary Doyle and Kathleen Smith. P. Ex. 2 at 23. Dr. Doyle requested that Dr. Smith participate in the examination as a result of her expertise in neonatology and infant development. Tr. at 26. Mrs. DeRoche avers that by that visit, "the extending of the arms had ceased and was replaced with what my husband and I described as exaggerated startling" or sudden jerking. P. Ex. B at 2; see also Decl. F. DeRoche at 3. Mrs. DeRoche further avers that Doctors Doyle and Smith observed the startling episodes themselves during the visit but considered the events normal; however, there is no specific mention in the records of this nor did Dr. Doyle testify accordingly.[14] P. Ex. B at 2; Decl. F. DeRoche at 3; Tr. at 96. The records reflect John-Paul suffered no fever following his previous vaccination and his temperature on December 2nd was 98.9° F. P. Ex. 2 at 23; Tr. at 27, 28. He appeared alert, meaning "he was awake and not fatigued appearing," but his HEENT review revealed "intermittent extreme alternating medical/inferior deviation of eyes"; yet, he also fixed and followed.[15] Tr. at 28; see also

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[14]Mrs. DeRoche claims that Dr. Snead later called these episodes myoclonic jerks and ascribed them to John-Paul's infantile spasms. Decl. F. DeRoche at 3, 4. Dr. Mary Beth Steinfield opined in a January 10, 1996 developmental consultation report that John-Paul's infantile spasms "were probably present as 'startles' since 4 months of age, but because he did not have 'salaam' type seizures, the startles were not picked up as seizures initially." P. Supp. Ex. 5 at 90.

[15]By this description Dr. Doyle meant

> John-Paul was intermittently moving his eyes to the middle and down in extreme angles, so it wasn't the normal fix and follow that [she] would see but [she] did record that he would fix and he would follow. So intermittently he would move his eyes in a way that [they] generally don't see kids do.

Tr. at 28. These movements were not explained by the presence of cataracts or other cornea problems, but the doctors concluded that the random eye movements may be due to strabismus or

P. Ex. 2 at 23. Dr. Doyle questioned whether John-Paul had strabismus.[16] P. Ex. 2 at 23. Neurologically, John-Paul exhibited "head lag; variable response to lifting head when prone; [increased] extensor tone/weak shoulder girdle" and gross "motor delay." P. Ex. 2 at 23; see also Tr. at 62-63. Dr. Doyle considered his head lag the same as that witnessed three days prior. Tr. at 62. By recording increased extensor tone, Dr. Doyle meant that John-Paul's muscles and tendons in his legs seemed much stiffer than expected. Tr. at 30. The concerns of weak shoulder girdle also raised questions about muscle weakness. Tr. at 30. At the close of the appointment, Dr. Doyle referred John-Paul to a physical therapist for his gross motor delay and abnormal muscle tone and an ophthalmologist for his possible strabismus. P. Ex. 2 at 23; P. Fourth Supp. Ex. at 183, 333; Tr. at 32-33, 36.

On December 12, 1994, Dr. Doyle spoke with Mrs. DeRoche about a complaint that although John-Paul's eye crossing had ceased several days before, he was now crossing his legs at the ankles. Tr. at 39; P. Fourth Supp. Ex. at 182. Mrs. DeRoche denied that rhythmic contractions accompanied these leg movements which would suggest seizure activity. Tr. at 39. Dr. Doyle concluded John-Paul had "[p]robable increased extensor tone and scissoring," events associated with cerebral palsy. Tr. at 40; see also P. Fourth Supp. Ex. at 182.

Dr. Doyle's conversation on December 13, 1994, with Dr. Ann Stout, the pediatric ophthalmologist, led her to believe John-Paul's tracking or fixing and following was progressively worsening. Tr. at 40-41. On December 16, 1994, Dr. Smith conversed with the physical therapist regarding her results; she found John-Paul delayed in all areas with skills at maybe the 2-3 month level. Tr. at 42-43; P. Fourth Supp. Ex. at 179. On the therapist's examination, John-Paul exhibited irritability, involuntary movements, and "[f]luctuating tone, primarily upper extremities." Tr. at 43; see also P. Fourth Supp. Ex. at 179. By December 16th, Drs. Smith and Stout oversaw John-Paul's care. Tr. at 44.

At his five month well-baby exam, conducted December 29, 1994, the treating physician described John-Paul as having an irregular shaped head; he also failed to follow with his eyes (wandering/staring eyes). P. Ex. 2 at 24. His mother reported that she "never know[s] he's hungry[,] [he's] not crying." P. Ex. 2 at 24; see also Tr. at 89. The examination notes also indicate that John-Paul's biological mother had a half-sister with epilepsy and another half-sister who died of SIDS. P. Ex. 2 at 24. By the date of the exam, John-Paul's twitching and jerking spells had ceased, but he began experiencing startle episodes. P. Ex. 2 at 24; P. Ex. B at 2. The physician made no comments about any further shot reactions. P. Ex. 2 at 24.

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eye muscle weakness. Tr. at 29.

[16]In a December 16, 1994 report on John-Paul's eye deviation problems, ophthalmologist Dr. Ann U. Stout opined that his strabismus began before his vaccinations and "the crossing is [not] diagnostic of a particular neurologic problem, nor to sixth nerve paresis." P. Fourth Supp. Ex. at 332. By February 3, 1995, Dr. Stout reversed her position, stating that "[m]ost likely, his intermittent [eye] deviation represents intermittent seizure activity." P. Fourth Supp. Ex. at 322.

By his six month appointment, John-Paul was rolling front to back, cooing, fixing his eyes, and sustaining little head control.[17] P. Ex. 2 at 25. His pediatrician reported a flattened left occiput, inconsistent fixing and following of the eyes, head lag, and a failure to lift his head. P. Ex. 2 at 25. The doctor assessed him as developmentally delayed but progressing with some gains. P. Ex. 2 at 25. A head circumference chart showed John-Paul's head growth tracked consistently until the age of six months. Tr. at 52. His pediatrician specifically reported there were no vaccine reactions, presumably to the OPV he received on December 29, 1994. P. Ex. 2 at 25. He received a DT and his third Hib vaccination at this time. Dr. O. Carter Snead followed him for additional neurological care.[18] P. Ex. 2 at 25.

On January 6, 1995, John-Paul underwent an electroencephalogram ("EEG") which returned "markedly abnormal," revealing abnormalities "consistent with severe generalized seizure disorder."[19] P. Ex. 3 at 42. An 8-hour video EEG recorded a few days later on January 10th was also abnormal but did not correlate the signaled episodes of eye crossing with electrographic changes, prompting Drs. Lan S. Chen and O. Carter Snead to conclude the eye crossing events "do not appear to be [a] seizure."[20] P. Ex. 3 at 41, 47; but see P. Fourth Supp. Ex. at 322 (ophthalmologist Dr. Stout stating in a February 3, 1995 report that "[m]ost likely, his intermittent [eye] deviation represents intermittent seizure activity").

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[17]It is unclear from the records whether Dr. Snead's initial appointment with John-Paul preceded this well-baby examination.

[18]John-Paul received the DT per Dr. Snead's recommendation. Stipulation of Undisputed Facts Re: Testimony of O. Carter Snead, M.D. ("Dr. Snead Stip."), filed February 1, 1999, at 2.

[19]John-Paul also underwent a brainstem auditory evoked potential study this date to rule out hearing loss; his BAEPs were normal. P. Ex. 3 at 52.

[20]Mrs. DeRoche monitored her son during the video EEG. She was asked to "signal" by way of a buzzer those times when she noticed anything abnormal in John-Paul's behavior. Tr. at 101. Mrs. DeRoche applied the buzzer any time John-Paul crossed his eyes. Tr. at 101. Mrs. DeRoche did not similarly signal her son's startling episodes during the video-EEG as she was convinced at that time from her conversations with Drs. Doyle and Smith that they were normal child reflexes or responses. Tr. at 96-97, 101.

Dr. Snead personally evaluated John-Paul a few days later on January 12, 1995.[21] P. Supp. Ex. 10 at 1. He recorded that according to his mother, John-Paul had "been in good health until 4 months of age when he received DPT shots." P. Supp. Ex. 10 at 1. On exam, John-Paul was alert and physically well but for a "dysmorphic feature occiput slightly flat over left side." P. Supp. Ex. 10 at 2. Neurologically, John-Paul was "mildly hypotonic." P. Supp. Ex. 10 at 2. John-Paul failed to reach for objects, sit alone, or sufficiently maintain head control in a pull to sit maneuver.[22] P. Supp. Ex. 10 at 2. Dr. Snead determined that John-Paul had "mild to moderate, primarily motor, developmental delay and [was at] risk for seizure." P. Supp. Ex. 10 at 2. He advised John-Paul's parents that, as supported by the video EEG conducted in the days before the exam, John-Paul's eye crossing episodes were "most likely not a seizure" although his abnormal EEG placed him at risk for developing convulsions. P. Supp. Ex. 10 at 2.

John-Paul had an MRI of the brain two weeks later, on January 27, 1995; the results were interpreted as normal. P. Ex. 3 at 47; P. Ex. 4 at 53, 56; but see P. Fourth Supp. Ex. at 322 (Dr. Stout's February 3, 1995 report to Dr. Doyle stating that a neuroradiologist who reviewed the MRI "said that the white matter development was abnormal, and that it was difficult to tell whether [John-Paul] would continue in development with the white matter or whether it would remain the same"). John-Paul's subsequent EEG on February 28, 1995, was abnormal and "consistent with modified hypsarrhythmia."[23] P. Ex. 3 at 40. At an appointment the same day, John-Paul's parents reported

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[21]Dr. Snead did not testify at the hearing conducted March 20, 1999. Although he was John-Paul's initial treating neurologist, he believed his previous paid consultation and testimony on behalf of respondent in other vaccine cases raised a conflict of interest that prevented him from offering formal testimony on the DeRoches' behalf. This is not the first time the undersigned has experienced such a refusal to testify. Within the context of this Program, the undersigned finds Dr. Snead's position and any governmental role, if such existed, an **outrageous impediment** to determining the truth and compensating vaccine-related injuries. Despite the court's willingness to subpoena Dr. Snead, petitioners did not want to face an adverse witness. However, pursuant to the undersigned's direction in a status conference and a follow-up Order dated November 20, 1998, the parties did elicit informal testimony from him which they submitted jointly through a Stipulation of Undisputed Facts Re: Testimony of O. Carter Snead, M.D., filed February 1, 1999. The court notes that its own review of literature addressing expert witness codes of conduct shows "there is no general ethical principle that prevents an expert from accepting concurrent engagements both for and adverse to the same party." Steven Lubet, Expert Witnesses: Ethics and Professionalism, 12 Geo. J. Legal Ethics 465, 474 (1999).

[22]Dr. Snead also reported that since John-Paul began his physical therapy program following the November 1994 appointment, his "mother perceived significant improvement in the child motor skills." P. Supp. Ex. 10 at 1.

[23]Dr. Snead subjected John-Paul to several other studies in the days prior to his February 28, 1995 appointment. For instance, he underwent a visual evoked potential study for possible partial blindness; the results were interpreted as normal. P. Ex. 3 at 49. He also had a somatosensory

he had "started having a myoclonic jerk of his upper extremities and his lower extremities" which "can last for several seconds"; these jerks occurred over the past several weeks. P. Ex. 3 at 47; see also P. Ex. 4 at 57. Dr. Snead found John-Paul alert and his physical examination unremarkable. P. Ex. 3 at 47. He demonstrated inconsistent eye tracking, poor head control, an inability to sit, and an absence of a lateral parachute reaction.[24] P. Ex. 3 at 47. Dr. Snead hesitated in diagnosing John-Paul with infantile spasms because of his atypical presentation and despite his "severely abnormal electroencephalogram."[25] P. Ex. 3 at 47. He nevertheless avowed that he would aggressively treat John-Paul "if he develops any clinical signs of infantile spasms." P. Ex. 3 at 48. He asked the parents to consider their options, which included possible ACTH treatment. P. Ex. 3 at 47-48.

Within two days after this appointment, on March 1, 1995, Mr. DeRoche called to report that John-Paul began experiencing an increase in his myoclonic spells. P. Ex. 4 at 57. In addition, he developed new "1-2 seconds spells which manifest[ed] as stiffening of upper body, widening of the

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evoked potentials study of the posterior tibial nerve (lower extremity) which showed delays "suggestive of a delayed peripheral and central conduction." P. Ex. 3 at 50. A similar study with the median nerve of the upper extremity returned abnormal "due to bilateral decreased peripheral conduction." P. Ex. 3 at 51. Genetic studies requested nine months later in November 1995, due to John-Paul's developmental delay and dysmorphic features, were normal. P. Supp. Ex. 5 at 75. A tomography of the brain completed that same month showed findings which if "maintained on a chronic basis . . . would suggest some degree of underlying brain hypoplasia or possibly atrophy." P. Ex. 5 at 79. Metabolic studies conducted in December 1995 did not indicate a specific inherited metabolic disorder. P. Ex. 4 at 61-62. Finally, skull x-rays taken in January 1996 to rule out lambdoidal synostosis were interpreted as showing "[m]ild brachycephaly with flattening of the occiput without evidence of cranial synostosis." P. Ex. 5 at 78.

[24]Between six and eight and a half months of age, John-Paul's head circumference dropped from the seventy-fifth percentile to the twenty-fifth percentile. Tr. at 52. At twenty-two months, John-Paul fell in the fifth percentile category. Tr. at 52.

[25]Dr. Snead believed that

> in February of 1995 John-Paul was not seen as exhibiting typical signs of infantile spasms. Head drop and forward movement of the arms, for example, were not exhibited but he leaned toward treating John-Paul with ACTH anyway because he felt John-Paul's condition would have eventually developed into the more classic form of infantile spasms.

Dr. Snead Stip. at 3. ACTH stands for "adrenocorticotrophic hormone" and is often given to arrest infantile spasms. Tr. at 172.

eyes and tearing"; he had experienced 8-12 such spells that morning.[26] P. Ex. 4 at 57. Following these events, the DeRoches agreed to immediately admit John-Paul that day for ACTH treatment. P. Ex. 4 at 57. Upon admission, he was physically alert but slow and somnolent. P. Ex. 4 at 57. Neurologically, he again exhibited inconsistent eye tracking, poor head control in pull to sit maneuvers, an inability to sit, and an absent lateral parachute response. P. Ex. 4 at 58. He was diagnosed with infantile spasms (clinically forme fruste), mixed developmental delay secondary to his infantile spasms, partial blindness secondary to his infantile spasms, and plagiocephaly[27]; John-Paul was then started on an ACTH course of treatment. P. Ex. 4 at 58.

During the ACTH therapy, John-Paul's March 8, 1995 electroencephalogram showed significant improvement but, nevertheless, abnormalities "indicative of a generalized seizure disorder." P. Ex. 3 at 39. Shortly after John-Paul began taking ACTH, his clinical seizures subsided. P. Ex. 3 at 43; P. Ex. 5 at 86. At his March 20, 1995 appointment, his parents reported a negative history since his last visit for "myoclonic jerks or stiffening of the upper part of the body" although they had noticed occasional "eye rolling motion or some eye crossing." P. Ex. 3 at 45. On exam, John-Paul appeared alert, well, and cooperative. P. Ex. 3 at 45. He followed light inconsistently and still exhibited poor head control although the latter had improved slightly. P. Ex. 3 at 45. An EEG conducted that visit was abnormal but showed "remarkable improvement"; Dr. Snead considered John-Paul's response to the ACTH treatment successful. P. Ex. 3 at 45. While Dr. Snead also raised concern that John-Paul's urine test "revealed elevated alanine, which might suggest lactic acidemia,"

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[26]An August 6, 1995 evaluation by Dr. Harley Kornblum with the Pediatric Neurology Clinic at the UCLA Medical Center reported the following history:

> Within weeks of [the January 6, 1995] EEG, the patient developed episodes of startling with full body extension jerks. These occurred 20 to 30 times per day and lasted less than a second. Initially these episodes occurred only in response to sudden stimuli such as noise, bright light or movement, but over the subsequent weeks, they began to occur without triggering stimuli. These episodes do not cluster. There [were] occasional episodes, very infrequently, of decreased responsiveness with eyelid flutter and up gaze. The patient was started on ACTH . . . on March 1, 1995. In the week following the starting of this medication, there was a sudden decrease in the seizure frequency, and after approximately 1 week of treatment, the patient began to be seizure free. Both types of episodes disappeared. A follow-up EEG on March 8, 1995, was much improved.

P. Ex. 5 at 86.

[27]Plagiocephaly is "an unsymmetrical and twisted condition of the head, resulting from irregular closure of the cranial sutures." Dorland's Illustrated Medical Dictionary 1301 (27th ed. 1988). Dr. Snead attributes John-Paul's plagiocephaly to his "poor head control and not to premature closure or some other malady." Dr. Snead Stip. at 3. It is "positional plagiocephaly." Dr. Snead Stip. at 3.

this was subsequently ruled out. P. Ex. 3 at 46; see also P. Ex. 4 at 67-69; Dr. Snead Stip. at 2. Although the DeRoches reported John-Paul to be stuporous during his treatment, by April 3, 1995, while on a tapered ACTH schedule, they described their child as "fixating [more] with his eyes," "more active," "more interactive," "smiling and . . . babbling a lot," and "roll[ing] from side to side." P. Ex. 3 at 43; P. Ex. 5 at 87. His exam on April 3, 1995, revealed inadequate but improved head control during the pull-to-sit maneuver. P. Ex. 3 at 43. An EEG conducted that day was normal. P. Ex. 3 at 37, 43. A developmental assessment conducted three days later on April 6, 1995, showed John-Paul at age 8½ months performing below the three month level. P. Supp. Ex. 9 at 142-43.

John-Paul completed his ACTH treatment by June 1995. P. Supp. Ex. 5 at 87. His developmental level prior to beginning the treatment was at 3 months when he was 31 weeks old; by the end of his treatment, Dr. Snead assessed his development as that of a 1 month old. P. Ex. 4 at 73; P. Ex. 5 at 87; P Supp. Ex. 5 at 87, 90. In the months and years following, John-Paul regained some of his lost milestones through therapeutic efforts. P. Ex. 2 at 27; P. Ex. 5 at 87-88; P. Supp. Ex. 5 at 87-89, 90-92; P. Supp. Ex. 7 at 100-02, 103-05, 106; P. Supp. Ex. 8 at 107-08; P. Supp. Ex. 9 at 117-18. He continued to have both normal and abnormal EEG results. P. Ex. 3 at 38 (March 20, 1995) (abnormal); P. Ex. 3 at 37 (April 3, 1995) (normal); P. Ex. 3 at 36 (June 27, 1995) (normal); P. Ex. 3 at 35 and P. Ex. 4 at 85 (October 4, 1995) (normal); P. Supp. Ex. 5 at 81 (June 20, 1996) (abnormal); P. Supp. Ex. 5 at 80 (September 26, 1996) (abnormal). As of October 1, 1998, the date of the last developmental progress note submitted, John-Paul at four years and two months of age was experiencing neuromuscular incoordination for which he was receiving physical therapy. P. Fourth Supp. Ex. at 270. John-Paul continued to suffer from severe mental retardation and significant developmental delays up until his death in early 2001 following a massive seizure.

As to the cause of John-Paul's problems, according to a January 10, 1996 developmental consultation report, Mrs. DeRoche attributed her son's problems to the DPT vaccine while Mr. DeRoche believed they may be genetic. P. Supp. Ex. 5 at 92. Dr. Kornblum noted in November 6, 1995, that the etiology of John-Paul's developmental delay was "uncertain." P. Supp. Ex. 5 at 93. Dr. Snead dismissed a causal relation between John-Paul's DPT vaccinations and his infantile spasms as early as his ten month well-baby appointment. P. Ex. 2 at 27. He did not know the cause of John-Paul's condition. Dr. Snead Stip. at 2. John-Paul experienced no other vaccine reactions than those discussed above nor exhibited any reactions following his daily ACTH injections. Tr. at 87, 147.

III. MEDICAL EXPERT REPORTS AND TESTIMONY

Petitioners' Expert: Mary Doyle, M.D.[28]

Dr. Doyle served as John-Paul's treating pediatrician between November 29, 1994 and December 16, 1994.[29] Tr. at 6, 42. At the hearing, she testified as both a factual witness and a medical expert. Dr. Doyle offered two medical opinions which are relevant to the legal issues posed in this case.

The first relevant opinion is that Dr. Doyle did not consider John-Paul neurologically impaired on November 29, 1994, immediately prior to the administration of his second DPT shot. Tr. at 16. While Dr. Doyle diagnosed John-Paul with gross motor delay as a result of his head lag, he did not exhibit fine motor, personal/social, or language delays. Tr. at 16, 19-20. She attributed John-Paul's poor head control to one of two causes. The first was a tonal problem or neck muscle weakness. Tr. at 30. Alternatively, she considered whether his delays, left-sided cranial flattening, and anterior ear displacement might be due to craniosynostosis, or premature closure of his left-sided skull sutures; Dr. Doyle ordered skull x-rays to eliminate this cause. Tr. at 20, 35, 58. At no time during this visit did Dr. Doyle deem John-Paul's problems neurological in nature.[30] Tr. at 16. John-Paul was not suffering from an acute encephalopathy, defined by her as "disturbed consciousness," which would be noticeable on exam. Tr. at 56, 58. Instead, he remained alert, quiet, and acted appropriate for his age; he was not fatigued, asleep, irritable or screaming. Tr. at 58. Moreover, although Dr. Doyle was suspicious that he had chronic encephalopathy, defined as an irreversible or long lasting encephalopathic condition, it did not appear that John-Paul was encephalopathic at the time of her exam. Tr. at 56-57. Therefore, because her "reasoning at that point was that John-Paul did not have a progressive neurological problem," she administered the second DPT vaccination. Tr. at 46. The next day, when the skull x-rays returned negative for craniosynostosis, Dr Doyle sought further explanations for John-Paul's head flattening and motor delays. Tr. at 21, 25-26, 35. Following consultation with Dr. Kathleen Smith, a colleague and physician trained in

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[28]Following her completion of medical school at Georgetown University in 1984, Dr. Doyle practiced pediatrics in various hospitals in the Los Angeles region. Tr. at 6. Dr. Doyle is board-certified in pediatrics. Tr. at 6. She does not possess any specific expertise in neurology but considers her knowledge equivalent to that held by most general pediatricians. Tr. at 6. In her practice, she sees children with neurological conditions and refers them to neurologists. Tr. at 55-56. Dr. Doyle was knowledgeable within her area of expertise and frank and credible in her testimony.

[29]Dr. Doyle's colleague, Dr. Kathleen Smith, handled much of John-Paul's treatment after December 16, 1994, because of her expertise in infant developmental delays. Tr. at 42.

[30]Even as of the December 12, 1994 conversation between Dr. Doyle and Mrs. DeRoche regarding John-Paul's scissoring episode, neither Dr. Doyle nor Dr. Smith were considering referring John-Paul to a neurologist. Tr. at 40.

neonatology and infant development, she arranged for a subsequent exam and the physicians met jointly with the DeRoches and their son on December 2, 1994. Tr. at 26-27.

The results of the December 2nd appointment highlight the second of Dr. Doyle's relevant medical opinions which is that she would not have predicted John-Paul's outcome based on her exam three days earlier. Dr. Doyle explained: "[A]ll of these muscle questions [eye, neck, shoulder] were getting at the – all these muscle observations were trying to get at the motor delay question that I noted a few days earlier." Tr. at 30. John-Paul's December 2nd condition suggested to Dr. Doyle that he suffered from cerebral palsy. Tr. at 32-35. To that end, she asked the DeRoches to videotape the jerking episodes they witnessed following the second vaccination so as to either rule in seizures or confirm a cerebral palsy diagnosis. Tr. at 33. She declined to tell the DeRoches then that John-Paul might be experiencing convulsions as she wished not to alarm them or make a hasty, uninformed conclusion. Tr. at 34. Whatever the cause of John-Paul's unusual behavior, his alertness on December 2nd ruled out in her mind any acute encephalopathic condition or need for hospitalization. Tr. at 35, 56. Nevertheless, she considered his condition changed and certainly different than expected. The following exchange between the court and Dr. Doyle reinforces this opinion:

> THE COURT: . . . [T]aking yourself back to the four-month visit on 11/29, if you had no further information post [sic] that date, in your mind the last time you see this child is on 11/29, can you tell me in plain English, are you concerned about [t]his child or what you're seeing, if there are concerns they're within the range of what might be expected with the various development of children at this point?
>
> THE WITNESS: Yes. I was concerned but . . .
>
> THE COURT: Now is this from memory or from your records?
>
> THE WITNESS: This is not from the record; this is from memory.
>
> THE COURT: Okay.
>
> THE WITNESS: That I was concerned but within the range of expected, meaning that I – and my thinking seems to be at the time that I anticipated that he might have some problems but they didn't seem major.

Tr. at 49-50. The court continued, asking Dr. Doyle to now figure the December 2nd results into her opinion:

> THE COURT: Does this [the December 2nd findings] follow from the 11/29 visit or is it something that's different than you would have expected?
>
> THE WITNESS: Yeah, much different.

> THE COURT: It's much different. So when you were back at 11/29 thinking, "I'll watch this and see how it plays out", you would not see this play out as it is on December 2nd?
>
> THE WITNESS: That's right.
>
> THE COURT: Okay, what you're seeing on December 2nd is something that you would not have expected from your 11/29 visit?
>
> THE WITNESS: That's right.

Tr. at 63-64.

Petitioners' Expert: John H. Menkes, M.D.[31]

Dr. Menkes also testified on petitioners' behalf. He had been John-Paul's treating neurologist since spring of 1996. Generally, Dr. Menkes opines that as a result of the two DPT vaccinations John-Paul received on September 30, 1994, and November 29, 1994, he suffered an acute encephalopathy and an aggravation of that injury which left him irreparably developmentally delayed and severely mentally retarded. P. Ex. 12 (Medical Expert Report of Dr. John Menkes) at 2, 3, filed October 2, 1998; Tr. at 120. Dr. Menkes opines in the alternative that the vaccinations caused John-Paul's infantile spasms. Tr. at 162. These theories are discussed in detail below.

First, Dr. Menkes believes John-Paul suffered the onset of a "rather extraordinary reaction" in the form of an acute encephalopathy within a temporally relevant period on the evening following his first DPT vaccination. P. Ex. 12 at 2; Tr. at 120, 147, 164-65. Dr. Menkes offers this opinion

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[31]Dr. Menkes is a board-certified pediatric neurologist and John-Paul's treating neurologist. P. Ex. 14 (Dr. Menkes's Curriculum Vitae) at 340, filed May 21, 1999; Tr. at 120. Following his postgraduate studies at Johns Hopkins University School of Medicine, he gained speciality training in pediatrics and neurology. P. Ex. 14 at 339. Since 1997, he has served as the Director of Pediatric Neurology at Cedars-Sinai Medical Center in Los Angeles, California. P. Ex. 14 at 339. In addition, for the past forty years, he has taught courses such as pediatrics, neurology, pediatric neurology, and psychiatry at such institutions as Johns Hopkins and UCLA. P. Ex. 14 at 339. He is currently a Professor Emeritus of Neurology and Pediatrics at UCLA. P. Ex. 14 at 339. Dr. Menkes is a member of many medical societies, medical boards, committees, and advisory boards. P. Ex. 14 at 340-41. He currently serves on the editorial boards of three journals and is an occasional reviewer for over a dozen other medical journals or texts. P. Ex. 14 at 341. Dr. Menkes has published numerous articles, studies, chapters, reviews and books on a range of medical topics. P. Ex. 14 at 342-53. Finally, Dr. Menkes has advocated numerous times on behalf of petitioners under the Vaccine Program and several times before the undersigned. As in past cases, the court found Dr. Menkes knowledgeable about his area of expertise and the facts of this case. He is a highly credible and respected proponent in his medical field and under the Program.

based on a medical definition for encephalopathy, rather than the Act's definition. Tr. at 120. He expressed a lack of familiarity with the revised Table definition. Tr. at 125. He defines encephalopathy broadly as "a disease of the brain." Tr. at 134, 164. In his view, the occurrence of an acute encephalopathy in this case is evidenced first by John-Paul's inconsolable crying and unusual screaming, which prompted a 911 call, and second by subsequent and dramatic behavioral changes in the form of "loss of alertness" and "normal interactiveness."[32] P. Ex. 12 at 2; Tr. at 120, 149, 164-65. According to Dr. Menkes, these post-vaccinal behavioral changes are supported by Mrs. DeRoche's testimony that John-Paul was never the same, the KIDS chart which evidences at three months a loss of certain milestones, and concerns at four months of less vocalization and head lag. Tr. at 121, 123, 164-68. Particularly, Dr. Menkes believes that John-Paul's failure to visually track a moving person (a milestone he lost between two and three months) constituted a "decrease or absence in response to the environment" and his decreased vocalizations (noticed by his mom at the end of the third month) represented a "decreased response to external stimuli." Tr. at 134-36. He further agreed with Dr. Doyle's characterization that head lag means "poor muscle tone," but also noted that at four months, it could suggest motor developmental delay or "be anything at this point." Tr. at 124.

Second, Dr. Menkes opines that John-Paul's second DPT vaccination aggravated this pre-existing encephalopathy. P. Ex. 12 at 2-3; Tr. at 125-26, 155. Dr. Menkes submits that "[a]n aggravation of a neurological condition is a worsening of the neurological condition that would not have been expected ahead of time," or a case in which the "status is worsening and worsening in a major respect." Tr. at 127, 129. He concedes that to his knowledge, this definition is not found in his textbook in relation to DPT or in any other DPT or unrelated medical literature.[33] Tr. at 127-29,

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[32]When asked whether high pitched screaming alone is sufficient to indicate an encephalopathy, Dr. Menkes answered, "I think I would, as a doctor, I would say this high pitched unusual screaming would make me concerned that there is something going on in the brain." Tr. at 148.

[33]Dr. Menkes proffers that the 1947 Brody and Sorley study cited in the Institute of Medicine's 1991 report supports a significant aggravation theory from a medical standpoint in that a child suffered progressively worse reactions following each of his DPT vaccinations. Tr. at 146. In the Brody case, a child suffered temporally-related multiple reactions to his first, second, and third pertussis vaccinations. Respondent's Exhibit ("R. Ex.") C (Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines 65-124 (1991)) at 91, filed December 7, 1998. These reactions were characterized by "[g]eneralized hypotonia and weakness with increased deep tendon reflexes in the lower extremities." R. Ex. C at 91. Following his fourth pertussis vaccination, the 43 month old child "within 25 minutes became somnolent. Severe flaccid paralysis developed within 12 hours, and he died of bronchopneumonia 7 weeks later." R. Ex. C at 91. Dr. Menkes concedes this case reference is only an anecdotal report, rather than a study. Tr. at 171. In further support of his aggravation theory, Dr. Menkes volunteers that given the very dangerous nature of whooping cough encephalopathy, a neurologist's recommendation to withhold the pertussis vaccine tells him "th[e] neurologist thinks that the risk of further aggravating the child's

132-33. In rendering his aggravation opinion, he relies foremost on the temporally-related onset of a new neurological finding – in this case, a hard-to-treat seizure disorder – within twenty-four hours following the second vaccination. P. Ex. 12 at 2-3; Tr. at 125-27, 133, 136-37, 139, 155. He also bases his opinion on Dr. Doyle's testimony that a "very dramatic change in this child's [extensor] tone" occurred within the three days following the second shot. Tr. at 126. Finally, he points to John-Paul's subsequent development of microcephaly. Tr. at 133. While he concedes the head circumference chart places John-Paul within the expected percentiles at four and five months, his drop-off at six months signals to a neurologist that he needs to be concerned with John-Paul's development. Tr. at 124-25. Because Dr. Menkes believes John-Paul suffered an aggravated injury, he does not believe the child suffered the onset of an acute encephalopathy following his second vaccination. Tr. at 135, 175. Nor does he see anything in the December 2nd notes which would indicate a "decreased or absent response to environment," although by the five month well-baby exam John-Paul experienced "decreased or absent eye contact" based on the "wandering eyes/day dream" notations in the records. Tr. at 134-35.

In supporting this aggravation theory, Dr. Menkes also concurred with Dr. Doyle about the unexpected nature of John-Paul's December 2nd condition. He stated:

> [I]f I saw this child at four months of age, with a bit of a head lag, I would not have expected two days later to have marked increase in extensor tone. That would have been a surprise to me. . . . But to suddenly find a child who had a head lag appearing two days later with increased extensor tone which wasn't there before, I'd be very worried that something new has happened, regardless of the history.

Tr. at 129-30. He would have had the same concerns had John-Paul presented without a history of DPT vaccination. Tr. at 130.

Lastly, Dr. Menkes believes the DPT vaccinations actually caused John-Paul's infantile spasms. In his view, an injury is more likely than not DPT-related if (1) the vaccine affects the central nervous system diffusely within 48 hours or less, (2) careful examination eliminates alternate causes, and (3) epidemiological evidence supports a causal relationship. Tr. at 140-41, 145, 161. More particularly, DPT-caused seizures are not simple, garden variety seizures, but are difficult ones to treat. Tr. at 142. Dr. Menkes believes John-Paul suffered a difficult convulsive disorder. Tr. at 126-27, 133. In addition, coincidentally-occurring central nervous system disorders, even severe ones, are often distinguishable from vaccine-related injuries through thorough evaluations conducted to identify other causes.[34] Tr. at 141-42. In this case, subsequent testing and examinations ruled out metabolic, infectious, and structural etiologies as potential explanations for John-Paul's problems.

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neurologic condition is greater than the risk of incurring whooping cough." Tr. at 179.

[34]Dr. Menkes concedes infantile spasms frequently manifest during the same time period physicians administer routine childhood immunizations. Tr. at 163.

P. Ex. 12 at 3; Tr. at 136. Finally, while Dr. Menkes admits the Institute of Medicine[35] rejected a causal link between the pertussis vaccine and infantile spasms and John-Paul failed to meet the National Childhood Encephalopathy Study's parameters, he proffers another potential scientific theory of causation. Tr. at 161, 174-75. He opines that in rare instances, the pertussis toxin can breach the blood-brain barrier, then act as a histamine antagonist to cause, similar to other histamine antagonists, infantile spasms. Tr. at 162. He references without satisfactory elaboration three studies in support of this position. Tr. at 161-62; P. Ex. 7, filed March 8, 1999; P. Ex. 15, filed March 8, 1999; P. Ex. 16, filed March 8, 1999.

Respondent's Expert: Joel Herskowitz, M.D.[36]

Dr. Herskowitz testified on respondent's behalf in this matter. Dr. Herskowitz opines to a reasonable degree of medical certainty that based on the contemporaneous medical records and affidavits submitted, John-Paul did not suffer an acute encephalopathy, as defined in the revised Table's "Qualifications and aids to interpretation," within three days following *either* vaccination. R. Ex. A (Medical Expert Report of Dr. Joel Herskowitz) at 3, 4, filed December 7, 1998; Tr. at 182.

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[35]The law establishing the Vaccine Program, P.L. 99-660, charged the Institute of Medicine of the National Academy of Sciences to review the medical and scientific literature regarding risks associated with the various vaccines covered under the Program. The specific committee assigned to review the adverse events associated with the DPT vaccine, the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, published its findings in 1991 in a report entitled Adverse Effects of Pertussis and Rubella Vaccines. See Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines (1991). Considering the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee, the court has consistently accorded great weight to the IOM's findings. See, e.g., Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418, at *23, n. 68 (Fed. Cl. Spec. Mstr. Mar. 30, 2001); Salmond v. Secretary of HHS, No. 91-123V, 1999 WL 778528, at *5, n. 10 (Fed. Cl. Spec. Mstr. Sept. 16, 1999).

[36]Dr. Herskowitz is a board-certified pediatric neurologist. R. Ex. B (Dr. Herskowitz's Curriculum Vitae) at 2, 3, filed December 7, 1998; Tr. at 185. Following his postgraduate studies at Chicago Medical School and the Albert Einstein College of Medicine, he gained speciality training in pediatrics, child psychiatry, and neurology. R. Ex. B at 1. Since 1988, he has served as a staff pediatric neurologist with the New England Medical Center Hospital in Boston, Massachusetts. R. Ex. B at 3. In addition, he is an Assistant Clinical Professor of Pediatrics at the Boston University School of Medicine and the Medical Director for the Boston Higashi School. R. Ex. B at 3. He has been a member of a number of medical societies and is an accomplished writer on topics involving pediatrics, child psychiatry, and neurology. R. Ex. B at 4-8. Dr. Herskowitz has testified on respondent's behalf in approximately 30 vaccine claims and reviewed about 60 cases. Tr. at 208. He has also testified several times before the undersigned. In this case, as in previous cases, the court considered Dr. Herskowitz an excellent and credible witness who demonstrated significant knowledge about his medical field and its application to the facts of this case.

That is, after neither of his vaccinations did John-Paul suffer a "significantly decreased level of consciousness," require hospitalization, or otherwise suffer a severe adverse reaction. R. Ex. A at 4. He did not have a recognized encephalopathy prior to his first vaccination. Tr. at 214. While he reportedly experienced high-pitched, unusual, inconsolable screaming and crying following his first DPT shot, these symptoms did not signal a significantly decreased level of consciousness as required by the Act. R. Ex. A at 4, 5. Nor did John-Paul exhibit any other significant behavior in conjunction with this screaming/crying to support a Table encephalopathy, such as "marked profound alteration in the mental state" or "bulging of the fontanelle." R. Ex. A at 4; Tr. at 186, 229. Indeed, the first episode was not even recorded in the medical records until the four month appointment. R. Ex. A at 4. In addition, while John-Paul's grandmother summoned the paramedics following the first vaccination, they administered no medical treatment other than an evaluation and did not recommend hospitalization. R. Ex. A at 4, 5. In fact, John-Paul was consolable, as he quieted following Mrs. Grabowski's administration of Tylenol. R. Ex. A at 5; Tr. at 186, 229.

Dr. Herskowitz believes the same observations can be made regarding the events following the second vaccination. Again, the DeRoches did not report or describe a significant decrease in John-Paul's level of consciousness or a dramatic change in his behavior, nor was hospitalization required or even emergency medical care sought. R. Ex. A at 4, 5; Tr. at 188-90. And although by December 2, 1994, John-Paul exhibited arm and leg extensions with eye crossings which in hindsight were seizures, he was alert on exam (meaning no marked alteration in John-Paul's mental state) and his eye deviations were "unassociated in the office with abnormal limb movement."[37] R. Ex. A at 4; see also Tr. at 189. In accordance with the Act, "[s]eizures in themselves are not sufficient to constitute a diagnosis of encephalopathy." R. Ex. A at 7. Moreover, any alterations in behavior, such as John-Paul's failure to vocalize as he had before, did not otherwise "meet temporal

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[37]Dr. Herskowitz testified that regardless of the EEG findings, the eye deviations and extensions (motor behavior) John-Paul experienced following the second vaccination were "more likely than not" seizures. Tr. at 190, 225. He opined:

> And I know there are fancy schmancy studies later on where they did video telemetry, simultaneous this and that. I don't care what it showed. That is more likely than not a seizure and if it was just the eyes crossing, well, maybe, possibly but the combination of the two makes to me more likely than not that it was a seizure.

Tr. at 190. However, while Dr. Herskowitz further admits seizures may indicate the onset of an encephalopathy, he notes convulsions alone fail to satisfy the Program criteria for a Table encephalopathy. Tr. at 210-11, 212-13. Incidentally, Dr. Herskowitz's opinion conflicts with Dr. Snead's, John-Paul's original treating neurologist. Dr. Snead did not believe the child's eye crossing episodes qualified as seizures based on the video EEG results. See P. Supp. Ex. 10 at 2. This difference in opinion illustrates the complexity of this case and, despite the best efforts of highly qualified doctors, their inability to diagnose with any certainty John-Paul's medical problems.

and symptomatic criteria for encephalopathy." R. Ex. A at 7. Finally, the head circumference chart also fails to confirm an encephalopathy at two or four months.[38] Tr. at 193.

Because John-Paul did not experience an acute Table encephalopathy, Dr. Herskowitz rejects that either vaccination aggravated an underlying encephalopathy or developmental and neurological condition. R. Ex. A at 7; Tr. at 183. However, Dr. Herskowitz grants that John-Paul experienced a progressive and insidious developmental downturn. Tr. at 187, 224, 227. He also concedes the onset of seizure activity after the second vaccination indicated something was wrong with John-Paul's brain. Tr. at 21l. At issue for him, though, is the onset date of John-Paul's problems. Tr. at 224. In his view, there is "evidence between the two DPT shots that there was abnormal development which . . . is brain based." Tr. at 214. At the same time and although not certain, he places the onset of this progressive fall-off at one to two months with the loss of social smiling.[39] Tr. at 187, 201, 225. This regression represents an alteration in John-Paul's interactive behavior which is later accompanied by alterations in his vocalizing and motor behavior. Tr. at 187, 227, 228. Dr. Herskowitz also attributes this loss of social skills to "sub-clinical seizures interrupting his contact with the environment." Tr. at 190; see also Tr. at 227. He "suspect[s] that [John-Paul] had abnormal electrical activity of the brain several months before the seizures became clinically apparent at the time of the second DPT shot." Tr. at 191. However, the DPT did not aggravate John-Paul's subclinical condition. Tr. at 191, 201. Dr. Herskowitz explains:

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[38]In response to Mr. DeRoche's cross-examination asking him to opine whether the seizures on the evening of November 29th constituted an encephalopathy in the medical (versus regulatory) sense, Dr. Herskowitz testified that if John-Paul was encephalopathic from a medical standpoint on November 29th, he was the previous day also based on John-Paul's "[a]bnormal behavior as evidenced in the pediatrician[']s examination and as evidenced by [Mrs. DeRoche's] observations." Tr. at 213. Petitioners interpret this testimony as a concession by respondent's expert that John-Paul was encephalopathic on the day of his second vaccination. The court is unwilling to give that much meaning to Dr. Herskowitz's response. At best, it is consistent with Dr. Menkes's testimony that John-Paul did not suffer an acute encephalopathy following the second vaccination since he developed one previously, sometime following the first DPT inoculation. Tr. at 120, 135, 175. The totality of Dr. Herskowitz's testimony, as detailed above, delineates clearly his opinion.

[39]Dr. Herskowitz concedes that although by two months John-Paul evidenced a lack of social smiling, he was also cooing and chuckling at the same visit. Tr. at 204. Dr. Herskowitz could not reconcile the neurological significance of these two findings, except to say that cooing is a language milestone and smiling is a social interactional milestone. Tr. at 204-06. He also acknowledges that findings involving John-Paul's ability to hold his head up were inconsistent. Tr. at 205. Again, the inconsistency of these findings and Dr. Herskowitz's own conflicting testimony regarding the onset date of John-Paul's problems (see supra at page 23, Dr. Herskowitz's testimony pointing to abnormal development between two and four months and/or a progressive fall-off in development beginning at one to two months) exemplifies the perplexing nature of John-Paul's clinical picture.

> I think that he would have gone on from his non-infantile spasm seizure disorder that I'm saying was clinically recognized the very day of the [second] DPT shot and he would have progressed to his [sic] close enough to be called infantile spasms and I think that if you – absent the second DPT shot that clinical course would have been no different.

Tr. at 191. Dr. Herskowitz described the progressive nature of John-Paul's condition as being all part of the same process:

> Looking at the KIDS record, which shows early question mark and deviation, listening to your wife's testimony today which I found very compelling of an intuition of abnormally [sic] of between two and three months substantiated maximally by the plane ride, leading one month later to the pediatrician's documentation further of some development deviations if not delay and then as we progress further deviations and delay which were accentuated by the side effect of ACTH therapy.

Tr. at 201; see also Tr. at 192-93 (Dr. Herskowitz suggesting that the ACTH therapy may be responsible for John-Paul's accelerated loss of brain growth and milestones), 202. Dr. Herskowitz agreed John-Paul unquestionably had a chronic encephalopathy at the time of the hearing in the general, medical sense. Tr. at 195-96.

Dr. Herskowitz also opines the DPT vaccine did not cause John-Paul's infantile spasms. R. Ex. A at 6. He first notes the Institute of Medicine concluded in its 1991 report entitled Adverse Effects of Pertussis and Rubella Vaccines that "[t]he evidence does not indicate a causal relation between DPT vaccine or the pertussis component of DPT and infantile spasms."[40] R. Ex. A at 6; see also R. Ex. C at 77; Tr. at 193. The IOM arrived at this conclusion after evaluating several studies addressing the causal relationship between pertussis and infantile spasms; the studies' results "argue[d] against an excess risk of infantile spasms attributable to the pertussis component of the vaccine." R. Ex. A at 6; see also R. Ex. C at 77. Dr. Herskowitz relies next on Dr. Menkes's own publication in the Textbook of Child Neurology which confirms that infantile spasms present most often between three and eight months of age, when DPT vaccinations are routinely given. R. Ex. A at 6; R. Ex. E (J.H. Menkes, *Infantile Spasms (West Syndrome), in* Textbook of Child Neurology 744, 747 (1995)) at 747, filed December 7, 1998; Tr. at 193. He also notes changes in the immunization schedule did not coincide with changes in the onset of infantile spasms in a Scandinavian study. Tr. at 194. Finally, respondent's expert points to the Miller study, the ten year follow-up report to the National Childhood Encephalopathy Study, which emphasized the absence of an etiologic link in previously reported analyses. R. Ex. A at 6; R. Ex. D (David Miller, Nicola

[40]Dr. Herskowitz also notes the IOM and other studies do not support a causal relationship between DPT and afebrile seizures. Tr. at 222-24. See Salmond, 1999 WL 778528, at *5 (discussing the IOM's 1991 report rejecting a causal relation between the vaccine and afebrile seizures).

Madge, Judith Diamond, Jane Wadsworth & Euan Ross, Pertussis Immunisation and Serious Acute Neurological Illnesses in Children, 307 Brit. Med. J. 1171-76 (1993)) at 3, filed December 7, 1998; Tr. at 193. However, Dr. Herskowitz believes that while the literature does not support a causal relationship, it is possible. Tr. at 197. In the end, Dr. Herskowitz reconciles that John-Paul's irreparably developmentally delayed state was simply the unfortunate consequence of his infantile spasms, unrelated to any DPT vaccinations. R. Ex. A at 7; but see Tr. at 215, 217-18 (Dr. Herskowitz stating he does not know the cause of John-Paul's problems).

IV. THE VACCINE ACT AND RELEVANT JURISPRUDENCE

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence. This requires that the trier of fact "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." Hodges v. Secretary of HHS, 9 F.3d 958, 963 (Fed. Cir. 1993) (Newman, J., dissenting) (citing Concrete Pipe and Products of California, Inc. v. Construction Laborers Pension Trust for Southern California, 508 U.S. 602 (1993), quoting In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring)).

For presumptive causation claims filed on or after March 24, 1997, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 C.F.R. §100.3(a) (1997).[41] Once a Table injury has been established by a preponderance of the evidence, the presumption of vaccine-relatedness may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine. §13(a)(1)(B). In this case, an encephalopathy is presumptively related to the vaccine if it complies with the definition at §100.3(b)(2) and first manifests within three days following the vaccination according to §100.3(a).[42]

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[41]Future references to the Secretary's regulation at §100.3 or its subsections shall be without citation to "42 C.F.R."

[42]Congress extended to the Secretary authority to promulgate revised Vaccine Injury Tables and "Qualifications and aids to interpretation." See §14(c). See also O'Connell v. Shalala, 79 F.3d 170, 176-77 (1st Cir. 1996); Terran v. Secretary of HHS, 195 F.3d 1302, 1314 (Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000). Under this authority, the Secretary's administrative revisions are in the form of regulations which are codified in the Code of Federal Regulations. The filing date of one's petition determines whether the case is governed by the statute's (42 U.S.C.A. §300aa-14) or a regulation's (42 C.F.R. §100.3) Vaccine Injury Table and "Qualifications and aids to interpretation."

To demonstrate entitlement to compensation in an off-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[a petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges, 9 F.3d at 961; Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.[43] See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N 6344. While petitioner need not show that the vaccine was the sole or even predominant cause of the injury, petitioner bears the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N 6344. Nor do petitioners 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,

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[43]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. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000). 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. Daubert, 509 U.S. at 590. 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; 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.

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, 9 F.3d at 960. Finally, a petitioner does 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.[44]

As discussed above, petitioners allege both Table and off-Table injuries as a result of the DPT vaccinations administered to their son on September 30, 1994, and November 29, 1994. The court addresses these claims categorically in the following section.

V. DISCUSSION

This is an extremely complex case, medically and legally. Mrs. DeRoche and Dr. Doyle, two individuals contemporaneously involved with John-Paul's care and treatment before and following his second vaccination, testified cogently and credibly. The medical records filed are detailed. In addition, the parties introduced expert testimony from highly respected and experienced physicians. Still, from all of this evidence, the court is left with an inconsistent and ill-defined picture of John-Paul's clinical condition before and after his second DPT vaccination. The undersigned cannot discern clearly from the evidence a medical agreement as to the diagnosis or timing of onset of John-Paul's injuries. For instance, Dr. Doyle did not consider John-Paul's post-vaccinal problems neurological in nature. Similarly, treating neurologist Dr. Snead dismissed that John-Paul's extremity extensions and eye crossings which began within three days of the second vaccination were seizures. In contrast, respondent's expert believes these events represented convulsions. As another example of John-Paul's confusing medical picture, Dr. Herskowitz places the onset of John-Paul's problems anywhere between one month and four months of age (his opinion varies), but Mrs. DeRoche did not have concerns until late in John-Paul's third month when his vocalizations diminished. Also, Dr. Doyle was alarmingly surprised by John-Paul's change in symptoms by December 2, 1994, three days following the second DPT, but Mrs. DeRoche testified her son's behavior did not change drastically within the seventy-two hours following his second vaccination. In addition, the KIDS chart, reflecting milestones gained and lost, is somewhat confusing and in several instances apparently conflicting. If there exists one consistency in John-Paul's medical

[44]In Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001), the undersigned proposed a five-prong test for establishing causation-in-fact by a preponderance of the evidence in the absence of epidemiological evidence. The standard requires that petitioner provide proof of (1) medical plausibility, (2) confirmation of medical plausibility from the medical community and literature, (3) an injury recognized by the medical plausibility evidence and literature, (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) the elimination of other causes. Stevens, 2001 WL 387418, at *23-*26. Because the last brief filed in this case predates the Stevens decision, the parties did not have an opportunity to evaluate or explain their position in light of this proposed standard. However, because petitioners' claim of a DPT-related injury is covered by the epidemiology of the NCES, the five-prong circumstantial evidence test of Stevens does not apply to this case.

history, it is that his diagnosis and treatment were a "work-in-progress" well after his second vaccination. That is, his treating physicians continued to gather information and "work" the case in an effort to better understand and define John-Paul's problems. Ultimately, the confluence of all the testimony and medical records results in a very perplexing medical picture which fails to fit comfortably into any of the several valid theories of recovery petitioners raised.[45]

After considerable thought and assessment, the court concludes that this is an extremely close case with legitimate but uncertain legal and medical issues. The undersigned holds, following a review of the entire record, that petitioners have not demonstrated by a preponderance of the evidence that the individual or cumulative DPT vaccines administered to John-Paul presumptively or actually caused his injuries or death nor did they aggravate any pre-existing injuries. While the court finds Drs. Doyle and Herskowitz most credible, neither could persuasively pinpoint the onset of John-Paul's problems. Also, the medical records do not support the onset of a Table acute encephalopathy following the first vaccination, and both petitioners' experts reject the onset of an acute encephalopathy following the second vaccination. While all agree John-Paul suffered some condition prior to his second DPT shot, no one concurs on the nature of that condition or its onset or aggravation date for purposes of a causation-in-fact or aggravation claim. More pointedly, there exists no single or identifiable acute event following the second vaccination to signal the onset of a worsening in John-Paul's condition. For these and additional reasons detailed more fully below, petitioners' claims fail.[46]

A. Petitioners' Table Onset Claims

Table encephalopathy

As stated, all claims filed on or after March 24, 1997, including the DeRoches', are governed by the Vaccine Injury Table promulgated by the Secretary's February 20, 1997 Final Rule. See 62 Fed. Reg. 7685 (Feb. 20, 1997) (codified at 42 C.F.R. §100.3 (1997)). Under that Table, the encephalopathy must have its onset within 72 hours of the vaccine's administration. §100.3(a). In

[45]To be clear, the court does not believe petitioners disingenuously put forth a variety of claims with the hopes that perhaps one might prevail.

[46]For reasons unknown to the undersigned, the parties could not settle this case. This is unfortunate and disappointing. Where the various treating physicians and highly credible experts provide well-reasoned yet conflicting assessments of the medical events (see, e.g., the different opinions of Drs. Snead and Herskowitz on whether John-Paul exhibited seizures within three days of his second inoculation), the sensible and reasonable approach, especially in light of the expressed congressional desire to compensate petitioners to dissuade tort actions against manufacturers and doctors, is to compromise the claim.

addition, pursuant to the *revised* "Qualifications and aids to interpretation" ("QAI" or "QAIs") which accompany the Table,[47] an individual has suffered an encephalopathy only if:

> such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.
>
> (i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
>
> > (A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness

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[47]The "Qualifications and aids to interpretation" are read in conjunction with the Vaccine Injury Table. Section 100.3(b) reads: "*Qualifications and aids to interpretation*. The following qualifications and aids to interpretation *shall apply* to the Vaccine Injury Table in paragraph (a) of this section." (Emphasis added.) This language tracks nearly word for word the Act's original statutory language at §14(b). In regards to the original statutory provisions at §§14(a) and (b), Congress stated that the QAIs provide "various descriptions and definitions that the Committee intends be used in interpreting the meaning of the Table." H.R. Rep. No. 99-908, Pt 1, at 19 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6360. See also Terran, 195 F.3d at 1307 ("Congress provided, in the form of a table, a list of vaccines, a parallel list of adverse medical conditions commonly associated with the use of each vaccine, and for certain medical conditions, a time period in which the first symptoms should become apparent following vaccination. These listings comprise the initial Vaccine Injury Table (the 'Initial Table'), and are read in conjunction with a separate subsection, the 'Qualifications and aids to interpretation' (the 'QAIs'), that provides explanations and definitions for terms used in the Initial Table.") (citations omitted). The court has routinely complied with and extended this legislative intent to the Secretary's regulations. See, e.g., Raj v. Secretary of HHS, No. 96-294V, 2001 WL 963984, at *4-*7 (Fed. Cl. Spec. Mstr. July 31, 2001) (evaluating petitioners' Table encephalopathy claim in light of §100.3(b)); Watt v. Secretary of HHS, No. 99-25V, 2001 WL 166636, at *7-*8 (Fed. Cl. Spec. Mstr. Oct. 26, 2000) (reissued for publication on January 26, 2001) (evaluating petitioners' Table encephalopathy claim in light of §100.3(b)); Riggs v. Secretary of HHS, 40 Fed. Cl. 440 (1998) (evaluating petitioner's Table encephalopathy claim in light of §100.3(b)); Shyface v. Secretary of HHS, No. 95-272V, 1997 WL 829404 (Fed. Cl. Spec. Mstr. Nov. 13, 1997), rev'd, 165 F.3d 1344 (Fed. Cir. 1999) (evaluating petitioner's Table encephalopathy claim in light of §100.3(b)). The court sees no reason to depart from this method of evaluation in this case.

persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

. . . .

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(*1*) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(*2*) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(*3*) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

§100.3(b)(2). See also 62 Fed. Reg. at 7689; 60 Fed. Reg. 7678, 7694-95 (Feb. 8, 1995) (codified at 42 C.F.R. §100.3 (1995)).[48] The court evaluates petitioners' claim against these provisions. Specifically, the court must determine within §100.3(b)(2)'s parameters whether John-Paul suffered the onset of a Table encephalopathy within seventy-two hours following his September 30, 1994 *or* November 29, 1994 vaccinations. Petitioners concede that John-Paul's high-pitched screaming on September 30, 1994, may not meet the Table's definition for an acute encephalopathy. P. Supp. Pre-Hrg Memo at 8; P. Post-Hrg Br. at 40. The court concurs and finds for the reasons stated below that petitioners failed to demonstrate a Table encephalopathy with respect to *either* vaccination.

John-Paul's first DPT vaccination

John-Paul allegedly experienced the following symptoms within twenty-four hours of his first DPT vaccination administered September 30, 1994: distress, inconsolable crying, and high-pitched screaming with stiffening. None of these events alone or in combination meet the Table's encephalopathy definition. While John-Paul's grandmother called 911 out of concern for her grandson's behavior, the responding paramedics found a mildly ill but otherwise alert, properly breathing child exhibiting no medical problems. He received Tylenol, quieted down (was consolable), and required no further medical treatment or hospitalization. Indeed, John-Paul was sleeping soundly by the time his parents arrived home from dinner. In the following three days, according to Mrs. DeRoche's own testimony, John-Paul experienced no further complications. John-Paul did not suffer a fever or convulsions. This is substantiated by the contemporaneous medical records which fail to record any encephalopathy diagnosis or any other neurological concerns within 72 hours following his first DPT shot, including any sustained significant decrease or loss of consciousness or increased intracranial pressure. If anything, the medical records reveal that John-Paul's pediatrician and parents considered him in relatively fine health until the November 29th appointment.

The court also rejects Dr. Menkes's testimony that John-Paul suffered a Table encephalopathy following the first DPT inoculation. Dr. Menkes admits unfamiliarity with the statutory/regulatory criteria. See Tr. at 125. Instead, he offers an opinion based on a broad medical definition for encephalopathy, not on the Table's revised version which binds this court. In any event, nothing in his testimony otherwise satisfies the revised QAI for encephalopathy. John-Paul's crying and screaming were quickly controlled by the administration of Tylenol which suggests against a serious condition. In addition, Dr. Menkes references a decrease in response to the environment and to external stimuli based on events occurring one to two months later, well outside the Table time period. Indeed, Dr. Menkes's opinion that John-Paul suffered an acute encephalopathy after the first DPT shot rests largely not on the specific events occurring within the crucial seventy-two hours following the vaccination, but on the developmental delays detected on the day of and subsequent to the second vaccination given two months later.

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[48]The Final Rule promulgated February 8, 1995, implemented the bulk of the substantive changes to the encephalopathy definition which apply in this case. The Secretary's February 20, 1997 revisions only clarified §100.3(b)(2)(i) by adding "(whether or not hospitalization occurred)."

Without persuasive evidence to the contrary, the court concludes the symptoms John-Paul experienced following his first vaccination were not as "extraordinary" as Dr. Menkes believed, but simply within the range of benign or local systemic reactions often witnessed following the DPT inoculation. See, e.g., Charney v. Secretary of HHS, No. 90-1125V, 1994 WL 116137 (Fed. Cl. Spec. Mstr. Mar. 22, 1994); Gamache v. Secretary of HHS, 5 F.3d 1505 (Fed. Cir. 1993). Certainly, the symptoms John-Paul suffered the evening of his first DPT vaccination do not satisfy the regulatory criteria for a Table encephalopathy. See, e.g., Raj, 2001 WL 963984, at *4-*7 (evaluating petitioners' Table encephalopathy claim in light of §100.3(b)); Watt, 2001 WL 166636, at *7-*8 (evaluating petitioners' Table encephalopathy claim in light of §100.3(b)).

John-Paul's second DPT vaccination

Within seventy-two hours of his second DPT vaccination administered November 29, 1994, John-Paul experienced twitching, arm extensions, and eye crossings which the experts agree in hindsight represented seizure activity. John-Paul also manifested increased extensor tone and weak shoulder girdle. He likewise exhibited the same head lag and gross motor delay detected by Dr. Doyle on exam immediately prior to the administration of his second DPT. Again, alone or in combination, these symptoms do not meet the Table criteria for an acute encephalopathy. The regulation clearly states that "[s]eizures in themselves are not sufficient to constitute a diagnosis of encephalopathy." §100.3(b)(2)(i)(E). Nor do John-Paul's seizures in combination with the other exam findings demonstrate an acute encephalopathy. There is no evidence that John-Paul suffered a significant decrease in his level of consciousness at all, much less for 24 hours straight. In fact, Mrs. DeRoche described John-Paul as fussy in the days following the inoculation, but she witnessed no drastic change in his behavior. Moreover, Drs. Doyle and Smith found John-Paul alert during their December 2nd exam. While John-Paul may have had problems with eye deviations, he also fixed and followed which negates any conclusions of absent eye contact. Even Dr. Menkes failed to find in the December 2nd records anything to support a decreased environmental response. There simply is no support that John-Paul suffered for at least 24 hours or more a decreased or absent response to the environment or with eye contact or an inconsistent or absent response to external stimuli in temporal relationship to the second vaccine. And, again, there is nothing from the records or the testimony which supports a finding of increased intracranial pressure as an indicator of an acute encephalopathy. Further, the DeRoches did not seek emergency medical care nor did John-Paul's treating physicians recommend it which suggests against a serious condition. Finally, no contemporaneous medical records diagnose John-Paul with an encephalopathy within the Table's time period. To the contrary, Dr. Doyle specifically testified that she did not believe John-Paul was suffering an acute encephalopathy at her November 29th and December 2nd exams. Because the records reflect John-Paul suffered delays prior to his December 2nd visit, Dr. Menkes also testified that John-Paul did not suffer an acute encephalopathy following his second DPT inoculation.

For the reasons stated, the court finds that John-Paul did not experience an acute encephalopathy, as defined by the regulations, within three days following his second vaccination.[49]

Other Table onset injuries

Petitioners do not allege any other Table claims and the medical records do not support an alternative Table injury. While John-Paul likely suffered seizures within seventy-two hours following the second vaccination, the Secretary removed residual seizure disorder as a Table injury for DPT claims filed after March 10, 1995. In addition, seizures in and of themselves do not satisfy the definition for a Table encephalopathy. See §100.3(b)(2)(i)(E).

B. Petitioners' Table and Off-Table Significant Aggravation Claims

The aggravation issues presented in this case are extremely complex. John-Paul's medical picture, despite the numerous contemporaneous examinations and subsequent re-evaluations, remains subject to reasonable interpretation and disagreement. For example, as mentioned several times before, Drs. Snead and Herskowitz disagree on whether John-Paul suffered seizures within 72 hours of his second vaccination. Complicating the matter further is viewing the medical issues through the prism of the statutorily created and still unsettled legal concept of significant aggravation. Petitioners allege both an on-Table aggravation, see §11(c)(1)(C)(i), and an aggravation in-fact, see §11(c)(1)(C)(ii)(I).

In resolving these issues, the court relies heavily upon the testimony of Drs. Doyle and Herskowitz. Dr. Doyle presented the first-hand knowledge of what the treating physicians saw and treated while Dr. Herskowitz provided, in the court's view, the most credible interpretation of this difficult medical picture. The court's discussion follows, beginning with a summary of the relevant facts.

Facts relevant to the significant aggravation analyses

By one-month of age, John-Paul was meeting all of his one-month and most of his two-month milestones. At two months, he failed to achieve or lost three milestones but also met most of his three-month developmental skills. He received his first DPT vaccination at two months on September 30, 1994. At three months of age, he attained four and five-month milestones but continued to lose or failed to regain others. Mrs. DeRoche regarded John-Paul as healthy and developmentally appropriate until four months of age, but for his apparent diminished vocalizations at the end of October 1994. At his four-month examination on November 29, 1994, immediately preceding his second DPT vaccination, John-Paul was alert with appropriate height, weight, and head circumference for his age. However, he also exhibited an asymmetrical or flat head with left ear displacement, poor head control and head lag, gross motor delay, and per the mother's stated

[49]Because petitioners failed to prove an acute encephalopathy following either vaccination, it follows they also failed to demonstrate a chronic encephalopathy under §100.3(b)(2)(ii).

concerns, a failure to vocalize as much as he had before although he continued to respond to noise and voices. He also failed to meet or otherwise regain a number of one to four-month milestones. Dr. Doyle attributed John-Paul's head lag to a neck muscle problem or craniosynostosis. Because the examination results did not indicate a progressive neurological condition, Dr. Doyle administered John-Paul's second DPT vaccination at the November 29, 1994 exam. The day of the vaccination, John-Paul appeared normal until 7:00 p.m., at which time he began exhibiting crossing of the eyes with subtle but involuntary arm and leg extensions. The movements were unnoticeable by morning, but his behavior continued for three days accompanied by fussiness. He did not cry or exhibit other alarming behavior and in his mom's view he did not suffer a "drastic" change in his behavior. Dr. Herskowitz opined in hindsight that John-Paul's eye crossing episodes and extremity extensions represented seizure activity; however, Dr. Snead did not.

On December 2, 1994, three days following his vaccination, Drs. Doyle and Smith re-evaluated John-Paul. By this time, exaggerated startling episodes replaced John-Paul's extremity extensions. On exam, he appeared alert and fixed and followed, but also exhibited intermittent extreme eye deviations which the physicians attributed to possible strabismus. John-Paul also exhibited the previously seen head lag, in addition to a variable response to lifting his head when prone, an increased extensor tone, and weak shoulder girdle. He was diagnosed again with gross motor delay. Dr. Doyle was now concerned John-Paul had cerebral palsy. At the close of the appointment, Dr. Doyle referred her patient to a physical therapist for his gross motor delay and abnormal muscle tone and an ophthalmologist for his possible strabismus. By December 12, 1994, John-Paul's eye crossings had ceased, but he was now crossing his legs at the ankles or "scissoring," an event Dr. Doyle associated with cerebral palsy. Also by this time, John-Paul's visual tracking had progressively worsened and he was delayed in all areas with skills at maybe the 2-3 month level.

In the following months, John-Paul continued to suffer developmental delay with some gains. His head circumference tracked consistently in the 75th percentile until six months of age when it began gradually dropping. By January 1995, he had two abnormal EEGs, and Dr. Snead diagnosed him with mild hypotonia and mild to moderate, primarily motor, developmental delay; John-Paul was also at risk for seizures. In February 1995, John-Paul began exhibiting myoclonic jerking of his upper and lower extremities which lasted for several seconds. He also had an EEG consistent with modified hypsarrhythmia in late February. By early March 1995, the jerks increased and he developed new brief spells manifested as stiffening of the upper body and widening of the eyes and tearing. He was diagnosed with infantile spasms (clinically forme fruste), mixed developmental delay secondary to his infantile spasms, partial blindness secondary to his infantile spasms, and plagiocephaly and immediately admitted for ACTH treatment. During his ACTH therapy, John-Paul's clinical seizures subsided, but he continued to have abnormal EEGs. His development dropped and by the end of his treatment, Dr. Snead assessed his development as that of a one-month old. In the months and years following, John-Paul regained some of his lost milestones through therapeutic efforts and continued to have both normal and abnormal EEG results. By the close of the record in this case, John-Paul suffered from significant delays in all areas of development and was severely mentally retarded.

Experts routinely testify that the DPT vaccine is contraindicated in individuals with pre-existing neurological conditions because of its potential to cause further injury. Dr. Menkes confirmed this at the hearing. The Secretary also concedes that "in rare instances, a vaccine may alter the clinical course of a pre-existing condition." 60 Fed. Reg. at 7688. In the following two sections, the court addresses petitioners' allegations of a Table significant aggravation under §11(c)(1)(C)(i) and significant aggravation by causation-in-fact under §11(c)(1)(C)(ii)(I).

Table significant aggravation of a pre-existing encephalopathy[50]

The legal issue

Whitecotton v. Secretary of HHS, 81 F.3d 1099 (Fed. Cir. 1996) is the seminal case on whether petitioners have successfully demonstrated the significant aggravation of an underlying injury within Table time period. See also Gruber v. Secretary of HHS, No. 95-34V, 1998 WL 928423 (Fed. Cl. Spec. Mstr. Dec. 22, 1998) (applying the Whitecotton principles). Whitecotton sets forth a four-prong test which involves a comparison of the person's pre-vaccinal condition with their current condition to see if there was "any change for the worse in a preexisting condition which result[ed] in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." §33(4); see also Whitecotton, 81 F.3d at 1107. A petitioner prevails if a significant aggravation occurred within the relevant Table time period. Whitecotton, 81 F.3d at 1107.

However, prior to applying the Whitecotton test, the court must address a preliminary legal issue. The threshold question involves the proper construction of §11(c)(1)(C)(i) which permits petitioners to allege that a vaccinee "had significantly aggravated . . . any illness, disability, injury, or condition *set forth in the Vaccine Injury Table* . . ." (Emphasis added.) The parties proffer two interpretations to the italicized portion: that petitioners in a Table significant aggravation claim must demonstrate as the precursor to the aggravation (1) *any* pre-existing condition (that is, any injury, including one that does not meet the QAIs) or (2) a pre-existing condition which qualifies under the relevant QAI as a Table injury.[51] In the past, neither interpretation generated debate, presumably because underlying injuries met with ease the statute's broad definition for encephalopathy at §14(b)(3). Now, the Secretary's 1995 revisions to the encephalopathy definition seriously complicate practical application of the second interpretation. In light of respondent's assertion that the second interpretation applies here, the construction of the statutory provision at §11(c)(1)(C)(i) becomes crucial, because the amended Table and respective QAI severely limits the qualified Table

[50]By the time of the parties' post-hearing oral arguments held May 26, 1999, the court had narrowed the case to a Table significant aggravation claim. Closings Tr. at 3.

[51]Pursuant to §13(a)(1)(A), to be awarded compensation, a petitioner must demonstrate "by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1)."

injuries. This is a case of first impression,[52] and the parties spent considerable time briefing the issue.

The parties' respective positions on the legal issue

Petitioners champion the first interpretation – that they need only demonstrate an underlying injury, however defined. They rely chiefly on Justice O'Connor's concurrence in Shalala v. Whitecotton, 514 U.S. 268, 277-79 (1995), for support. Petitioners' Supplemental Post-Hearing Brief ("P. Supp. Post-Hrg Br.") at 14, filed August 2, 1999. Justice O'Connor wrote:

> To establish a table case, the statute requires that a claimant prove by a preponderance of the evidence either (1) that she suffered the first symptom or manifestation of the onset *of a table condition* within the period specified in the table or (2) that she suffered the first symptom or manifestation of a significant aggravation *of a pre-existing condition* within the same period.

Whitecotton, 514 U.S. at 277 (emphasis added by petitioners). Petitioners believe Justice O'Connor intentionally distinguished onset and significant aggravation cases such that a Table significant aggravation claim need not involve a "Table condition," or an underlying injury meeting a specific QAI. P. Supp. Post-Hrg Br. at 14. Petitioners also note the Federal Circuit found the Whitecottons entitled under a presumptive significant aggravation theory without specifically determining that their daughter Maggie suffered a pre-existing *Table* encephalopathy according to §14(b)(3). P. Supp. Post-Hrg Br. at 14.

Respondent defends the second interpretation, arguing that "for presumptive causation, petitioners . . . must demonstrate that the preexisting condition meets the table definition for that condition." Closings Tr. at 34. See also R. Post-Hrg Memo at 20; Respondent's Second Post-Hearing Memorandum ("R. Second Post-Hrg Memo") at 2, filed August 13, 1999. Respondent relies on the Federal Circuit's language in Whitecotton, 81 F.3d at 1102-03, which states:

> [T]he statute also permits recovery if an individual suffers a significant aggravation of a table injury within the statutory time period.
>
> * * *

[52]For all its direction, Whitecotton did not address directly whether the QAIs apply to Table significant aggravation claims. The special master and the Federal Circuit glossed over in their onset and significant aggravation analyses whether Maggie Whitecotton suffered an encephalopathy *as defined by §14(b)(3),* the precursor to the Secretary's administrative changes at issue here.

> [A claimant] must show that [the child] suffered the first symptom or manifestation of the significant aggravation of a table injury within the table time period following [the child's] vaccination. 42 U.S.C. § 300aa-11(c)(1)(C)(i).

(Emphasis added by respondent.) R. Post-Hrg Memo at 20; see also R. Second Post-Hrg Memo at 5.[53] Counsel also points to the plain meaning of the regulatory provision at 42 C.F.R. §100.3(b) which states the QAI section "*shall apply* to the Vaccine Injury Table." R. Post-Hrg Memo at 22 (emphasis added); see also Closings Tr. at 36, 40; R. Second Post-Hrg Memo at 6. Respondent writes:

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[53]Respondent also argues that Whitecotton's four prong test and Gruber do not apply in the DeRoche case because they are pre-regulation cases, that is they relied upon the original Vaccine Injury Table, not the amended Table, and in any event, petitioners did not suffer an underlying Table injury to warrant the standard's application. R. Post-Hrg Memo at 21, n. 11; R. Second Post-Hrg Memo at 11, n. 5. Alternatively, if Whitecotton's standard does govern the DeRoches' claim, petitioners fail the fourth prong because based on Hoag v. Secretary of HHS, No. 94-67V, 1998 WL 408783 (Fed. Cl. Spec. Mstr. Apr. 22, 1998) (reissued for publication June 10, 1998), aff'd, 42 Fed. Cl. 238 (1998), which turned on the date that the infantile spasms diagnosis could be made, John-Paul "did not experience myoclonic jerks of his extremities, as well as an EEG consistent with modified hypsarrhythmia, until late February 1995," well outside the three day time period. R. Second Post-Hrg Memo at 13. In John-Paul's case, no records or testimony support that the twitching, arm and leg extensions and eye deviations exhibited within seventy-two hours "signaled the onset of the infantile spasm syndrome." R. Second Post-Hrg Memo at 13; see also R. Second Post-Hrg Memo at 14. For respondent, "the pre-vaccination progressive disorder evolved expectantly into infantile spasms." R. Second Post-Hrg Memo at 13-14.

Petitioners counter that John-Paul manifested the first symptom of his significant aggravation within seventy-two hours of his second vaccination, as evidenced by the onset of seizures within that time period, change in muscle tone, eye crossings, and Dr. Doyle's opinion that John-Paul's condition was "distinctly different" from three days earlier. P. Supp. Post-Hrg Br. at 41-46; see also Petitioners' Reply to Respondent's Supplemental Post-Hearing Brief ("P. Reply") at 9-11, filed October 15, 1999. Petitioners also contend John-Paul suffered an encephalopathy by December 2, 1994, according to the experts, and that he experienced "a substantial and detrimental clinical change" within three days following the second shot. P. Supp. Post-Hrg Br. at 42, 43. Petitioners distinguish their case from Hoag in so far as John-Paul's seizures began within three days of the second vaccination and steadily progressed, increasing in frequency and evolving into myoclonic jerks until his diagnosis with infantile spasms. P. Supp. Post-Hrg Br. at 41-42, 43, n. 23, 46. Petitioners further note that in significant aggravation, the issue is not the diagnosis date of the infantile spasms syndrome but when the deterioration, however manifested, begins. P. Reply at 12. Petitioners do not believe that any events occurring after the seventy-two hour time period constitute the onset of the aggravation. P. Supp. Post-Hrg Br. at 46, 48; P. Reply at 10-11.

> Thus, when "any illness, disability, injury, or condition listed on the Vaccine Injury Table," 42 U.S.C. § 300aa-11(c), has manifested itself following the administration of a listed vaccine, a special master must engage the applicable Qualifications and Aids to Interpretation section before determining a claimant's entitlement to presumptive causation.

R. Post-Hrg Memo at 22-23. To do otherwise "render[s] superfluous the term 'shall.'" R. Post-Hrg Memo at 23; see also Closings Tr. at 44; R. Second Post-Hrg Memo at 6. Respondent argues that "[t]he statutory requirements to make a *prima facie* significant aggravation claim are analogous to those requirements to make out a *prima facie* initial onset claim." R. Post-Hrg Memo at 23 (citing Whitecotton, 81 F.3d at 1103); see also R. Second Post-Hrg Memo at 5, 6. Under this reasoning, because proving an onset Table claim requires resort to the Table injury definitions in §100.3(b), and both presumptive onset and aggravation cases fall under the same provision at §11(c)(1)(C), then proving a Table significant aggravation claim likewise requires application of the QAI for the injury alleged. Closings Tr. at 35-38, 40. Respondent's counsel acknowledges, however, the practical difficulties of this application to the proof of a significant aggravation of an underlying encephalopathy. Closings Tr. at 41-42; R. Second Post-Hrg Memo at 9-10. By respondent's own argument, to prove a significant aggravation of a Table encephalopathy as defined in the QAI, one must by definition prove first that the individual suffered an acute encephalopathy and a chronic encephalopathy lasting six months prior to the aggravating vaccination and then, second, that following the aggravating vaccination the individual suffered a significant worsening of that pre-existing encephalopathy.

However, respondent's counsel admittedly could not think of a situation where a person would have an acute and chronic encephalopathy in a pre-existing condition. Closings Tr. at 51. As a result, the government offered "that in significant aggravation cases in which claimants allege that the Table injury of encephalopathy occurred before the date of vaccination, the six month requirement of chronicity is met by proof of persistence of symptoms for six months from the date of such pre-vaccination injury." R. Second Post-Hrg Memo at 10; see also Respondent's Reply to Petitioners' Second Post-Hearing Memorandum ("R. Reply") at 2, filed October 15, 1999. In the end, the government believes John-Paul did not suffer an underlying Table acute encephalopathy anytime prior to his second vaccination so petitioners' claim must fail. R. Second Post-Hrg Memo at 9.[54]

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[54]Counsel also contends the principles of sovereign immunity, in a waiver such as that created by the Act, require that the court narrowly construe statutory or regulatory provisions or ambiguities in favor of immunity or in favor of the government. R. Post-Hrg Memo at 23-25. Where two plausible statutory interpretations exists, "the Chief Special Master must choose the interpretation that produces the more limited award." R. Post-Hrg Memo at 25. Respondent also argues the statutory and regulatory language is clear and should be read in a manner that gives each word operative effect. R. Post-Hrg Memo at 25. The court should not resort to the legislative history in the face of plain and unequivocal language. R. Post-Hrg Memo at 25. See also Burch v. Secretary of HHS, No. 99-946V, 2001 WL 180129 (Fed. Cl. Spec. Mstr. Feb. 8, 2001); Mayo v. Secretary of

Petitioners challenge respondent's position on three fronts. First, they argue respondent's adherence to the second interpretation "effectively abolishes on-Table significant aggravation encephalopathy cases." P. Supp. Post-Hrg Br. at 2; see also P. Supp. Post-Hrg Br. at 4, 16. That is, it is nearly medically impossible to demonstrate the aggravation of an already serious underlying injury, such as an acute and chronic encephalopathy. P. Supp. Post-Hrg Br. at 3-4. Respondent's reading thus violates congressional intent to provide a presumptive significant aggravation claim generally and particularly for those suffering the exacerbation of a pre-existing *minor* injury. P. Supp. Post-Hrg Br. at 11, 15, 16; P. Reply at 2, 7. This "abolishment" is neither intended by the Secretary nor supported by the medical literature. P. Supp. Post-Hrg Br. at 11, 12, 19, 20, 24, 27; P. Reply at 2-3. In petitioners' view, the Secretary's failure to follow proper administrative procedures contributed to the publication of a regulation which, when enforced as respondent now suggests, effectively eliminates encephalopathy aggravation cases.[55] P. Supp. Post-Hrg Br. at 20, 24-25, 27-40.

Second, petitioners contend respondent's interpretation treats Table onset and Table significant aggravation cases involving encephalopathy differently, making compensation harder for those pursuing aggravation cases but suffering the same injuries as an onset petitioner. P. Supp. Post-Hrg Br. at 2, 4. Thus, injuries otherwise sufficient under an onset claim may be insufficient in the context of an aggravation claim if the petitioner fails to prove both a pre-existing acute *and* chronic encephalopathy. P. Supp. Post-Hrg Br. at 4, 16. For petitioners, this again violates congressional intent to create a fair, generous, and expeditious compensation scheme which lowers petitioners' burden by providing for presumptive causation. P. Supp. Post-Hrg Br. at 8-10. This distinction is not supported by the literature and again potentially eliminates significant aggravation cases. P. Supp. Post-Hrg Br. at 12.

Finally, petitioners assert that the revised definition for encephalopathy "directly conflicts with the congressional definition of 'significant aggravation' contained in the Vaccine Act." P.

HHS, No. 91-395V, 1996 WL 337323 (Fed. Cl. Spec. Mstr. June 6, 1996).

[55]Petitioners request that the regulation promulgated February 8, 1995, be invalidated for several reasons. P. Supp. Post-Hrg Br. at 27, 35-36, 39; Closings Tr. at 6. First, they contest the Secretary's authority to revise or abolish significant aggravation claims – a consequence of her regulatory changes to the encephalopathy definition. P. Supp. Post-Hrg Br. at 15; Closings Tr. at 6. Second, petitioners dispute that medical findings support the 1995 revisions (as they relate to the encephalopathy definition or significant aggravation cases) or that the Secretary complied with congressionally-mandated procedural guideposts in issuing those changes. P. Supp. Post-Hrg Br. at 11, 12, 19, 27-40; Petitioners' Second Supplemental Post-Hearing Brief ("P. Second Supp. Post-Hrg Br.") at 3, 6, 8, filed April 5, 2000. The First Circuit addressed similar claims in O'Connell and held that "[t]he Secretary had authority to issue the [Final Rule promulgated February 8, 1995] about which the petitioners complain, and she exercised that authority in a procedurally appropriate and substantively permissible manner." O'Connell, 79 F.3d at 182. Terran subsequently ruled that "the 1995 Table is a valid regulatory enactment." Terran, 195 F.3d at 1315.

Supp. Post-Hrg Br. at 2. That is, the Secretary's revisions equate "significant aggravation" with an acute and chronic encephalopathy although §33(4) makes no mention of a "Table" injury. P. Supp. Post-Hrg Br. at 12-13. Moreover, the Secretary's alterations contravene Justice O'Connor's statements in Shalala v. Whitecotton that significant aggravation does not require a pre-existing *Table* injury. P. Supp. Post-Hrg Br. at 13-14.

The court's ruling on the legal issue

Having carefully considered the parties' arguments, the court agrees with respondent and finds that to prove a Table significant aggravation claim brought pursuant to §11(c)(1)(C)(i), petitioner must first demonstrate *an underlying Table injury as that injury is defined by the applicable "Qualifications and aids to interpretation."* The reasons for this ruling are several.

First, the second interpretation of §11(c)(1)(C)(i) best complies with the clear statutory language. As respondent rightfully notes, it is well settled that the court should not resort to legislative history in the face of plain and unequivocal language. R. Post-Hrg Memo at 25. See also Rosete v. Office of Personnel Management, 48 F.3d 514, 517 (Fed Cir. 1995); Hellebrand v. Secretary of HHS, 999 F.2d 1565, 1569 (Fed. Cir. 1993). The plain language at §11(c)(1)(C)(i) states the significant aggravation must be of "any illness, disability, injury, or condition *set forth in the Vaccine Injury Table*." (Emphasis added.) The original Vaccine Injury Table at §14(a) as well as the Table applicable here, §100.3(a), lists the injuries, disabilities, illnesses, and conditions covered for each vaccine. Clearly, the "set forth" language in §11(c)(1)(C)(i) requires an initial review of the applicable Vaccine Injury Table to designate the Table "illness, disability, injury, or condition" to be aggravated. The Table injury is further one defined by the QAI. This is so because, as discussed at page 28-29, note 47, the Vaccine Injury Table and the "Qualifications and aids to interpretation" are always construed together. See Terran, 195 F.3d at 1307. Petitioners proffered no serious disagreement with this stated proposition. The parties also offer no persuasive argument that Congress meant to discard this fundamental intent simply because it authorized the Secretary to revise the Table administratively. And in any event, as the statute required, the Secretary expressly maintained the statutorily-created interdependent relationship between the Table and the QAIs in the regulatory provisions of §100.3(a) and (b). Moreover, in her February 8, 1995 Final Rule, wherein she promulgated the regulations at issue, the Secretary construed the *statutory* language as requiring proof of an underlying *Table* injury:

> The Department is aware that in rare instances, a vaccine may alter the clinical course of a pre-existing condition. Under section 2111 (c)(1)(C) [§11(c)(1)(C)(i)] of the Act, "significant aggravation" of a pre-existing condition may establish eligibility for compensation provided the Petitioner is able to demonstrate *that a Table injury occurred* and that the prior condition was significantly aggravated during the Table time frame.

60 Fed. Reg. at 7688 (emphasis added). The Federal Circuit in Whitecotton concurred in this interpretation, citing directly to the statutory provision at issue here: "Petitioner must show that she

suffered the first symptom or manifestation of the significant aggravation *of a table injury* within the table time period following her vaccination. *42 U.S.C. §300aa-11(c)(1)(C)(i).*" Whitecotton, 81 F.3d at 1103 (emphasis added). Hence, a literal reading of §11(c)(1)(C)(i) requires that petitioners filing claims based on this provision demonstrate an injury listed on the Table and consequently one satisfying the criteria in the relevant "Qualifications and aids to interpretation."

Second, it is widely accepted that the court read statutes and regulations in a manner which gives each provision operative effect. Respondent's interpretation gives effect to the injuries and time frames outlined in the Vaccine Injury Table (under §14(a) or §100.3(a)) which is essential to petitioners' second burden under §11(c)(1)(C)(i) to demonstrate "the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death . . . *within the time period after vaccine administration set forth in the Vaccine Injury Table*." (Emphasis added.) Petitioners' advanced interpretation divests the Table(s) of purpose. That is, under the first interpretation, petitioners are not required to demonstrate a Table injury or an injury within a Table-prescribed time period. This completely ignores the statutory language at §11(c)(1)(C)(i) in so far as it expressly references the Vaccine Injury Table. Furthermore, if §11(c)(1)(C)(i) does not require resort to the Table and thus the QAIs for aggravation cases, it also does not for presumptive onset claims; this then renders meaningless §14(b) or §100.3(b) *in their entirety for every theory of recovery*. As the Federal Circuit in Whitecotton stated,

> *[t]he statutory requirements to make out a prima facie significant aggravation claim are analogous to those required to make out a prima facie initial onset claim.* Petitioner must show that she suffered the first symptom or manifestation of the significant aggravation of a *table injury* within the table time period following her vaccination. 42 U.S.C. §300aa-11(c)(1)(C)(i).

Whitecotton, 81 F.3d at 1103 (emphasis added in part). It is well-settled that the QAIs prescribe petitioners' proof in a Table onset encephalopathy case. Therefore, under Whitecotton the "Qualifications and aids to interpretation" likewise prescribe petitioners' proof of a Table significant aggravation claim.

Third, the DeRoches' reliance on Justice O'Connor's use of the phrase "pre-existing condition" in Whitecotton, 514 U.S. at 277, to support their interpretation is misplaced. The Justice's entire discussion and that of the Court's relates to the significance of "first symptom or manifestation" for Table onset cases. Justice O'Connor did not focus on the Whitecotton's significant aggravation claim other than to note that the Federal Circuit's initial interpretation of the phrase "first symptom or manifestation" "deprives the 'significant aggravation' language in the provision of all meaningful effect." Whitecotton, 514 U.S. at 277. In fact, Justice O'Connor cautioned:

> Today's decision is quite limited. . . . The Court of Appeals also did not address the Whitecottons' argument, rejected by the Special Master, that their daughter suffered a significant aggravation of whatever pre-existing condition she may have had as a

> result of the vaccine. This factual challenge appears to be open as well, as does a challenge to the legal standard used by the Special Master to define "significant aggravation."

Whitecotton, 514 U.S. at 278.[56]

Application of the court's ruling under the revised "Qualifications and aids to interpretation"

The second interpretation is far easier reached than applied. Just as respondent's counsel was unable to think of a significant aggravation case meeting the Secretary's revised encephalopathy definition, so is this court. While one must apply the QAIs in Table significant aggravation claims pursuant to §11(c)(1)(C)(i), the revised encephalopathy definition, as written, makes this statutory mandate infeasible. This is because §100.3(b)(2) is restricted by its own language to Table *onset* cases, that is, cases where the injury occurs within the prescribed period following vaccination. The definition also effectively abolishes most significant aggravation claims based on an encephalopathic injury. Section 100.3(b)(2) states in relevant part:

> a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, *within the applicable period*, an injury meeting the description below of an acute encephalopathy, *and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination*.

(Emphasis added.) The Secretary restricted the definition to Table *onset* cases by the italicized phrase, "within the applicable period." In significant aggravation cases, any pre-existing encephalopathic injury must occur, **by definition**, *before* the aggravating inoculation is administered. By limiting the encephalopathy definition to those petitioners suffering the onset of their injury within the Table time frame of three days *following* vaccination, §100.3(b)(2) cannot be applied to Table aggravation claims. **In essence, the definition conflicts with the very notion of aggravation of a pre-existing or pre-vaccination injury**.[57] Section 100.3(b)(2) further abolishes most encephalopathy-based Table aggravation claims because any petitioner whom successfully meets the definition has already sustained a Table-onset injury and would have no reason to pursue a Table significant aggravation claim based on an underlying encephalopathy. Moreover, by requiring in

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[56]The court's ruling is not without precedence. In Haley v. Secretary of HHS, No. 90-2727V, 1999 WL 476272, at *12 (Fed. Cl. Spec. Mstr. June 21, 1999), Special Master Wright determined that because one could reasonably conclude that the vaccinee's structural defects of the brain satisfied the Act's broad definition for encephalopathy (*i.e.*, the pre-revised version), petitioners could properly pursue a Table significant aggravation claim. Petitioners went on to successfully demonstrate their claim pursuant to the Whitecotton four-prong aggravation test. Haley, 1999 WL 476272, at *18.

[57]Requiring a chronic encephalopathy "for more than 6 months *beyond the date of vaccination*" also restricts the definition to post-vaccination injuries.

addition to an acute encephalopathy a chronic encephalopathy lasting *more than six months* (for instance, if the court eliminates the definition's post-vaccination references and retains chronic encephalopathy as an element of proof), petitioners cannot pursue a significant aggravation claim unless they received the aggravating vaccination after the six month period has passed – such as maybe following the booster shot. Given the temporally close routine schedule for immunizations (usually at 1, 2, 4, 6, 12, 15, and 18 months of age), many petitioners would be without recourse under the Vaccine Program for injuries aggravated by their early set of vaccinations; claimants would have to pursue traditional civil litigation instead. See Closings Tr. at 61 (respondent's counsel agreeing with the court's conclusion that the Secretary's chronic encephalopathy requirement "foreclose[s] individuals from claiming a presumptive significant aggravation off of their first three scheduled DPT shots").

To be sure, as petitioners in this case recognize, there is no evidence the Secretary actually intended to eliminate Congress's express provision of a Table significant aggravation theory of recovery in §11(c)(1)(C)(i), nor render useless the tools in the Table and the QAIs to prove that theory. In fact, the Secretary acknowledged in promulgating the regulations that "the Department is limited to the authority delegated by Congress, and is obligated to act consistent with Congressional intent." 60 Fed. Reg. at 7679 (citations omitted). The Secretary further recognized that "[t]he purpose of the Qualifications and Aids to Interpretation is to describe those circumstances" "under which such causation or aggravation can reasonably be determined to occur." 60 Fed. Reg. at 7680 (citations omitted). There is also no evidence the Secretary meant to abolish recovery under the Program for petitioners failing to establish an underlying chronic encephalopathy. Clearly, this would frustrate congressional intent to reduce tort litigation against the manufacturers and administrators since those petitioners' only other recourse would be civil litigation. See Closings Tr. at 47. What is clear from the Final Rule is that the Secretary recommended the encephalopathy definition revisions based on the IOM, NCES, and Miller study findings,[58] and to bring the Table definition in line, *per the statutory mandate*, with the latest and best scientific knowledge. 60 Fed. Reg. at 7678, 7679, 7682-85. The Secretary also promulgated the changes to put into "layman's" terms those clinical signs and symptoms indicative *of a vaccine-related, and thus post-vaccination,* encephalopathic injury. 60 Fed. Reg. at 7687. Unfortunately, by focusing exclusively, as it appears HHS did, on what constituted a medically-supported Table onset encephalopathy, little attention was paid to the revisions' potential legal impact on significant aggravation cases, resulting in the interpretive dilemma now faced by this court.[59]

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[58]All these reports focused on adverse events following vaccination, rather than the aggravating impact of the DPT vaccination on pre-existing encephalopathies or other injuries – just one more indicator that the Secretary's focus in making the revisions was a Table encephalopathy not a Table aggravation injury.

[59]In the February 8, 1995 Final Rule, the Secretary hardly discussed the effect of the revisions on aggravation cases. In fact, her only statements on the matter are in response to commentators' concerns "that the proposed revisions do not take into account the condition of tuberous sclerosis complex (TSC), which some believe can be aggravated by DTP vaccine." 60 Fed. Reg. at 7691. The

The interpretive dilemmas created by the Secretary's revisions must be resolved by resort to canons of statutory and regulatory construction. Generally, the court must not look to the legislative history if the statutory language is plain and unequivocal on its face. Rosete, 48 F.3d at 517; Hellebrand, 999 F.2d at 1569. "The statutory language should be conclusive '*except in the rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters.*'" Warner Cable v. Doyle, 66 F.3d 867, 876 (7th Cir. 1995), cert. denied, 516 U.S. 1141 (1996) (citations omitted) (emphasis added). "[A] literal construction is *inappropriate* if it would lead to absurd results or would thwart the obvious purposes of the statute." Warner Cable, 66 F.3d at 876 (emphasis added). See also United States v. American Trucking Assns., Inc., 310 U.S. 534, 542-44 (1940); Haggar Co. v. Helvering, 308 U.S. 389, 394 (1940) ("All statutes must be construed in the light of their purpose. A literal reading of them which would lead to absurd results is to be avoided when they can be given a reasonable application consistent with their words and with the legislative purpose."). In the case of absurd results, "[i]t is a principle of statutory interpretation . . . that a court . . . should try to construe a statute in a way which is consistent with the intent of Congress." Hellebrand, 999 F.2d at 1570-71. In addition, the court should adhere to "the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative." Mountain States Telephone & Telegraph Co. v. Pueblo of Santa Ana, 472 U.S. 237, 249 (1985) (internal quotation marks omitted). These same principles of statutory interpretation apply to the interpretation of regulations. Trustees of Indiana Univ. v. United States, 618 F.2d 736, 739 (Cl. Ct. 1980); see also DGS Contract Service, Inc. v. United States, 43 Fed. Cl. 227, 239 (1999). "Thus, if fairly possible, legislative regulations must be construed to avoid conflict with a statute." Exxon Corp. v. United States, 40 Fed. Cl. 73, 90 (1998) (citing Smith v. Brown, 35 F.3d 1516, 1526 (Fed. Cir. 1994) (citations omitted)). See also Trustees of Indiana Univ., 618 F.2d at 739 ("[A] regulation must be interpreted so as to harmonize with and further and not to conflict with the objective of the statute it implements."). Further, "[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." Chevron U.S.A., Inc., v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843, n. 9 (1984).

Secretary answered that even with the removal from the Table of a residual seizure disorder, "to receive a presumption of causation, petitioners may still argue that an encephalopathy (as defined in the revised Qualifications) occurred within 3 days of vaccine administration and that this encephalopathy significantly aggravated the pre-existing Tuberous Sclerosis." 60 Fed. Reg. at 7691. She further submitted that this same analysis would apply to TSC aggravation claims based on the MMR vaccine; petitioners would first have to prove either a Table encephalopathy or a Table residual seizure disorder, including onset within the applicable Table time period, and then "that [either] injury significantly aggravated the underlying TSC." 60 Fed. Reg. at 7691. The undersigned finds these statements telling in two respects. First, they highlight the cursory treatment the Secretary gave to the impact of the changes on significant aggravation cases. Second, they evidence a completely different legal analysis for significant aggravation claims than that now advocated by respondent's counsel seven years later.

Mindful of these principles, the court rules that in applying §100.3(b)(2) to the DeRoches' Table encephalopathy significant aggravation claim, the phrases "within the applicable period" and "then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination" shall be omitted from the regulation.[60] Consequently, the court also reads out of the regulation §100.3(b)(2)(ii) which defines the chronic encephalopathy component of the definition. While Congress expressly delegated authority to the Secretary to modify the Vaccine Injury Table, and thus the QAIs, the Secretary has created a definition inconsistent with the objectives of the Vaccine Act.[61] The literal application of §100.3(b)(2) to presumptive significant aggravation claims, as required by §11(c)(1)(C)(i), leads to absurd results and thwarts congressional intent to provide petitioners a Table significant aggravation theory of recovery and a corresponding definition for encephalopathy-based cases. See, e.g., Song v. Secretary of HHS, 31 Fed. Cl. 61, 65-66, n. 6 (1994), aff'd by unpublished opinion, 41 F.3d 1520 (Fed. Cir. 1994) (discussing *in dicta* the purpose and function of §14(a)(I)(E) according to the legislative history). The court's omissions harmonize the regulation with and further the statute's purpose. These exclusions are also harmless. The omitted language simply restates in the definition requirements already imposed upon petitioner elsewhere in the statute at §11(c)(1)(C)(i) (demonstration of the claimed injury within the applicable Table time

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[60]Even respondent suggests re-wording §100.3(b)(2) to make it mesh with §11(c)(1)(C)(i)'s requirement that petitioner suffer an underlying Table injury in presumptive aggravation claims. See R. Second Post-Hrg Memo at 10; R. Reply at 2. However, the court's proposed omissions overcome the interpretive dilemmas presented by the Secretary's revisions, whereas respondent's does not. Incidentally, this is not the first time the court has manipulated language to correct deficiencies in the Vaccine Act. In Amendola v. Secretary of HHS, 989 F.2d 1180, 1183, 1185 (Fed. Cir. 1993), the Federal Circuit read in reverse §§11(a)(5)(A) and (B) because subsection (A) provided an exception to the general rule stated in subsection (B). Noting that the "gate-keeping provisions [at issue] would not qualify as exemplars of the statutory drafting art," the Circuit concluded that inverting the sections advanced the legislative intent behind the provisions, thereby correcting the confusion which resulted from the sections' previous "technical clarification." Amendola, 989 F.2d at 1182, 1185.

[61]Entirely rejecting the revised definition's application because of the interpretive dilemma it creates is unacceptable. This would only leave petitioner without *any* encephalopathy definition for purposes of determining whether he/she suffered the aggravation of a pre-existing encephalopathic condition set forth in the Vaccine Injury Table under §11(c)(1)(C)(i). This is tantamount to adopting a third interpretation: that a pre-existing condition must be one listed on the Table, but not one conforming to a QAI (for example, an encephalopathy that does not meet the strict definitions of the QAI as amended in 1995 by the Secretary). While such a reading of the statutory language is attractive because it avoids the practical difficulties of applying the QAI for encephalopathy under a significant aggravation analysis, it violates congressional intent. As discussed, Congress specified that the QAIs go hand in hand with the Vaccine Injury Table. There is no basis for ignoring this established relationship.

period) and §11(c)(1)(D)(i) (demonstration of residual effects for more than six months).[62] In addition, the omissions remain true to the congressional intent without materially changing the Secretary's aim to clarify what constitutes a medically-supported Table acute encephalopathic injury. Finally, the court's interpretation abides by principles of sovereign immunity by interpreting the statute and its corresponding regulation in a manner which most benefits the federal government and limits petitioners' claims against the Secretary. See, e.g., Burch v. Secretary of HHS, No. 99-946V, 2001 WL 180129, at *7 (Fed. Cl. Spec. Mstr. Feb. 8, 2001) (finding that in instances where "there exist[s] more than one 'plausible' reading of the statutory provision at issue, or two possible interpretations of 'equal likelihood,'" the court "must choose the interpretation that produces the more limited award").

Application of the court's ruling to this case

In light of the court's finding that petitioners must first demonstrate an underlying encephalopathy which meets §100.3(b)(2)'s definition, the DeRoches fail in their Table significant aggravation claim. This is so because none of the symptoms John-Paul exhibited prior to his second DPT vaccination satisfy the Table encephalopathy criteria, even after the court's elimination of the confounding and redundant language in §100.3(b)(2).

The medical records and Mrs. DeRoche's testimony support that John-Paul was a healthy and relatively normally developing child for his first two months of life. He suffered no serious illness and, according to the experts, he did not experience an encephalopathy medically or regulatorily speaking prior to his first DPT vaccination. Further, the court has already concluded that John-Paul's adverse reaction to his September 30, 1994 DPT shot did not rise to the level of an acute encephalopathy, as defined by the revised "Qualifications and aids to interpretation." John-Paul's health between his first and second DPT vaccinations is a little more complicated, but is still not reflective of a Table encephalopathy. While Dr. Menkes testified that John-Paul's visual tracking problems between two and three months of age represented a "decreased or absent response to the environment," he did not opine, nor do the records support, that John-Paul's failure to fix and follow persisted for 24 hours straight, such that he responded only to loud voices or painful stimuli. Nor can petitioners support that any "decreased or absent responses to external stimuli," reflected by John-Paul's diminished vocalizations at three months, lasted the required 24 hour period. The medical records and testimony also fail to describe any increased intracranial pressure as a possible clinical feature of an acute encephalopathy. Finally, prior to the second vaccination, John-Paul was neither hospitalized nor received urgent medical care outside of the paramedics' September 30th

[62]The Secretary's rulemaking reference to the six-month "residual effects" period suggests the chronic encephalopathy element is a nearly identical restatement of the statute's §11(c)(1)(D)(i) requirement. Compare 60 Fed. Reg. at 7688 with §100.3(b)(2). See also 57 Fed. Reg. 36878, 36880 (Aug. 14, 1992) (codified at 42 C.F.R. §100.3 (1995)) (indicating that in addition to meeting the revised acute encephalopathy definition, petitioner would also have to prove *under the statutory requirement at §11(c)(1)(D)(i),* "that the chronic condition was a sequela . . . or a residual effect of the acute event, lasting 6 months").

response. Given Mrs. DeRoche's admitted watchful and worrisome nature, the court believes John-Paul's parents would have noticed and acted upon an illness "sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)."

At best, the court has an unclear picture of a child with certain pre-existing developmental delays. John-Paul's loss of milestones and diagnosis of head lag are important pieces to understanding his puzzling medical picture, but these events do not prompt a Table encephalopathy finding. Dr. Herskowitz's testimony offers the best support for an underlying Table injury, but even that does not meet the QAI's criteria. For example, while Dr. Herskowitz intimated that John-Paul suffered an encephalopathy before November 29th based on Dr. Doyle's abnormal exam findings that day and John-Paul's mother's vocalization observations, nothing in this testimony meets the statute's strict encephalopathy definition. Nor is it the case with Dr. Herskowitz's opinion that John-Paul suffered "brain-based" abnormal development between his first and second DPT vaccinations or even sooner with the alterations in interactive behavior evidenced by the early loss of social smiling. The court simply cannot conclude, as suggestive as Dr. Herskowitz's testimony is of an underlying "brain-based" and therefore possible encephalopathic illness, that John-Paul's condition prior to the second shot constituted a Table encephalopathy *by definition*. Ergo, petitioners' presumptive significant aggravation claim fails.

In the event the court's analysis is incorrect

If the court is legally wrong that an underlying injury in a Table significant aggravation claim must meet the relevant "Qualifications and aids to interpretation," what would be the outcome under petitioners' proposed analysis? In this case, Dr. Herskowitz testified that John-Paul exhibited "brain-based" abnormal development prior to his second DPT shot. While avoiding the direct question, he also implied John-Paul suffered a medically-defined encephalopathy prior to his second DPT administration. Tr. at 213-14. He then opined that John-Paul suffered the onset of seizures within the Table time period of seventy-two hours and agreed the onset of seizures is consistent with and can indicate the onset of an encephalopathy. Tr. at 210, 211. He further theorized that John-Paul would have progressed from his non-infantile spasm seizure disorder recognized the day of the second vaccination to infantile spasms. Tr. at 191. Drs. Doyle and Menkes agreed John-Paul exhibited questionable developmental problems prior to his second vaccination (Dr. Menkes believed John-Paul suffered an encephalopathy as a result of his first vaccination) and then opined that within the Table time period, John-Paul's condition changed in an unexpected manner. That is, he began to exhibit new and more serious symptoms. His condition rapidly deteriorated and within two weeks of his second vaccination, he was globally delayed. His illness quickly developed into infantile spasms and serious developmental delay. Are these facts sufficient to demonstrate a Table significant aggravation under petitioners' first interpretation and Whitecotton? The court thinks not.

Consider that in Gruber, the undersigned determined under Whitecotton that the third DPT vaccination aggravated petitioners' daughter's underlying neurologic disorder within the Table time

period.[63] Gruber, 1998 WL 928423. Prior to her third DPT shot, Irene Gruber began exhibiting "subtle episodes of eye fluttering" which her parents and pediatrician initially dismissed as normal childhood startles. Gruber, 1998 WL 928423, at *1. In retrospect, the experts agreed these episodes represented myoclonic seizures. Gruber, 1998 WL 928423, at *7. The court did not expressly determine whether these seizures met any of the QAI criteria. Within three days of her third DPT shot, Irene experienced the "*first episode* of a *new type* of seizure." Gruber, 1998 WL 928423, at *11 (emphasis in original). Having concluded that petitioners clearly met the first three prongs of the Whitecotton test, the court found "[t]he appearance of a different seizure type within the Table time period [to be] very significant" for purposes of the fourth prong. Gruber, 1998 WL 928423, at *11. Those new seizures

> marked the beginning of partial onset seizures which continued in Irene, along with more pronounced and prolonged myoclonic seizures, in a progressively deteriorating course, characterized by seizures so frequent and sometimes severe that the quality of her life was profoundly diminished.

Gruber, 1998 WL 928423, at *11. The court agreed with petitioners' expert that those seizures showed a "distinct and sudden change in Irene's seizure disorder following vaccination." Gruber, 1998 WL 928423, at *11.

The DeRoches' claim is distinguishable from Gruber because of John-Paul's unclear medical picture. Unlike in Irene Gruber's case, no obvious or significant change in John-Paul's pre-existing condition is evident within the Table time period. Certainly, petitioners would satisfy prongs one through three of the Whitecotton test. John-Paul's condition prior to the second vaccination (prong one) was that of a relatively normal and healthy child. Although he lost or failed to gain several milestones in his first four months, John-Paul successfully attained other expected milestones, including some beyond what was anticipated for his age. He suffered from head lag, an asymmetrical head and diminished vocalizations, but did not exhibit seizures or any other neurological concerns. His head circumference was further within normal limits. Under prong two, his current condition (at the time of the evidentiary hearing and the close of the record in this case) was one of post-infantile spasms, serious developmental delay and severe mental retardation. His

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[63] Whitecotton requires in Table significant aggravation cases that a special master employ a four-prong test to:

> (1) assess the person's condition prior to administration of the vaccine, (2) assess the person's current condition, . . . (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute[, and] (4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table.

Whitecotton, 81 F.3d at 1107.

head circumference was well below normal levels and he suffered from chronic encephalopathy. Thus, under prong three and based on an objective comparison, his current condition clearly represented a "change for the worse in a preexisting condition which result[ed] in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." §33(4).

Unfortunately, petitioners' claim fails under prong four. There simply is no hard evidence that the first symptom or manifestation of John-Paul's significant aggravation occurred within the three-day Table time period. Clearly, all agree that within hours of his second vaccination, John-Paul experienced the onset of abnormal behavior. Doctors Menkes and Herskowitz recognized this behavior retrospectively as seizure activity. And, the records confirm that John-Paul's activity progressed from the startles episodes witnessed the day of the vaccination to frequent myoclonic seizures and eventually infantile spasms. But, it bears repeating that Dr. Snead, John-Paul's own treating neurologist, refuted that his patient suffered the onset of seizures within the Table time frame. Moreover, nothing in the records or the testimony evidences a dramatic downturn or a signaling event within three days which convinces this court that the first symptom or manifestation occurred within the applicable time period. It is simply not clear from the record when John-Paul's pre-vaccination problems became aggravated or that his alleged seizures marked the first manifestation of his subsequent downturn. The insidious nature of his condition is perhaps best demonstrated by his mother's characterization of his behavior in the days following the second DPT. She noticed subtle changes in behavior but no dramatic events or downturns in John-Paul's health. While in contrast Drs. Doyle and Smith clearly had concerns by the December 2nd appointment, neither attributed John-Paul's questionable exam findings to an acute neurologic condition. Unfortunately, the court simply cannot ascertain the precise date the aggravation first manifested. For this reason, petitioners' claim also fails under the Whitecotton test.[64]

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[64]In Hoag v. Secretary of HHS, No. 94-67V, 1998 WL 408783 (Fed. Cl. Spec. Mstr. Apr. 22, 1998) (reissued for publication June 10, 1998), aff'd, 42 Fed. Cl. 238 (1998), the undersigned found against petitioners in a Table significant aggravation case involving infantile spasms. In that case, the undersigned concluded from the experts' testimony that "[t]he dispute . . . settles on the question of when the diagnosis of the infantile spasm syndrome can be made." Hoag, 1998 WL 408783, at *9. Petitioners' expert arguably agreed that if the infantile spasm syndrome could be diagnosed prior to the DT shot in question, as respondent's expert opined, there would be no aggravation. Hoag, 1998 WL 408783, at *9. Because petitioners had successfully demonstrated prongs one through three of Whitecotton, petitioners' claim hung on the diagnosis date of the infantile spasm syndrome which would signal whether the first symptom or manifestation of the worsening of Cassandra Hoag's underlying epileptic syndrome fell within the three day Table time period for purposes of prong four. Hoag, 1998 WL 408783, at *9. The court found more persuasive respondent's expert's testimony that the syndrome could not be firmly diagnosed until May 1991 with the occurrence of the classical infantile spasm seizures, about two months after the administration of the DT vaccine in question. Hoag, 1998 WL 408783, at *9. That diagnosis confirmed, in line with respondent's expert's opinion, "that the course of Cassandra's seizures fit the typical evolutionary course of the infantile spasm syndrome" and thus, there was "no change in the expected course" of her pre-existing condition and "no aggravation." Hoag, 1998 WL 408783, at *9. Because the diagnosis

Off-Table significant aggravation of a pre-existing condition

Petitioners also allege an off-Table significant aggravation of John-Paul's condition which pre-existed his second vaccination. See §11(c)(1)(C)(ii)(I). As with Table significant aggravation cases, off-Table significant aggravation law is largely unchartered territory. In the past, special masters have evaluated these cases under the two-prong criteria employed in causation-in-fact onset claims. The standard required petitioner to demonstrate (1) that the vaccine *can cause* the significant aggravation of the underlying injury alleged, and (2) that *it did so* in the particular case. See, e.g., Crockett v. Secretary of HHS, No. 94-15V, 1997 WL 702559, at *10 (Fed. Cl. Spec. Mstr. Sept. 30, 1997). During the evidentiary hearing in this case, the undersigned imparted that petitioners' off-Table significant aggravation theory, for purposes of prong one, must be rooted in medical literature as is required in off-Table onset claims. Tr. at 130-31. Because Dr. Menkes could not objectively and medically substantiate an aggravation theory, the court disregarded petitioners' claim. Tr. at 130-31. As a result of this bench "ruling," the parties focused their energies on the Table significant aggravation claim and, by the parties' post-hearing arguments, the court had narrowed the case down to a Table significant aggravation claim. Closings Tr. at 3. However, upon further consideration of the legal issues in this case and the development of significant aggravation law under Whitecotton and subsequent rulings, the court concludes the original standard articulated in Misasi v. Secretary of HHS, 23 Cl. Ct. 322 (1991), offers a sensible starting point for analyzing causation-in-fact significant aggravation claims. The court explains its rationale for this finding and then measures petitioners' claim against this standard.

The original Misasi standard

In Misasi, Judge Andewelt sustained the special master's opinion denying compensation. Petitioners in that case alleged that the DPT vaccine significantly aggravated, on Table, their daughter's pre-existing oculo-cerebral dysgenesis ("OCD"), a congenital malformation of the brain and eyes.[65] On the appeal, Judge Andewelt enunciated a four prong test "[t]o evaluate whether an

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could not be made until May 1991, a date outside the three-day Table time period following the administration of the DT vaccine in March 1991, petitioners' claim failed. Hoag, 1998 WL 408783, at *13.

Hoag is not particularly helpful here. Neither expert in the DeRoches' case rested their opinion on the diagnosis date of John-Paul's infantile spasms. Nor did the experts testify with any depth to the extent John-Paul's pre-vaccination delays or post-vaccination seizure activity represented a classical evolving pattern for infantile spasm syndrome. In fact, the medical records reflect John-Paul suffered an atypical form of infantile spasms, and he never experienced the classical infantile spasm seizure, or jackknife seizure, which in the Hoag case confirmed the infantile spasm syndrome diagnosis.

[65]Special Master French seems to have considered this an on-Table significant aggravation claim although she does not state this directly. Petitioners clarified their position on appeal to Judge

individual suffered a significant aggravation of a particular condition."[66] Misasi, 23 Cl. Ct. at 324. The test required that the court:

> (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered.

Misasi, 23 Cl. Ct. at 324. A petitioner satisfied §13(a)(1)(A) by establishing "by a preponderance of the evidence that the individual's current condition constitutes a significant aggravation of the individual's predicted condition had the vaccine not been administered." Misasi, 23 Cl. Ct. at 324. See also Whitecotton, 81 F.3d at 1104 ("Only if the person's current condition is significantly worse than the person's predicted condition had the vaccine not been administered, is the person entitled to compensation under the significant aggravation theory as explained in Misasi, 23 Cl. Ct. at 324."). A "significant aggravation" occurred under the Act if there was "any change for the worse in a preexisting condition which result[ed] in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." §33(4).

The special masters briefly employed the original Misasi standard in on-Table significant aggravation cases until the U.S. Court of Federal Claims recognized that the strict application of the test improperly placed on petitioners the burden of proving that the vaccine actually caused the aggravation of their injuries. As the court remarked in Reusser v. Secretary of HHS, 28 Fed. Cl. 516, 528 (1993), "the Misasi test . . . essentially involves proving that the cause of the injury sustained is *not* due to a pre-existing condition." (Emphasis added.) This violated the Act's intention to provide petitioners a *presumption* of causation in Table significant aggravation claims. Reusser, 28 Fed. Cl. at 527-28. See also O'Connor v. Secretary of HHS, 24 Cl. Ct. 428, 429, n. 2 (1991), aff'd, 975 F.2d 868 (Fed. Cir. 1992) ("In making a *prima facie* showing of presumed causation, petitioners need not prove causation or disprove possible alternative causes for the deterioration in the child's preexisting condition following the vaccination."); Whitecotton, 81 F.3d at 1106 ("Effectively, then, *Misasi required petitioners to show that the vaccine had caused the aggravation of their injuries.* This contradicted the statutory table-injury scheme whose purpose was to remove from petitioners the difficult burden of proving causation.") (emphasis added). O'Connor and Reusser resolved the statutory infringement by leaving refutation of the pre-existing condition's role to petitioners' rebuttal case which arose only after respondent successfully demonstrated that the natural

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Andewelt, arguing "that OCD falls within the statutory definition of encephalopathy" and, thus, the DPT vaccine significantly aggravated their daughter's underlying Table encephalopathy. Misasi, 23 Cl. Ct. at 324.

[66]Judge Andewelt noted Special Master French employed "essentially the same standard." Misasi, 23 Cl. Ct. at 324, n. 1.

progression of the pre-existing condition, rather than the vaccine, caused petitioners' injuries. O'Connor, 24 Cl. Ct. at 429, n. 2; Reusser, 28 Fed. Cl. at 528. When the appropriateness of the Misasi standard came up again in Whitecotton, the Federal Circuit resolved the confusion by articulating an explicit four-prong standard based on Reusser's skeletal test. Whitecotton, 81 F.3d at 1107. The special masters now apply the Whitecotton standard in almost all Table significant aggravation claims.[67] [68]

Ironically, the Misasi standard is particularly suited for off-Table significant aggravation claims for the very reasons the O'Connor, Reusser, and Whitecotton courts altered its application. According to the Federal Circuit, Misasi

> recognized that the primary difficulty in adjudicating the significant aggravation claims of children with a pre-existing condition, is that it is very difficult to know at the age when a child is vaccinated what symptoms would have naturally manifested themselves as the child matured and what symptoms might have remained latent absent the vaccination.

Whitecotton, 81 F.3d at 1105, citing Misasi, 23 Cl. Ct. at 327. Misasi alleviated this difficulty by creating an easily administered four-prong test which charged petitioners with showing that the post-vaccinal condition differed significantly from that expected to result from the underlying condition. In essence, petitioners were forced to disprove the pre-existing condition's role. While that burden was improper for presumptive causation claims, it is befitting in actual causation cases where the burden remains with petitioner to eliminate alternate causes. See, e.g., Wagner v. Secretary of HHS, No. 90-2208V, 1997 WL 617035, at *10, *11-*12, *17 (Fed. Cl. Spec. Mstr. Sept. 22, 1997); Williams v. Secretary of HHS, No. 90-3091V, 1998 WL 156967, at *11 (Fed. Cl. Spec. Mstr. Mar. 18, 1998); Almeida v. Secretary of HHS, No. 96-412V, 1999 WL 1277566, at *5 (Fed. Cl. Spec. Mstr. Dec. 20, 1999); but see Wagner v. Secretary of HHS, 37 Fed. Cl. 134, 138-39 (1997); Vant Erve v. Secretary of HHS, 39 Fed. Cl. 607, 615, n. 19 (1997); Shifflett v. Secretary of HHS, 30 Fed. Cl. 341, 347 (1994). In any significant aggravation case, as respondent usually argues, a potential alternate cause is necessarily the pre-existing condition. Hence, in off-Table significant aggravation claims, petitioner's *prima facie* burden includes disproving that the underlying condition explains the deterioration of the child's pre-existing condition following the vaccination. Misasi's original

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[67]To be sure, the Whitecotton test and the original Misasi standard were intended for on-Table claims, not off-Table aggravation cases. See Williams v. Secretary of HHS, No. 90-3091V, 1998 WL 156967, at *13 (Fed. Cl. Spec. Mstr. Mar. 18, 1998) ("[T]he test enunciated in Whitecotton is *specifically* limited to Table injuries.").

[68]As the Federal Circuit recognized in Whitecotton, significant aggravation is a "difficult concept," "one of the most slippery and difficult to apply" under the Act. Whitecotton, 81 F.3d at 1105. "Misasi constituted the Court of Federal Claims' initial attempt to formulate a legal construct for deciding claims of significant aggravation." Whitecotton, 81 F.3d at 1105.

test embodies this burden in steps three and four.[69] The assessments in prongs one and two round out the test and are practical applications of the statutory definition of "significant aggravation" which inherently involves a comparative analysis. See Whitecotton, 81 F.3d at 1107. By demonstrating that the vaccinee's current condition represents a "significant aggravation," as that phrase is defined by the Act, of the child's expected condition, petitioners are entitled to compensation under an off-Table significant aggravation theory.[70] See Whitecotton, 81 F.3d at 1105. The court concludes that the original Misasi standard holds firm to the causation-in-fact burdens imposed by the Act and relevant actual causation jurisprudence.

Application of the Misasi standard to this case

Utilizing the significant aggravation test espoused, petitioners failed to demonstrate that the second DPT vaccine administered on November 29, 1994, significantly aggravated John-Paul's underlying condition.

(1) assess the individual's condition prior to administration of the vaccine, i.e., evaluate the nature and extent of the individual's pre-existing condition

According to his mother and the KIDS chart, John-Paul met most of his one to three month milestones. At three months, he was also attaining four and five month milestones. Even with the loss of two 1-2 month milestones at two months of age, he was achieving similar developmental skills. The records and the experts confirm he sustained no apparent encephalopathy prior to his first DPT vaccination. His head circumference was also well within normal limits prior to and following the second vaccination. For all intents and purposes, John-Paul's mother and his treating physicians deemed him relatively healthy prior to the second vaccination. Other than his September 30th reaction, he suffered no apparent illnesses. At worst, his mother suspected a decrease in his vocalization skills towards the end of October 1994. On November 29, 1994, immediately prior to the administration of the second DPT shot, Dr. Doyle examined John-Paul. He was alert (non-encephalopathic either acutely or chronically), but exhibited poor head control and head lag; the doctor consequently diagnosed him with gross motor delay. According to the monthly KIDS chart,

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[69]Again, these are the same steps discarded by Whitecotton because they forced petitioners to prove causation-in-fact in violation of the legislative intent. Whitecotton, 81 F.3d at 1106-07. The Federal Circuit concluded: "We agree with the court's analysis in Reusser and O'Connor that, as originally conceived, the Misasi test improperly required a petitioner to prove, as part of her *prima facie* case, that petitioner's significant aggravation was not caused by a pre-existing injury." Whitecotton, 81 F.3d at 1106. In causation-in-fact claims, it is petitioner's burden, as part of her *prima facie* case, to demonstrate that the injury was not caused by an alternate cause, such as the pre-existing injury.

[70]Assuming, of course, respondent fails to successfully support a "factor unrelated" defense.

he failed to meet or otherwise regain a number of one to four month milestones, but he was not diagnosed with fine motor, personal/social, or language delays. In addition to the head lag, he had an asymmetrical head and left ear displacement. He was also vocalizing less than he had before although he continued to respond to noise and voices. His examination, including his height, weight, and head circumference, was otherwise within normal limits.[71]

(2) assess the individual's current condition after the administration of the vaccine

John-Paul's condition at the time of the closing of the record in this case was that he was post-infantile spasms, irreparably developmentally delayed, and seriously mentally retarded. He suffered from a chronic encephalopathy. His Individualized Education Program for October 1998-October 1999, the last developmental records filed, proposed objectives such as walking short distances without falling; stopping, turning, and sitting in a low classroom chair without assistance; and climbing independently on playground riding toys. This IEP covered the time period when John-Paul was roughly four to five years of age.

(3) predict the individual's condition had the vaccine not been administered

The court assumes a difficult task in garnering testimony from experts about how an underlying condition might develop absent an intervening vaccination. The Misasi court recognized this difficulty. Misasi, 23 Cl. Ct. at 327. The inquiry necessarily requires some speculation; it is especially suppositional when the pre-existing condition is not a precise, identifiable illness whose pathological path can be easily discerned through medical literature. In such cases, the special masters may have testimony on what is *not* expected, rather than what is. Such is the case here.[72]

When Dr. Doyle examined John-Paul prior to his second DPT vaccination, she did not consider him encephalopathic or otherwise neurologically impaired. Instead, she determined that John-Paul exhibited certain head control problems likely attributable to either neck muscle weakness

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[71]Dr. Herskowitz intimated that John-Paul's pre-vaccination condition "could . . . be just a little sluggishness, is he a little bit tired today or is this the start of something bad." Tr. at 185; see also Tr. at 202 ("[T]his could just be a little – you know, not knowing the child, a little sluggishness, a little of this maybe not feeling well, maybe coming down with a virus or it could be the start of something bad."). But see Tr. at 204 (Dr. Herskowitz opining that "major" events preceded the second vaccination).

[72]In contrast, in Gruber, a Table significant aggravation case, the child's having an identified underlying illness – a known, albeit idiopathic, syndrome called Severe Myoclonic Epilepsy – allowed the experts to testify with some confidence about the prognosis and clinical course associated with the illness although science had much yet to reveal about the syndrome. Gruber, 1998 WL 928423, at *5, *6, *12.

(a tonal problem) or craniosynostosis. By his December 2nd appointment, however, Dr. Doyle witnessed a different child. John-Paul appeared alert just as he had three days prior, but he was also experiencing extreme and alternating eye deviations. His previous head lag/gross motor delay was now accompanied by an increased extensor tone, a weak shoulder girdle, and an inability to lift the head while prone. In addition, John-Paul was experiencing extremity extensions, although Dr. Doyle did not steadfastly attribute this behavior to convulsions. Dr. Doyle's worries switched from muscle tone issues or craniosynostosis to cerebral palsy and strabismus. John-Paul went on from that December 2nd appointment to have several abnormal EEGs, increased myoclonic jerking episodes, a modified hypsarrhythmic finding, a regression in development, and finally, an infantile spasms diagnosis and treatment with ACTH. Important for our purposes here, Dr. Doyle testified that while she had concerns as of November 29th that John-Paul might suffer further problems, "they didn't seem major." Tr. at 49-50. Because she did not consider John-Paul's condition neurological in nature, she saw no reason to withhold his second DPT vaccination. Most compelling, she did not predict and was genuinely surprised by John-Paul's subsequent presentation as evidenced by her notable exchanges with the court, supra at pages 17-18.

Dr. Menkes concurred with Dr. Doyle's characterization of John-Paul's medical picture and testified:

> [I]f I saw this child at four months of age, with a bit of a head lag, I would not have expected two days later to have marked increase in extensor tone. That would have been a surprise to me. I might have been less surprised if mommy had called me and said, "this child is having these funny movements", and I would have interpreted these as seizures. I would have said, "Well, you know, this child was sort of iffy to start with. I was concerned about him to start with, not too surprised he has seizures." But, to suddenly find a child who had a head lag appearing two days later with increased extensor tone which wasn't there before, I'd be very worried that something new has happened, regardless of the history.

Tr. at 129-30. He would have had the same concerns had John-Paul presented without a history of DPT vaccination. Tr. at 130.

On the contrary, Dr. Herskowitz believes the developmental concerns charted early on in the KIDS report and reported by Mrs. DeRoche foreshadowed John-Paul's ultimate clinical course and condition. He predicted John-Paul's problems would have been no different absent the second DPT shot. He explained that John-Paul "would have gone on from his non-infantile spasm seizure disorder . . . recognized the very day of the [second] DPT shot and he would have progressed to his [sic] close enough to be called infantile spasms." Tr. at 191. For Dr. Herskowitz, the progressive nature of John-Paul's condition was all part of the same insidious developmental process which began between one to two months of age. Going into the second vaccination, John-Paul "was in early phases of developmental deviation, soon to become manifested by developmental delay." Tr. at 200. Dr. Herskowitz also considered this abnormal development brain-based. In his view, by John-Paul's December 2nd presentation on exam, Dr. Doyle "could not blink away the fact that this

is a serious pathologic process." Tr. at 203. He attributed her opinion that the December 2nd events were unexpected to an emotional response, the effect of her suspicions having now been confirmed.[73]

(4) compare the individual's current condition with the predicted condition had the vaccine not been administered

The fourth prong essentially assesses whether the current condition represents an unpredicted worsening or "significant aggravation" of the natural progression of the pre-existing condition. If the vaccinee's course of illness deviated in a negative way clinically or otherwise from the natural progression of the underlying condition, then the balance logically tilts towards the vaccine as the cause of the worsening, absent proof of another intervening cause.

In this case, the contrasting physicians' opinions and parental observations complicate the comparison between John-Paul's current condition and his predicted condition had the vaccine not been administered. At the case record's closing, he was post-infantile spasms, irreparably developmentally delayed, and severely mentally retarded; this is undisputed. But petitioners have not persuasively demonstrated that John-Paul's "current" condition at that time represented an unpredicted worsening in the natural progression of his pre-existing condition. Certainly, Dr. Doyle anticipated on November 29th that John-Paul might have some developmental concerns in the future, but she did not expect major problems nor even consider his pre-existing condition neurological. She also did not find John-Paul encephalopathic immediately prior to her administration of his second DPT shot or at his December 2nd appointment. At best, Dr. Doyle found her patient's December 2nd condition something "much different" than expected three days earlier. Tr. at 63-64. Upon closer inspection, her testimony fails to persuasively support an unpredicted worsening in the natural progression of John-Paul's underlying condition. First, given Dr. Doyle's detection of relatively minor pre-vaccinal problems and dismissal of a pre-existing *neurological* condition, one wonders what underlying condition the DPT could have aggravated. Is it conceivable the vaccine aggravated John-Paul's non-neurological condition neurologically? The court finds this unlikely.

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[73]Dr. Herskowitz explained:

> I mean, it struck her as discontinuous. What I'm suggesting is that at that point she could not blink away the fact that this is a serious pathological process. She had suspected it before but it had declared itself. And I think that that, if I may be so bold as to suggest that that – you know, that really had a big impact on her and it made it seem different because the emotional undertones of the visit were tremendously different but if you listen to John-Paul's mother, there were some significant things going on more than a month earlier. That child is not vocalizing, who goes through a whole plane ride, thousands of miles, doesn't make any noise at all. That's not normal. So I think that major things were going, they just didn't grab the pediatrician.

Tr. at 203-04.

Second, there is no evidence John-Paul suffered an acute event immediately following his second vaccination; Dr. Doyle did not consider John-Paul acutely encephalopathic on December 2nd. Although not specific to aggravation claims, Special Master Hastings held in Liable v. Secretary of HHS, No. 98-120V, 2000 WL 1517672 (Fed. Cl. Spec. Mstr. Sept. 7, 2000), that there is no evidence to support a causal relationship between the DPT and an illness in the absence of an acute neurologic injury. Third, Dr. Doyle's and her colleague's continued efforts into early 1995 to understand and conclusively diagnose John-Paul's illness further belies that he suffered a discernable and unpredicted significant "change for the worse in a preexisting condition." The court simply cannot ascertain from Dr. Doyle's testimony when an aggravation in John-Paul's underlying condition began. This is a common problem in aggravation cases and especially in those involving neurologic injuries. From Dr. Doyle's summation of events, the court sees John-Paul's post-vaccinal clinical course as progressive with no precise onset of a significant aggravation.

As for Dr. Menkes's aggravation testimony, it fails to reconcile with the parents' observations or the medical records. The court is hard pressed to agree with petitioners' expert that John-Paul suffered a dramatic downturn immediately following the second shot (as a sign of deviation from the natural clinical course of the underlying illness), in light of Mrs. DeRoche's own testimony to the contrary. Mrs. DeRoche is not a physician, obviously, and unlikely would notice changes in John-Paul's tone, shoulder girdle, etcetera, but she was a watchful parent. She reported that John-Paul's eye crossing and extremity extensions were subtle and that other than these events and being fussy, her son's behavior did not change dramatically in the days following the vaccination. Moreover, Dr. Menkes's aggravation opinion does not comport with those held by the treating physicians on the scene, who responded to John-Paul's December 2nd condition by referring him to a physical therapist and an ophthalmologist, rather than a neurologist which would suggest the onset of a more serious condition. Petitioners simply have not sufficiently rebutted Dr. Herskowitz's opinion that John-Paul's pre-vaccination history showed signs of a serious, insidious brain-based illness that progressed as expected.

Clearly, the parents' observations and the doctors' different reads of the same pre- and post-vaccinal events point out the perils of trying not only to get a handle on John-Paul's pre-November 29th condition, but to detect an unpredicted deviation in the natural progression of his pre-existing condition. In order to find an unexpected worsening of John-Paul's previous condition in the days following his vaccination, the court would have to pick and choose its corroborating evidence while ignoring other to the contrary. For instance, the court would have to accept Dr. Herskowitz's testimony that John-Paul did indeed suffer a brain-based or neurological illness beforehand in order to find that the vaccine aggravated the underlying condition neurologically with seizures in the days immediately following the administration. In doing so, how can the court dismiss Dr. Doyle's contemporaneous observations and opinion that John-Paul did not suffer neurological problems before the second shot? Similarly, accepting Dr. Herskowitz's opinion that John-Paul suffered seizures within three days of the second vaccination would require rejection of Drs. Doyle's,

Smith's, and Snead's treating opinions.[74] Further, whatever the alarm raised by Dr. Doyle's and Dr. Smith's observations on December 2nd, Mrs. DeRoche reported a child suffering from fussiness and subtle eye crossings and extremity extensions, but no dramatic changes in behavior. It makes no sense at this time to second-guess the DeRoches or John-Paul's treating physicians.[75] Thus, based on only a subtle but not dramatic change in John-Paul's behavior and his physicians' conservative referrals for treatment, the undersigned cannot reasonably conclude that his post-vaccinal course was anything but insidious, progressive, and in line with what was expected. The court simply cannot point to a single, obvious, or serious dramatic event as representative of an unpredicted worsening in John-Paul's expected clinical course if one existed. Accordingly, petitioners failed to mount a successful off-Table significant aggravation claim under the Misasi standard.

C. Petitioners' Additional Causation-in-Fact Claim

Off-Table DPT-related infantile spasms or other injury

Because of the availability of an epidemiological study, the National Childhood Encephalopathy Study ("NCES"), causation-in-fact claims involving the DPT vaccination are generally evaluated under the criteria announced in Liable v. Secretary of HHS, No. 98-120V, 2000

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[74]Because of Dr. Snead's unwillingness to testify out of deference to his consultant position with the government, Mr. DeRoche chose not to subpoena Dr. Snead for fear of encountering an unwilling or hostile participant. Unfortunately, Dr. Snead's reservations prevented counsel and the court from delving in depth into his opinions regarding John-Paul's initial care and symptoms and the extent to which his patient's clinical course departed from what he expected. As John-Paul's initial treating neurologist, this information would have been insightful. At most, the court learned Dr. Snead "leaned toward treating John-Paul with ACTH . . . because he felt John-Paul's condition would have eventually developed into the more classic form of infantile spasms." Dr. Snead Stip. at 3.

[75]Second-guessing, during litigation, medical judgments made contemporaneously to treatment sets a dangerous precedent in the absence of convincing evidence of the incorrectness of the concurrent diagnosis or treatment. The special masters routinely grant considerable weight to treating physicians' opinions rather than engage in or permit the "re-diagnosis" of a vaccinee's illness years later. See, e.g., Rogers v. Secretary of HHS, No. 94-89V, 2000 WL 1337185, at *13 (Fed. Cl. Spec. Mstr. June 6, 2000); Rogers v. Secretary of HHS, No. 94-89V, 2000 WL 1517675, at *4 (Fed. Cl. Spec. Mstr. Sept. 8, 2000) (Order Denying Respondent's Motion for Reconsideration and Order Denying Petitioner's Motion to Strike); Cruz v. Secretary of HHS, No. 96-820V, 1998 WL 928418, at *6, n. 28, *8 (Fed. Cl. Spec. Mstr. Dec. 21, 1998); Brown v. Secretary of HHS, No. 90-904V, 1992 WL 191100, at *6 (Cl. Ct. Spec. Mstr. July 27, 1992). In this case, the treating physicians and other medical personnel offered their best opinions considering the circumstances presented and following extensive and rigorous evaluations. The court hesitates to ignore the resulting opinions without substantial cause.

WL 1517672 (Fed. Cl. Spec. Mstr. Sept. 7, 2000). In that case, Special Master Hastings held that a petitioner claiming a DPT-related injury meets her actual causation burden by demonstrating that

> a neurologically-intact vaccinee (1) suffers, within seven days after a pertussis vaccination, a neurologic episode that would have qualified as a 'serious acute neurologic illness' under the NCES; (2) goes on to experience chronic neurologic dysfunction of the type described in the NCES; and (3) no other cause for that dysfunction can be identified.

Liable, 2000 WL 1517672, at *12. Applied here, Dr. Menkes admits that John-Paul would not meet the NCES's parameters. Petitioners failed to demonstrate that John-Paul in-fact suffered the onset of a serious acute neurological illness after either of his vaccinations. Even reasoning that the DeRoches' son would have been mentioned to the NCES investigators, since a diagnosis of infantile spasms was a reportable injury, the IOM's subsequent finding of no causal relation between the pertussis vaccine and infantile spasms or epilepsy precludes a successful causation-in-fact claim based on the NCES. See, e.g., Jenkins v. Secretary of HHS, No. 90-3717V, 1999 WL 476255, at *9, *11 (Fed. Cl. Spec. Mstr. June 23, 1999); Raj, 2001 WL 755418, at *8, *12. Dr. Menkes acknowledges the IOM's findings in this regard. Although Dr. Menkes proffers another potential scientific theory of causation to combat the IOM's findings, that being the pertussis toxin can in rare instances breach the blood-brain barrier, then act as a histamine antagonist to cause infantile spasms, he does not fully explain this theory nor if or how John-Paul's case fits his hypothesis.

Finally, no other persuasive evidence supports a causal relationship between the vaccines and John-Paul's condition. None of John-Paul's treating physicians concluded in their contemporaneous medical records that his infantile spasms were causally related to any of his vaccinations (separately or in tandem). Notably, John-Paul received his vaccinations during the same time period infantile spasms typically present, making the assignment of cause difficult. The medical records also support that following his first vaccination, other than the post-vaccinal screaming and crying episode, he was otherwise healthy. Mrs. DeRoche witnessed no immediate reaction after the September 30, 1994 incident. One month following this vaccination, at his October 27, 1994 well-baby visit, his pediatrician reported a healthy, normal child with no accounts of shot reactions or other concerns. Indeed, other than the paramedic records dated September 30th, John-Paul required no medical attention in the month following his first vaccination. His mother's affidavit and hearing testimony confirms this history; Mrs. DeRoche attested that John-Paul remained a healthy child with normal development in the two months following his vaccination. While in hindsight John-Paul likely suffered startle seizures within seven days following his second vaccination, the IOM has determined, as Dr. Herskowitz noted, that there exists no causal relationship between the pertussis vaccine and afebrile seizures. Nor does the evidence clearly support the onset of an acute encephalopathy in this case, even one medically defined as a "disease of the brain," *within a medically supported time frame*. Tr. at 133-35. For instance, Dr. Menkes testified the medical records do not show a decrease or absence in response to the environment between November 29th and December 2nd. Tr. at 135. While John-Paul exhibited a decrease or absence in eye contact at his fifth month appointment, as evidenced by the "wandering eyes" and "day dreams" notations, this

did not indicate an acute encephalopathy according to Dr. Menkes because the events had been going on for a while. Tr. at 135. In addition, John-Paul's diminished vocalizations represented a decreased response to external stimuli but they predated his second vaccination. Tr. at 135-36. Dr. Herskowitz felt John-Paul's vocalization problems and decline of social smiling demonstrated "insidious[] and progressive[]. . . alterations in his behavior," but he could not attribute them to a specific cause. Tr. at 227. The decline in John-Paul's head circumference between 4-6 months signified "[s]omething happened to this child," but Dr. Menkes did not say it was an acute encephalopathy. Tr. at 136. Dr. Herskowitz testified equivocally that if John-Paul had an encephalopathy on November 29th, medically speaking, he did so the day before based on the pediatrician's exam findings and Mrs. DeRoche's observations. Tr. at 213. At best, Dr. Herskowitz conceded that "we have evidence between the two DPT shots that there was abnormal development which I believe is brain based," but this was not tied to a medically supported time frame for causation. Tr. at 214. For all of these reasons, the court rejects the actual causation claims described above.[76] [77] [78]

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[76]Petitioners also argued the vaccinations "in tandem" caused John-Paul's problems, see supra at page 2, note 3. In his strongly worded dissent in Lampe v. Secretary of HHS, 219 F.3d 1357 (Fed. Cir. 2000), Judge Plager faulted the undersigned (and the U.S. Court of Federal Claims and the Federal Circuit by their affirmances) for "limit[ing] [the causation-in-fact] analysis to each administration of the DPT vaccine as a separate potential instance of causation, rather than considering causation by the series of vaccine administrations as a whole." Lampe, 219 F.3d at 1370 (J. Plager, dissenting). The Lampes alleged that their daughter's "seizure disorder was the result of a severe, progressive allergic reaction to the cumulative series of administrations of the DPT vaccine." Lampe, 219 F.3d at 1369 (J. Plager, dissenting). Looking at the series of DPT vaccinations as a whole, rather than each distinctly as the undersigned did, Judge Plager believed petitioners' expert testimony and evidence clearly supported the causation theory that Rachael Lampe suffered an injury as a result of the "cumulative effect of an allergic reaction to the DPT vaccination." Lampe, 219 F.3d at 1372 (J. Plager, dissenting). The DeRoches' claim is dissimilar in several important ways. First, John-Paul had only two DPT vaccinations and his pre- and post-vaccinal clinical picture is ill-defined. In Lampe, Judge Plager rested his opinion on Rachael's apparent and progressively worse reactions to all four of her DPT shots. Lampe, 219 F.3d at 1372 (J. Plager, dissenting). Second, the DeRoches specifically blame the *second* vaccination for the aggravation of John-Paul's underlying condition; Dr. Menkes also bases his aggravation opinion on this separate and distinct administration. Finally, petitioners' experts failed to address the "in tandem" theory in any detail, outside of the claims already addressed.

[77]Under the Act, the court evaluates respondent's "factor unrelated" evidence only after petitioners meet their *prima facie* burden. The DeRoches failed to mount a sufficient case-in-chief under any theory of recovery. However, had petitioners been successful, the court would have rejected the government's factor unrelated defense to the extent it attributes John-Paul's problems in whole or part to his infantile spasms. Dr. Snead did not know the cause of John-Paul's condition. Dr. Snead Stip. at 2. Dr. Herskowitz likewise testified that he did not know the cause of John-Paul's developmental disabilities and John-Paul did not have an *infantile spasm* seizure disorder prior to his second vaccination. Tr. at 191, 201, 214-15, 217-18. Further, Dr. Kornblum noted in November

VI. CONCLUSION

John-Paul's death is tragic and the court has the utmost sympathy for Mr. and Mrs. DeRoche, who, as dedicated parents, admirably pursued and presented John-Paul's case. Congress, however, designed the Program to compensate only those individuals who can demonstrate a causal or temporal link between their injuries and a listed vaccine by a preponderance of the evidence. In this case, the evidence simply does not demonstrate such a link. Based on the foregoing, the court finds after considering the entire record in this case that petitioners are not entitled to compensation under the Vaccine Act.

In so finding, the court reiterates that this was a complex case medically and legally. As the Federal Circuit recognized in Whitecotton, significant aggravation is a "difficult concept," "one of the most slippery and difficult to apply" under the Act. Whitecotton, 81 F.3d at 1105. It is an ever evolving concept which has been visited on many levels in the past thirteen years. The decision in this case should not be read to bar future similar claims. It is conceivable that further discussions regarding the aggravation concept could produce a different result. The court is open to such a discussion. In the absence of a pre-judgment settlement or a motion for review filed pursuant to RCFC Appendix J, the Clerk of the Court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

6, 1995, that the etiology of John-Paul's developmental delay was "uncertain." P. Supp. Ex. 5 at 93. Dr. Menkes testified that John-Paul's infantile spasms were, besides being atypical, also of the type where the cause was unknown. Tr. at 143 ("But here we don't really have true infantile spasms. You have some sort of variant there."). According to the statutory language at §13(a)(2)(A), a "factor unrelated" "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." The Federal Circuit held disorders of unknown origin cannot constitute the basis of a factor unrelated defense. Whitecotton, 17 F.3d at 377-78. Other cases have held that idiopathic infantile spasms alone cannot be a "factor unrelated" under §13(a)(1)(B). See, e.g., Santos v. Secretary of HHS, No. 90-449V, 1991 WL 33226, at *1 (Cl. Ct. Spec. Mstr. Feb. 21, 1991); Hale v. Secretary of HHS, 22 Cl. Ct. 403, 409 (1991); Johnston v. Secretary of HHS, 22 Cl. Ct. 75, 78-79 (1990). Respondent also failed to present evidence in support of another alternate cause for John-Paul's disabilities. Based on all of the above, the court would have found respondent unsuccessful in her efforts to rebut petitioners' evidence that the DPT vaccine caused John-Paul's injuries.

[78]Because of petitioners' inability to demonstrate that the vaccinations actually caused John-Paul's post-vaccinal symptoms, infantile spasms, or mental retardation, the court need not resolve whether their administrations caused his unfortunate death more than seven years later.

Gary J. Golkiewicz
Chief Special Master