OFFICE OF SPECIAL MASTERS

No. 94-0626V

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TY and DEBRA LEARY, AS LEGAL REPRESENTATIVES OF THEIR MINOR DAUGHTER, ASHLEY E. LEARY,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

DECISION ON ENTITLEMENT

Petitioners, Ty Leary and Debra Leary (Mr. Leary and Ms. Leary or the Learys), as legal representatives of their minor daughter, Ashley Leary (Ashley), seek compensation under the National Vaccine Injury Compensation Program (Program).[1] The Learys concede that Ashley suffers "a variant of Carbohydrate Deficient Glycoprotein Syndrome (CDGS)," a genetic, metabolic disturbance. Petitioners' Pre-Trial Memorandum (P. Memo), filed May 27, 1997, at 1; *see also* Amended Petition (Am. Pet.), filed August 13, 1996, ¶ 4; Transcript (Tr.), filed November 10, 1997, at 6. In addition, the Learys concede that Ashley exhibited "mild symptoms of an encephalopathy" related to her CDGS before she received a diphtheria-pertussis-tetanus (DPT) vaccination on April 11, 1994. Tr. at 6; *see also* P. Memo at 1, 12. The Learys assert that Ashley's encephalopathy qualifies as an injury or as a condition listed within the Vaccine Injury Table (Table), § 300aa-14. Am. Pet. ¶ 5. The Learys claim that Ashley sustained the first symptom or manifestation of onset of a significant aggravation of her encephalopathy when she experienced "[four] clusters of brief seizures, 50 to 100 seizures in all" within three days after her April 11, 1994 DPT vaccination. P. Memo at 1; *see also* Am. Pet. ¶¶ 6-7. Thus, the Learys contend that they are entitled to the

[1] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-1 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

Program's legal presumption that Ashley's April 11, 1994 DPT vaccination caused the significant aggravation of Ashley's encephalopathy. P. Memo at 16.[2]

Respondent denies that the Learys are entitled to the Program's legal presumption of causation. *See* Supplement to Respondent's Prehearing Memorandum (R. Supp. Memo), filed May 22, 1997, at 4; Respondent's Post-Hearing Brief (R. Brief), filed January 23, 1998, at 2, 4. Respondent argues that § 300aa-14(b)(3)(B) prohibits the special master from defining Ashley's metabolic encephalopathy as a Table condition. R. Supp. Memo at 3-4; R. Brief at 3-5. Thus, respondent maintains that the Learys may not pursue a significant aggravation theory under the Table. R. Supp. Memo at 3; R. Brief at 3. Rather, respondent insists that the Learys are limited to proving that Ashley's April 11, 1994 DPT vaccination caused actually a significant aggravation of Ashley's metabolic encephalopathy. R. Supp. Memo at 3; R. Brief at 3. In the alternative, respondent asserts that Ashley's CDGS--a factor unrelated to vaccination--is wholly responsible for Ashley's current condition. Respondent's Prehearing Submissions (R. Memo), filed May 21, 1997, at 7.

BACKGROUND

Beginning in April 1990, Ms. Leary received periodic medical attention from Ronald E. Burmeister, M.D. (Dr. Burmeister), for a uterine "fibroid" and for "[p]rimary infertility." Petitioner's exhibit (Pet. ex.) 7 at 2; *see also* Pet. ex. 7 at 22. In June 1990, Dr. Burmeister noted "a positive Mycoplasma culture" that he decided to treat "later." Pet. ex. 7 at 3. Also in June 1990, Dr. Burmeister recommended "Clearplan to test ovulation." *Id.* In January 1991, Dr. Burmeister performed a "cervical dilatation" followed by an "insemination Huhner test." Pet. ex. 7 at 5-6. By February 1991, Dr. Burmeister concluded that any "significant enlargement" of Ms. Leary's fibroid would interfere with a pregnancy. Pet. ex. 7 at 6. In anticipation of surgery, Dr. Burmeister instituted a course of "Lupron" to shrink the fibroid. *Id.* In May 1991, Dr. Burmeister performed a "myomectomy" to remove the fibroid. Pet. ex. 7 at 7; *see also* Pet. ex. 7 at 24.

Ms. Leary's infertility persisted. Pet. ex. 7 at 8. In November 1992, Dr. Burmeister diagnosed hypothyroidism. Pet. ex. 7 at 10, 24. He prescribed "synthroid." Pet. ex. 7 at 10. In late November 1992, Ms. Leary began a course of Clomid. Pet. ex. 7 at 10. In December 1992, Dr. Burmeister performed an "[i]ntrauterine insemination." Pet. ex. 7 at 11. In late December 1992, Ms. Leary began a second course of Clomid. *Id.* In January 1993, C.D. Stephenson, M.D. (Dr. Stephenson), performed another intrauterine insemination. Pet. ex. 7 at 13. In late February 1993, Ms. Leary began a third course of Clomid. Pet. ex. 7 at 15. In March 1993, Dr. Burmeister did not attempt another, scheduled intrauterine insemination because of a problem with the sperm sample.

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[2] In their amended petition, and in their prehearing memorandum, the Learys identify other legal theories of their case. However, the Learys agree that their other legal theories are subsumed essentially into their significant aggravation claim. Tr. at 114.

Id. However, in March 1993, Ms. Leary conceived naturally. *See* Pet. ex. 7 at 16, 21, 25. Dr. Burmeister estimated the date of delivery as November 28, 1993. Pet. ex. 7 at 16.

Ms. Leary received routine prenatal care during her pregnancy with Ashley. *See* Pet. ex. 3A at 96. Ms. Leary experienced spotting one day very early in her pregnancy. Pet. ex. 7 at 16. At some later point in Ms. Leary's pregnancy, a "chromosome analysis" of amniotic fluid revealed "no evidence of any structural abnorm[ality]" in "15 out of 20 cells." Pet. ex. 7 at 17. The analysis revealed also "multiple random translocations"[3] attributed to "mycoplasma contamination" in the remaining five cells. *Id.* A subsequent blood test was "neg[ative]" for "toxoplasma antibody." Pet. ex. 7 at 13. Ms. Leary's pregnancy was apparently "normal" otherwise. *See, e.g.*, Pet. ex. 7 at 16-19; Pet. ex. 5 at 1.

Ashley was born on December 9, 1993, by Caesarean section. Pet. ex. 3A at 98. She weighed eight pounds, six ounces. Pet. ex. 3A at 95. She measured 20½ inches long. *Id.* Her APGAR scores were seven at one minute and eight at five minutes.[4] *Id.* At birth, Ashley suffered "fetal distress." *Id.* She required suctioning for "meconium-stained amniotic fluid [with] meconium below [the] cord." *Id.*; *see also* Pet. ex. 3A at 97-98. In addition, Ashley exhibited transient tachypnea[5] of the newborn (TNN). Pet. ex. 3A at 100. Yet, upon discharge from the hospital on December 12, 1993, Ashley was "doing well." *Id.*

As an infant, Ashley received routine medical attention from R.E. Ortega, M.D. (Dr. Ortega). On December 12, 1993, Ashley presented to Dr. Ortega "for her two week check-up." Pet. ex. 2 at 1. She weighed eight pounds, five ounces. Pet. ex. 2 at 18. She measured 22 inches long. *Id.* Dr. Ortega noted that Ms. Leary had "no concerns" regarding Ashley's health. Pet. ex. 2 at 1. According to Dr. Ortega, Ashley could hear. Pet. ex. 2 at 18. In addition, according to Dr. Ortega, Ashley could regard a face. *Id.* Dr. Ortega determined that Ashley was "normal" for her age. *Id.*

Ashley returned to Dr. Ortega's office on January 8, 1994, "for her hepatitis B vaccine." Pet. ex. 2 at 1. Dr. Ortega recorded that while Ashley was "doing well at home," Ms. Leary expressed "concern" about "some lesions on [Ashley's] right thigh." *Id.* Dr. Ortega examined the "pinpoint lesions." *Id.* He identified six lesions: "four in a row" on Ashley's right thigh; "one on the upper

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[3] A translocation is "a structural chromosome aberration in which one segment of a chromosome is transferred to a nonhomologous chromosome, the result of breakage of both chromosomes with repair in abnormal arrangement." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1744 (27th ed. 1988).

[4] An APGAR score is a numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex irritability, and color. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1498 (27th ed. 1988).

[5] Tachypnea is "excessive rapidity of respiration." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1659 (27th ed. 1988).

thigh and one on the inner thigh." *Id.* He described each lesion as a "slight depression of the skin." *Id.* He concluded that the lesions did not seem "to be affecting [Ashley] in any way." *Id.* He suggested to Ms. Leary that "diagnosis possibilities" for the lesions included "birthmarks" or blemishes from "instrumentation" used "during C-section." *Id.* He recommended only observation, with a "plastic surgery evaluation in the future" if the lesions did "not resolve by" themselves. *Id.*

On February 7, 1994, Ashley presented to Dr. Ortega "for her 2 month checkup." Pet. ex. 2 at 2. She weighed 12 pounds, seven ounces. Pet. ex. 2 at 18. She measured 24 inches long. *Id.* According to Dr. Ortega, Ashley continued to do "well at home." Pet. ex. 2 at 2. Nevertheless, Dr. Ortega noted, Ms. Leary was "worried" about "SIDS," reporting that Ashley made "lots of little funny noises," such as occasional "'gasps' when taking a breath." *Id.* However, Dr. Ortega recorded, Ashley had "never stopped breathing" or exhibited "a color change" with the noises. *Id.* Dr. Ortega "reassured" Ms. Leary regarding the "[b]reathing patterns of babies." *Id.* Upon examination, Ashley was "normal." *Id.* She could "follow" and "coo" and "smile." Pet. ex. 2 at 18. Dr. Ortega observed that Ashley's lesions remained "unchanged." Pet. ex. 2 at 2. He considered again an eventual "evaluation" of the lesions "by Plastic Surgery." *Id.* After discussing the "benefits, alternatives and risks of immunizations" with Ms. Leary, Dr. Ortega administered Ashley's first "Tetramune," a combination of diphtheria toxoid, tetanus toxoid, pertussis and hemophilus B conjugate vaccine, and Ashley's first oral polio vaccine (OPV). *Id.*

On March 7, 1994, and on March 9, 1994, Ms. Leary telephoned Dr. Ortega's office. Pet. ex. 2 at 2-3. Ms. Leary had "a few questions about [Ashley's] diet." Pet. ex. 2 at 3. In addition, Ms. Leary had "[questions] about R[espiratory]S[yncytial]V[irus]."[6] *Id.*; *see also* Pet. ex. 2 at 2.

Dr. Ortega evaluated Ashley on March 28, 1994, for a two-day history "of cough and stuffy nose." Pet. ex. 2 at 3. Upon examination, Ashley displayed no signs of "acute distress." *Id.* However, Dr. Ortega observed that Ashley's "[r]ight T[ympanic]M[embrane]" was "red." *Id.* In addition, he appreciated "upper respiratory congestion" without "fine rales" or "wheezing" in Ashley's "[l]ungs." *Id.* Dr. Ortega recommended "[s]ymptomatic treatment," including a course of "Amoxicillin." *Id.* Ashley suffered apparently "loose stools" from the Amoxicillin. Pet. ex. 2 at 4. On April 1, 1994, a physician switched Ashley to "other med[ication]s" for her upper respiratory infection. *Id.*

On April 11, 1994, Ashley presented to Dr. Ortega "for her 4 month checkup." Pet. ex. 2 at 4. She weighed 15 pounds, four ounces. Pet. ex. 2 at 18. She measured 25¾ inches long. *Id.* She was "afebrile," having finished a course of "Bactrim" on April 10, 1994. Pet. ex. 2 at 4. Again, Dr. Ortega noted that Ashley was "doing well at home." *Id.* Indeed, Ms. Leary had "[n]o concerns" apparently about Ashley's health. *Id.* Dr. Ortega concluded that a review of Ashley's systems was "normal." *Id.* However, he commented that while Ashley's "tone" was

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[6] RSV is "a paramyxovirus resembling the influenza virus." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1842 (27th ed. 1988). RSV is capable of causing "bronchopneumonia and bronchiolitis" in children. *Id.*

"W[ithin]N[ormal]L[imits]," she exhibited only "fair" support "on her legs." *Id.* He suggested that "if" Ashley exhibited "any problems with tone or development," she should "return" to his office "for a reevaluation." *Id.* Dr. Ortega administered Ashley's second Tetramune and Ashley's second OPV. *Id.*

Ms. Leary telephoned Dr. Ortega's office at 8:33 a.m. on April 12, 1994. Pet. ex. 2 at 4. In a message for Dr. Ortega, Ms. Leary reported that Ashley "had a reaction" to the "DPT" vaccination that she received on April 11, 1994. *Id.* Ms. Leary stated that Ashley exhibited "a startled look" with body stiffening lasting "10-15 min[utes]." *Id.* Ms. Leary added that Ashley was "extremely irritable for about 1½ h[ou]r[s]" after the episode. *Id.* However, Ms. Leary related that Ashley "slept fine" during the night. *Id.* A nurse returned Ms. Leary's telephone call for Dr. Ortega. The nurse confirmed that Ashley's episode did not involve "jerking, eye rolling, color change or other signs of seizure." *Id.* In addition, the nurse confirmed that Ashley was "acting normally" otherwise. *Id.* The nurse "[r]eassured" Ms. Leary about Ashley's episode. *Id.* The nurse advised Ms. Leary to "discuss risks [and] benefits of DPT [with] Dr. Ortega again [at Ashley's] 6 month exam." *Id.*

On April 14, 1994, Ashley presented to Dr. Ortega for evaluation of three episodes involving a "blank" look, "shallow" breathing and unusual movements of "both arms" and "legs." Pet. ex. 2 at 5. Upon examination, Ashley was "alert, active and in no acute distress." *Id.* She was "afebrile." *Id.* Her "neck" was "supple without any meningeal signs." *Id.* Dr. Ortega noted only Ashley's "slightly decreased tone in the lower extremities" that he had observed "in [his] previous exam" on April 11, 1994. *Id.* Nevertheless, Dr. Ortega determined to "[a]dmit" Ashley "to the hospital for further management and evaluation" of a possible seizure disorder. *Id.*

Ashley entered Rockford Memorial Hospital on April 14, 1994. *See* Pet. ex. 3. During the admission process, Ms. Leary informed Dr. Ortega for the first time that Ashley "had some startle episodes" that "resolved spontaneously" following her "first dose of Tetramune and OPV" in February 1994. Pet. ex. 3 at 1; *see also* Pet. ex. 3 at 8. According to Dr. Ortega, Ms. Leary "did not think" that the startle episodes "were significant." Pet. ex. 3 at 1. In addition, Ms. Leary related a "mild concern" that Ashley "was not holding her head as well as" another child Ms. Leary knew. *Id.*

Dr. Ortega referred Ashley for consultation with Muhammed Sheikh, M.D. (Dr. Sheikh), a neurologist. Pet. ex. 3 at 8. Dr. Sheikh performed an electroencephalogram (EEG) on April 14, 1994. Pet. ex. 3 at 34. The EEG was "markedly abnormal," showing a "hypsarrhythmic pattern."[7] *Id.* Dr. Sheikh diagnosed "infantile spasms." Pet. ex. 3 at 8. Because he did not know the "etiology" of Ashley's infantile spasms, Dr. Sheikh recommended numerous medical tests, including a "spinal tap" to "r[ule]/o[ut] infection," a "M[agnetic]R[esonance]I[maging] of [Ashley's] brain to

[7] Hypsarrhythmia is "Gibbs' term for an electoencephalographic abnormality sometimes observed in infants, with random, high-voltage slow waves and spikes that arise from multiple foci and spread to all cortical areas." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 810 (27th ed. 1988).

r[ule]/o[ut] malformations" and a "metabolic series." *Id.* Results of the medical tests were essentially normal. *See* Pet. ex. 3 at 11-13.

On April 14, 1994, Dr. Ortega prescribed "Clonopin" to control Ashley's infantile spasms. Pet. ex. 3A at 13. However, Ashley continued to exhibit seizures. Pet. ex. 3 at 11. During some seizures, Ashley experienced "apnea." *Id.*; *see also* Pet. ex. 3A at 17. Therefore, on April 17, 1994, Dr. Ortega transferred Ashley to the Pediatric Intensive Care Unit. Pet. ex. 3 at 11.

K. Schmidt, M.D. (Dr. Schmidt), a geneticist, evaluated Ashley on April 18, 1994. Pet. ex. 3 at 9. Dr. Schmidt described Ashley's "nasal bridge" as "deep with an up-turned nose." *Id.* Dr. Schmidt noted that Ashley's "upper lip" was "tented." *Id.* In addition, Dr. Schmidt noted that Ashley "held" her mouth "open." *Id.* Dr. Schmidt discovered "bilateral simian creases"[8] with "5th finger clinodactyly"[9] in Ashley's extremities. *Id.* And, Dr. Schmidt observed several "deep pits" on Ashley's thighs. *Id.* However, according to Dr. Schmidt, Ashley's "dysmorphic features" were "of unknown significance." Pet. ex. 3 at 10. Thus, Dr. Schmidt could not identify a "genetic etiology" for Ashley's infantile spasms. *Id.*

A repeat EEG on April 18, 1994, was "markedly abnormal" with a "disorganized background." Pet. ex. 3 at 35. "[M]ulti-focal spikes" suggested a "hypsarrhythmic pattern." *Id.* During the EEG, Ashley experienced "a generalized seizure lasting 50 seconds." *Id.*

While Ashley was in the Pediatric Intensive Care Unit, Thomas Root, M.D. (Dr. Root), investigated the potential "relationship" between Ashley's April 11, 1994 "DPT" vaccination and Ashley's infantile spasms; the "risks of complications from" the administration of ACTH following "oral polio vaccine;" and the risks of complications from the administration of ACTH following "possible varicella exposure." Pet. ex. 3 at 12; *see also* Pet. ex. 3 at 4; Pet. ex. 3A at 22-23. Based upon "a brief literature search," Dr. Root concluded that studies examining the association between DPT and infantile spasms did not show an "overall increased incidence" of infantile spasms following DPT. Pet. ex. 3 at 4. In addition, Dr. Root advised that he "found no data on [the] specific risk" regarding the administration of "steroids" following OPV. Pet. ex. 3A at 22. However, Dr. Root speculated that the administration of steroids following OPV involved some increased risk "[secondary to] immune compromise." *Id.* On April 19, 1994, Dr. Sheikh discontinued Clonopin, instituting instead "ACTH," a steroid. Pet. ex. 3 at 11; *see also* Pet. ex. 3A at 25.

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[8] A simian crease is "a single transverse palmar crease formed by fusion of the proximal and distal palmar creases." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 395 (27th ed. 1988). Simian creases "frequently" appear "in congenital disorders, such as Down's syndrome and rarely in normal persons." *Id.*

[9] Clinodactyly is the "permanent lateral or medial deviation or deflection of one or more fingers." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 354 (27th ed. 1988).

On April 20, 1994, Dr. Ortega completed a Vaccine Adverse Event Reporting System (VAERS) form. Pet. ex. 2 at 11. Dr. Ortega indicated that Ashley "had 'startle spells' with stiffening of the body and irritability" within 12 hours after she received "immunizations" on April 11, 1994. *Id.* According to Dr. Ortega, Ashley did not suffer any reaction to previous vaccinations. *Id.*

Ashley remained in the Pediatric Intensive Care Unit until April 21, 1994. Pet. ex. 3 at 11. Although Ashley experienced several seizures after her transfer to the Pediatrics ward, *see* Pet. ex. 3A at 28, 30, she was "clinically stable without any seizures" by April 23, 1994. Pet. ex. 3 at 12. Indeed, Dr. Sheikh noted that despite "mild hypotonia,"[10] Ashley was able to track "well." Pet. ex. 3A at 31. Except for increased "blood pressure" for which Dr. Ortega prescribed "Lasix" on April 25, 1994, Ashley remained clinically stable. Pet. ex. 3 at 12. Moreover, a repeat EEG on April 25, 1994, showed "significant improvement." Pet. ex. 3 at 36. Dr. Ortega discharged Ashley from the hospital on April 25, 1994, with instructions to "[c]ontinue ACTH." Pet. ex. 3 at 13.

On April 28, 1994, Ashley presented to Dr. Ortega "for follow-up." Pet. ex. 2 at 6. Ms. Leary reported that Ashley had displayed "some irritability" since her discharge from the hospital. *Id.* In addition, Ms. Leary reported that Ashley had suffered "some seizures at home." *Id.* However, Ms. Leary indicated that the seizures were "not as significant as" Ashley's previous seizures. *Id.* Further, Ms. Leary reported that Ashley exhibited "less head support and decreased tone in general." *Id.* Upon examining Ashley, Dr. Ortega determined that Ashley did "not track well." *Id.* And, he confirmed that Ashley was "not controlling her head well." *Id.* He reviewed Ashley's "medications" with Ms. Leary. *Id.* He recommended another "follow-up" examination for the following week. *Id.*

Dr. Sheikh evaluated Ashley on May 2, 1994. Pet. ex. 4 at 1. The Learys reported that while Ashley's seizures had "improved slightly," Ashley suffered still "2-3 clusters of seizures a day." *Id.* Dr. Sheikh commented that Ashley's seizures did "not appear" to be "classic flexor spasms" because the episodes involved also "staring and stiffening." *Id.* Dr. Sheikh described Ashley as "very irritable" and "sleepy" during the evaluation. Pet. ex. 4 at 2. Dr. Sheikh depicted Ashley's tone as "significantly decreased" with "poor head control." *Id.* Dr. Sheikh noted that Ashley displayed "questionable tracking." *Id.* Dr. Sheikh scheduled Ashley for an EEG on May 4, 1994. Pet. ex. 4 at 1.

Ashley's May 4, 1994 EEG was "moderately abnormal," showing epileptiform discharges" that were "consistent with seizures of focal origin." Pet. ex. 3 at 37. However, the EEG was "markedly improved" compared with Ashley's other EEGs. *Id.* Indeed, the EEG did not reveal "evidence of hypsarrhythmic pattern." *Id.*

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[10] Hypotonia is "a condition of diminished tone of the skeletal muscles." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 810 (27th ed. 1988).

Throughout the remainder of May 1994, and into mid-June 1994, Dr. Ortega and Dr. Sheikh monitored Ashley for her seizure disorder. *See, e.g.*, Pet. ex. 2 at 8-10; Pet. ex. 2A at 2, 4, 23; Pet. ex. 4 at 2-6. While a May 16, 1994 EEG did "not show any hepsarrhythmic [sic] pattern," Pet. ex. 4 at 5, Dr. Sheikh determined based upon an EEG finding of "very active epileptiform focus over the left temporal region" that Ashley began to experience "a new type of seizures" with "staring and stiffening." Pet. ex. 4 at 3; *see also* Pet. ex. 3 at 38. Dr. Sheikh tapered Ashley's ACTH dosage. Pet. ex. 4 at 4. In addition, Dr. Sheikh prescribed Phenobarbital. *Id.* Because he suspected "a neurodegenerative disorder," Dr. Sheikh planned diagnostic measures "to rule out neuronal ceroid lipofuscinosis[11] and other lysosoneural [sic] enzymes." Pet. ex. 4 at 6; *see also* Pet. ex. 2A at 23.

Meanwhile, Ashley's development lagged. *See, e.g.*, Pet. ex. 4 at 6. Ashley was not able "to track well." Pet. ex. 4 at 3; *see also* Pet. ex. 2 at 10; Pet. ex. 4 at 5. In addition, she "was poorly interactive." Pet. ex. 4 at 5. Further, she "was diffusely hypotonic." Pet. ex. 4 at 3; *see also* Pet. ex. 2 at 10; Pet. ex. 2A at 4, 23; Pet. ex. 4 at 4-6. Ashley received a referral to an "Infant and Toddler Development Program" during June 1994. Pet. ex. 9 at 1. However, Ashley's "health" was so "unstable" that therapists were not able immediately to evaluate comprehensively Ashley for services. *Id.*

On June 20, 1994, the Learys sought a second opinion regarding Ashley's condition from Harry Chugani, M.D. (Dr. Chugani), a professor of pediatrics, neurology and radiology at Wayne State University School of Medicine. *See* Pet. ex. 2 at 8, 10; Pet. ex. 5. Dr. Chugani professed apparently "special interests in infantile spasms." Pet. ex. 2 at 10. In the chronology of Ashley's health that he recorded, Dr. Chugani stated that "Ashley's difficulties began" within "[t]en hours" after Ashley's "second DPT immunization," when the Learys observed Ashley experience "clusters of startle movements." Pet. ex. 5 at 1. Dr. Chugani noted that Ashley's initial "EEG revealed hypsarrhythmia" that resolved with ACTH therapy. *Id.* However, according to Dr. Chugani, other seizure types soon emerged. *Id.*

After examining Ashley, Dr. Chugani described Ashley as "rather behind" in her development. Pet. ex. 5 at 2. Dr. Chugani observed that Ashley was "very floppy," failing to "sit" and "roll over." *Id.* Dr. Chugani observed also that Ashley exhibited "poor visual fixation." *Id.* In addition, Dr. Chugani mentioned "a rather unusual finding of numerous pimples on" Ashley's "right thigh" and "buttocks." *Id.*

Dr. Chugani performed a positron-emission tomography (PET) scan accompanied by an EEG. Pet. ex. 5 at 2; Pet. ex. 5 at 4. The EEG showed a "diffusely slow" background. Pet. ex. 5

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[11] Neuronal ceroid lipofuscinosis describes a "juvenile type" of "profound mental retardation." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 815 (27th ed. 1988). The "onset" occurs generally "between five and ten years." *Id.* The condition is marked by "a prolonged course" with "death during late adolescence." *Id.* "[C]ommon among Scandinavians," the condition "shows a 'salt and pepper' pigmentary degeneration (atypical retinitis pigmentosa)" accompanied by "cerebellar ataxia, polymyoclonia, and dementia." *Id.*

at 2. In addition, the EEG showed "sharp wave activity" in the "right posterior." *Id.* The PET scan showed "a focus of decreased glucose metabolism in the right temporal and parietal cortex." *Id.* According to Dr. Chugani, "images" reflecting "a lag of metabolic maturation in the brain" were "more typical" of a "neonatal pattern" than of "a six-month old." *Id.* Dr. Chugani commented that the PET scan "also showed the very typical pattern found in infantile spasms, which include metabolic activation of the basal ganglia and brain stem." *Id.*

Dr. Chugani recommended replacing Ashley's prescription for Phenobarbital with a prescription for Vigabatrin, "an extremely effective anticonvulsant" available in Canada. Pet. ex. 5 at 3. Nevertheless, Dr. Chugani projected that "surgical intervention" to "resection" Ashley's "right temporoparietal region," while "sparing the motor cortex," might be necessary. *Id.* In addition, Dr. Chugani recommended a repeat PET scan to determine whether Ashley's "brain metabolic patterns" were maturing "into the infant stage." *Id.*

On June 22, 1994, Stephen Burton, M.D. (Dr. Burton), a neurologist in Ontario, Canada, "assessed" Ashley. Pet. ex. 5A at 1. Dr. Burton agreed with Dr. Chugani that Ashley was "a good candidate for the drug Vigabatrin." *Id.* Dr. Burton offered to prescribe the anticonvulsant. *Id.*

By early July 1994, Ashley was "showing some developmental gains." Pet. ex. 2A at 25.; *see also* Pet. ex. 2A at 5. While Ashley "was unable to roll, did not have head control, and did not bear any weight" because of "diffuse hypotonia," she "appeared to track quite well" when Dr. Sheikh examined her "in the Pediatric Neurology Clinic" on July 6, 1994. Pet. ex. 2A at 25; *see also* Pet. ex. 2A at 5. In addition, Ashley "vocalized." Pet. ex. 2A at 25. Dr. Sheikh expressed satisfaction with Ashley's progress, noting that Ashley had "not had any seizures since June 17, 1994." *Id.*; *see also* Pet. ex. 2A at 5.

Dr. Ortega examined Ashley on July 6, 1994, too. Pet. ex. 2A at 5. He discussed with Ms. Leary "[t]he issue of" future "immunizations." *Id.* However, Dr. Ortega indicated that he would not administer any more "[p]ertussis" vaccine to Ashley. *Id.*

In mid-July 1994, Ashley became "very irritable" as she began teething. Pet. ex. 2A at 5. In addition, Ashley developed "watery eyes." Pet. ex. 2A at 10; *see also* Pet. ex. 2A at 25; Pet. ex. 6 at 6-7. Then, in an August 18, 1994 telephone message for Dr. Sheikh, Ms. Leary reported that Ashley appeared "dizzy" on August 17, 1994, exhibiting eye movements "as if she [were] looking" or "tracking something visible." Pet. ex. 2A at 25; *see also* Pet. ex. 6 at 6-7. Ms. Leary reported also that Ashley "startled" at least twice on August 17, 1994: once as Ms. Leary "went to pick [Ashley] up" for feeding and once as Ms. Leary "went to lay [Ashley] down" after feeding. Pet. ex. 2A at 25; *see also* Pet. ex. 2A at 10. According to Ms. Leary, Ashley "threw [her] arms out" during the second startle episode. Pet. ex. 2A at 25. Ms. Leary reported finally that Ashley was "getting more irritable." *Id.* Dr. Sheikh scheduled an EEG for August 22, 1994. *Id.* However, Dr. Sheikh performed apparently the EEG on August 19, 1994. Pet. ex. 3A at 106. The "markedly abnormal EEG" reflected "diffuse slowing and multifocal epileptiform discharges." *Id.*

Between August 19, 1994, and August 31, 1994, Ashley suffered additional seizures despite anticonvulsant medication. Pet. ex. 2A at 27. The "breakthroughs" were "more intense" than Ashley's initial seizures. *Id.* Dr. Sheikh consulted Dr. Chugani about Ashley's condition. *See* Pet. ex. 2A at 26-27. Dr. Chugani recommended "Tegretol." Pet. ex. 2A at 27-28. Ashley "started on Tegretol on August 31, 1994." Pet. ex. 2A at 30.

Dr. Sheikh performed apparently another EEG on September 1, 1994. Pet. ex. 3A at 105. Dr. Sheikh informed Ms. Leary that the EEG "looked bad." Pet. ex. 2A at 29. Dr. Sheikh described the EEG as "markedly abnormal." Pet. ex. 3A at 105; *see also* Pet. ex. 2A at 30. In addition, according to Dr. Sheikh, the EEG reflected "features of modified hypsarrhythmia." Pet. ex. 3A at 105; *see also* Pet. ex. 2A at 29-30.

Dr. Sheikh evaluated Ashley "in the Pediatric Neurology Clinic on September 7, 1994." Pet. ex. 2A at 30. Ashley exhibited possibly some regression with the recurrence of her seizures because she "did not interact and tracked very poorly" during the examination. *Id.* Although Dr. Sheikh planned to "obtain blood for lymphocyte[] electron microscopy to rule out neuronal ceroid lipofucinosis," and although Dr. Sheikh planned to schedule another "MRI," he noted that Ms. Leary preferred apparently to transfer Ashley's neurological monitoring to Dr. Chugani. *Id.* In addition, Dr. Sheikh acknowledged that Ms. Leary intended to pursue "compensation from [the] vaccine injury act." *Id.* While Dr. Sheikh opined that there existed "clearly" a temporal association between Ashley's April 11, 1994 DPT vaccination and Ashley's infantile spasms, he declined to state "for sure" that the DPT vaccination caused the infantile spasms. *Id.*

Throughout Fall 1994, Ashley continued to suffer seizures prompting several "medication changes." Pet. ex. 9 at 1; *see also* Pet. ex. 8 at 4-5, 8-9. The Learys scheduled apparently an appointment for late December 1994 with Peter Huttenlocher, M.D. (Dr. Huttenlocher), a neurologist at the University of Chicago Hospitals. *See* Pet. ex. 8 at 9. However, on the day of the appointment, Ashley suffered a seizure "lasting several minutes" and accompanied by cyanosis, necessitating hospitalization at Rockford Memorial Hospital "for observation." *Id.* On December 28, 1994, Dr. Ortega referred Ashley to the Pediatric Neurology Service at the University of Chicago Hospitals for "further evaluation [and] management" of her seizure disorder. Pet. ex. 8 at 9; *see also* Pet. ex. 8 at 5, 73. At the University of Chicago Hospitals, Ashley's attending physician was James H. Tonsgard, M.D. (Dr. Tonsgard). Pet. ex. 8 at 73. Ashley's admitting physician was M. Campbell, M.D. (Dr. Campbell). *Id.*

Dr. Tonsgard prepared an "Admit Note" on December 28, 1994. Pet. ex. 8 at 2. While Dr. Tonsgard recorded that Ashley experienced "10-15 [minutes] of arching" and "startling," as well as one-and-one-half hours of crying, "9 [hours] after [her] 4 mo[nth] DPT shot," he questioned whether Ashley's condition began actually at age two months because Ashley exhibited a "startle" two times "after [her] 2 mo[nth]'s DPT shot." *Id.*; *see also* Pet. ex. 8 at 65-66. Dr. Tonsgard reviewed briefly other aspects of Ashley's medical history. *See* Pet. ex. 8 at 2. Dr. Tonsgard concluded that Ashley's "poorly controlled" seizure disorder was "not morphologically explainable." Pet. ex. 8 at 3. He considered various diagnostic procedures. *Id.*

Dr. Campbell echoed some of Dr. Tonsgard's concerns. *See* Pet. ex. 8 at 9. Relying upon Ashley's "records," Dr. Campbell placed the onset of Ashley's seizures "several hours after administration of [Ashley's] 2nd DPT and OPV vaccinations" when Ashley was "age 4 mo[nths]." Pet. ex. 8 at 8. Dr. Campbell recognized that "DPT can cause encephalitis."[12] Pet. ex. 8 at 9. However, Dr. Campbell indicated that Ashley's "clinical [history]" was "not particularly suggestive of" encephalitis. *Id.* Moreover, Dr. Campbell described the development of "infantile spasms and [the] hypsarrhythmia pattern [on EEG] within just three days of [a DPT] vaccine" as "unusual." *Id.* Thus, in Dr. Campbell's view, one "[w]ould have to be suspicious of earlier seizure activity or [an] unrecognized congenital or metabolic abnormality." Pet. ex. 8 at 9-10.

In addition, Dr. Campbell criticized the "rather rapid" pace with which Ashley's treating physicians had "started" and changed Ashley's anticonvulsants. Pet. ex. 8 at 10. Dr. Campbell advocated "more traditional medications" with fewer changes to the regimen. *Id.* At the outset, Dr. Campbell recommended discontinuing one anticonvulsant, Neurontin, in favor of Phenobarbital. *Id.*

Like Dr. Tonsgard, Dr. Campbell considered various diagnostic procedures. *See* Pet. ex. 8 at 10. In particular, Dr. Campbell recommended a "[d]ermatology consult for suggestions to etiology of [Ashley's] skin lesions." *Id.* Dr. Campbell considered also various therapeutic options, such as a "ketogenic diet." *Id.*

During Ashley's hospitalization, Dr. Campbell reviewed "[with] neuroradiology" some of Ashley's previous "MRI films." Pet. ex. 8 at 10. According to Dr. Campbell, the films "suggest[ed] patchy white matter abnormality [consistent with] dysmyelination."[13] *Id.* Thus, Dr. Campbell concluded that the films "raise[d] the possibility of [a] white matter [disease]." *Id.*

Ashley remained in the hospital for two days. Pet. ex. 8 at 15. Her course was "unremarkable." *Id.* And, her condition was "unchanged." *Id.*

In January 1995, Ashley entered again the University of Chicago Hospitals. *See* Pet. ex. 8 at 19-59. Ashley's attending physician was Dr. Huttenlocher. Pet. ex. 8 at 19. He planned to institute a "trial" ketogenic diet. Pet. ex. 8 at 23. Ashley appeared to tolerate well the diet during her four-day hospitalization. *See* Pet. ex. 8 at 35.

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[12] Encephalitis is the "inflammation of the brain." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 548 (27th ed. 1988).

[13] Dys is a "combining form signifying difficult, painful, bad, disordered," or "abnormal." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 515 (27th ed. 1988). Myelination, also myelinazation, is "the act of furnishing with or taking on myelin." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1086 (27th ed. 1988).

Following Ashley's discharge from the University of Chicago Hospitals in late January 1995, Dr. Huttenlocher monitored Ashley's progress on the ketogenic diet. *See* Pet. ex. 8 at 60, 70. In March 1995, Ashley's "course" was "complicated by febrile illness and vomiting." Pet. ex. 8 at 60. Nevertheless, according to Dr. Huttenlocher, Ms. Leary reported that Ashley appeared "somewhat more alert" on the ketogenic diet. *Id.* In April 1995, Ashley suffered at least two bouts of significant emesis leading to dehydration. Pet. ex. 8 at 65-67. She entered the University of Chicago Hospitals for "intravenous fluids." Pet. ex. 8 at 65. During Ashley's hospitalization, Ashley's treating physicians attributed Ashley's "emesis and intolerance" to the ketogenic diet. Pet. ex. 8 at 66. However, in June 1995, Dr. Huttenlocher commented that Ashley was tolerating "the diet well." Pet. ex. 8 at 70. Indeed, Dr. Huttenlocher stated, Ashley's frequent but "brief" seizure activity was "less severe" than previous seizure activity. *Id.* Dr. Huttenlocher stated also that Ashley's physical therapist noted "progress," particularly in Ashley's "sitting balance." *Id.* Further, Dr. Huttenlocher stated, Ashley's EEG "show[ed] improvement." *Id.* Thus, Dr. Huttenlocher concluded that Ashley was doing "as well as one [could] expect." *Id.*

Mark S. Lubinsky, M.D. (Dr. Lubinsky), Medical Director of the Genetics and Birth Defects Center at Children's Hospital of Wisconsin, and Christine Sauer (Ms. Sauer), a genetics counselor, evaluated Ashley on August 23, 1995, "for possible syndrome identification and possible determination of etiology for her seizures." Pet. ex. 11 at 1; *see also* Pet. ex. 10. Dr. Lubinsky described Ashley's initial growth as "generally good." Pet. ex. 11 at 1. However, Dr. Lubinsky noted that over time, Ashley's "head circumference" had declined to "approximately" the "5th percentile" for her age. *Id.* Dr. Lubinsky stated that Ashley's "various seizures" presented "major problems." *Id.* But, because Ashley was "very slowly progressing," Dr. Lubinsky indicated that Ashley did not exhibit "true degeneration." *Id.*

While examining Ashley, Dr. Lubinsky observed several distinctive physical features, including "pits" in Ashley's skin suggesting "some atrophy of the underlying fat;" possible "eversion of the nipple on the left," accompanied by "a few small probable accessory nipples;" and "mild" to "significant hirsutism"[14] on portions of Ashley's body. Pet. ex. 11 at 1-2. According to Dr. Lubinsky, "[a] biopsy of one of the" pitted "areas was nonspecific." Thus, Dr. Lubinsky was not able to "identify a specific condition" at the time of Ashley's evaluation. Pet. ex. 11 at 2. Nevertheless, Dr. Lubinsky commented that "the unusual indentations" in Ashley's skin "might represent a mild abnormality of fat distribution" that is "seen occasionally in a condition known as" CDGS. *Id.* Dr. Lubinsky added that CDGS may "show eversion of the nipples, and severe developmental delay," too. *Id.* Therefore, Dr. Lubinsky decided to perform "a definitive biochemical test" for CDGS. *Id.* In addition, Dr. Lubinsky obtained "a small skin sample for

[14] Hirsutism is "abnormal hairiness." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 768 (27th ed. 1988).

fibroblasts culture to test" for "chromosomal mosaicism."[15] *Id.* Further, Dr. Lubinsky considered "an appropriate Endocrine consultation" regarding Ashley's "hair growth." Pet. ex. 11 at 2-3.

In October 1995, Dr. Lubinsky reported that Ashley tested "positive" for CDGS. Pet. ex. 12 at 1; *see also* Pet. ex. 12 at 3. Dr. Lubinsky offered that the positive result was consistent with some of Ashley's external abnormalities. Pet. ex. 12 at 1. Dr. Lubinsky lamented that "a variety of delays which can be severe" are "typical" of CDGS. *Id.* However, Dr. Lubinsky concluded that the diagnosis of CDGS did not "explain" Ashley's hirsutism. *Id.*

Donna Krasnewich, M.D., Ph.D. (Dr. Krasnewich), assessed Ashley at the National Institutes of Health over a two-day period in February 1996. Pet. ex. 21 at 1; *see also* Pet. ex. 16. Dr. Krasnewich described her "chance to evaluate Ashley" as "a rare opportunity" because Ashley represented one of "only about 25-30 cases" of CDGS in the United States. Pet. ex. 21 at 1. After reviewing Ashley's "clinical picture," Dr. Krasnewich concluded that certain features, such as Ashley's "apparently normal growth, relative microcephaly, normal appearance of [the] cerebellum on MRI, difficult[-]to[-]control seizure disorder and severe developmental delay," distinguished Ashley "from the most common CDGS group, Type I patients." *Id.* Rather, Dr. Krasnewich believed initially that Ashley represented "Type II CDGS." *Id.*

Dr. Krasnewich provided "sera to Helena Stibler, Ph.D. (Dr. Stibler), at Karolinska Institute in Stockholm[, Sweden] for further typing by transferrin[16] isoelectric focusing (IEF)." Pet. ex. 21 at 1. According to Dr. Krasnewich, Dr. Stibler had conducted additional CDGS research "since her initial report of the syndrome with Jaek Jaeken." *Id.* In Dr. Krasnewich's view, "clarifying [Ashley's] diagnosis" would "give the [Learys] and [sic] better sense of the prognosis." Pet. ex. 21 at 2.

Dr. Stibler obtained a "moderately elevated" value for "carbohydrate-deficient transferrin (DCT)" in Ashley's serum sample. Pet. ex. 17 at 1. In conducting "isoelectric focusing/Western blotting of transferrin and TBG" in Ashley's serum sample, Dr. Stibler determined that the sample showed "uncommon isoforms of both transferrin and TBG." *Id.* Dr. Stibler stated that the abnormal "findings" in Ashley's TBG were "definitely distinct from type I, II and III" CDGS. *Id.* In addition, Dr. Stibler stated that the abnormal "findings" in Ashley's TBG were consistent with findings in other "identified cases with CDG syndrome type IV." *Id.* Further, Dr. Stibler stated that Ashley's "clinical picture" appeared "compatible with type IV" CDGS. *Id.* Dr. Stibler decided to continue her investigation of Ashley's serum sample, examining specifically "antithrombin and antitrypsin." *Id.*

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[15] Mosaicism is a term used in genetics to describe "the presence in an individual of two or more cell lines that are karyotypically or genotypically distinct and are derived from a single zygote." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1055 (27th ed. 1988).

[16] Transferrin is "serum ß-globulin that binds and transports iron." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1743 (27th ed. 1988).

According to Dr. Stibler, Ashley's antitrypsin isoforms and Ashley's antithrombin isoforms were seemingly "normal." Pet. ex. 18 at 1. Thus, Dr. Stibler commented that the "results" were only "partly similar" to laboratory findings in other "patients with CDG syndrome typ[e] IV." *Id.* Nevertheless, Dr. Stibler concluded that Ashley did not exhibit type I, II or III CDGS, offering that Ashley appeared "most like type IV from a glycoprotein point of view." *Id.* Dr. Stibler commented that other type IV patients whom she reviewed had "been much younger than Ashley." *Id.* Therefore, Dr. Stibler could not provide information about possible "age-related changes" reflected in the studies of Ashley's serum sample. *Id.*

TESTIMONY

Ms. Leary

Ms. Leary acknowledged that she experienced difficulty with conceiving Ashley. *See, e.g.*, Tr. at 39. Regardless, Ms. Leary said, Ashley was a "healthy baby girl," who was "eating well" and "growing well," from birth to age two months. Tr. at 37-38; *see also* Tr. at 39. Indeed, Ms. Leary offered, Ashley "seemed to be following [] the typical pattern of a normal child." Tr. at 39; *see also* Tr. at 37-38. Ms. Leary related that Ashley "responded to" people "immediately." Tr. at 38. In addition, Ms. Leary related, Ashley began to smile by age "four weeks or so." *Id.*; *see also* Tr. at 37. Further, Ms. Leary related, Ashley began "to track" objects, like "a brightly[-]colored dinosaur" toy, by age "three to four weeks." Tr. at 37-38. Finally, Ms. Leary related, Ashley was able to lift her head from a prone position "very well" by age two months. Tr. at 39. Ms. Leary asserted that she was concerned only about "dimples" that she observed on Ashley's "upper thigh" shortly after Ashley's birth. Tr. at 40; *see also* Tr. at 66. Ms. Leary stated that when she mentioned the dimples to Dr. Ortega during Ashley's second examination, he indicated that the dimples were "just cosmetic." Tr. at 40; *see also* Tr. at 66. However, Ms. Leary admitted that she was concerned also about gasping sounds that Ashley made between birth and age two months. *See* Tr. at 65. But, again, Ms. Leary stated that when she mentioned Ashley's peculiar breathing to Dr. Ortega, he indicated that infants make "little baby noises" because "their lungs are still developing and forming." Tr. at 65.

Ms. Leary testified that Ashley exhibited her first "startle" episode on February 11, 1994, at age two months. Tr. at 40-42; *see also* Tr. at 68. Ms. Leary remembered that she "was dressing [Ashley] for [Ashley's] first portrait." Tr. at 40. According to Ms. Leary, she "was a little brisk in getting [Ashley] ready." Tr. at 41. Ms. Leary recounted that as she "lowered [Ashley]" from a "sitting" position to a "dressing table" after placing Ashley's "arms through [Ashley's] dress," Ashley "stiffened" and "looked scared." Tr. at 41; *see also* Tr. at 40, 62. Ms. Leary elaborated that Ashley's "arms went out," Tr. at 40; *see also* Tr. at 41, 62, 68, Ashley's legs "went straight," Tr. at 42; *see also* Tr. at 62-63, and Ashley's "eyes got a little big." Tr. at 41; *see also* Tr. at 68. Ms. Leary added that Ashley emitted "a little gasp" during the episode. Tr. at 68. Ms. Leary offered that she "was kind of alarmed" by Ashley's episode. Tr. at 41; *see also* Tr. at 44. Thus, Ms. Leary said, she discussed the episode with "a girlfriend" and with Dr. Ortega. Tr. at 72; *see also* Tr. at 44. Ms.

Leary stated that both assured her that the episode represented "a normal reflex." Tr. at 44; *see also* Tr. at 72.

Ms. Leary estimated that between February 11, 1994, and April 11, 1994, Ashley experienced "five to six" additional startle episodes that were "the same as" Ashley's February 11, 1994 startle episode. Tr. at 42-43; *see also* Tr. at 62-63, 65. Ms. Leary related that each additional startle episode occurred "always at night" as she "was putting [Ashley] into her bassinet." Tr. at 42; *see also* Tr. at 43, 62. Ms. Leary declared that because each additional startle episode involved "a movement," she "never questioned" the additional startle episodes "any further." Tr. at 42. Besides, Ms. Leary said, Ashley "continued to eat well and grow" between February 11, 1994, and April 11, 1994. Tr. at 44; *see also* Tr. at 68. And, Ms. Leary recalled, Ashley "started to giggle" by age four months. Tr. at 44. Yet, Ms. Leary noted, Ashley's "baby sitter made comments" about Ashley's head control when Ashley was approximately "three months of age." Tr. at 39-40; *see also* Tr. at 65-66, 68-69.

Ms. Leary described Ashley as "fine" when she presented to Dr. Ortega for a routine examination on April 11, 1994, at age four months. Tr. at 45. Ms. Leary remembered that Dr. Ortega performed "typical testing" before Ashley received a DPT vaccination. *Id.*; *see also* Tr. at 66. Ms. Leary offered that Ashley "cried" when she received the DPT vaccination. Tr. at 46. Otherwise, Ms. Leary indicated, she did not observe any "immediate change" in Ashley. *Id.* Ms. Leary remembered also that she discussed Ashley's head control with Dr. Ortega. *See* Tr. at 45-46, 66-67. Although Ms. Leary recalled that Dr. Ortega informed her that Ashley's development "wasn't as advanced as" other four-month old children's development, Tr. at 67, Ms. Leary asserted that Dr. Ortega told her that she should not be "alarmed with" Ashley's head control. Tr. at 46; *see also* Tr. at 45, 66-67. Indeed, Ms. Leary proclaimed, Ashley "did pass" the April 11, 1994 examination "with flying colors." Tr. at 45.

Ms. Leary testified that as she was holding Ashley between 6:30 p.m. and 7:30 p.m. on April 11, 1994, Tr. at 46, Ashley exhibited a "continuous cluster," Tr. at 69; *see also* Tr. at 46-47, 63, of "startle seizures," Tr. at 64; *see also* Tr. at 69, accompanied by "hysterical" crying. Tr. at 69; *see also* Tr. at 46, 64. Ms. Leary stated that during the seizures, Ashley's "arms went out and [Ashley's] body stiffened." Tr. at 64; *see also* Tr. at 63, 69. Ms. Leary added that during the seizures, Ashley "had a look of just terror on her face." Tr. at 65; *see also* Tr. at 68. Ms. Leary said that the "series" of seizures lasted between ten minutes and 15 minutes. Tr. at 47; *see also* Tr. at 46, 48. Ms. Leary indicated that she "did not count" the number of seizures that Ashley experienced on April 11, 1994. Tr. at 48. But, Ms. Leary declared, the number of seizures "impressed" her. *Id.*

Ms. Leary recounted that while she attempted to "comfort" Ashley, Mr. Leary telephoned "the doctor." Tr. at 48; *see also* Tr. at 64. Ms. Leary remembered that by the time the doctor "called back," Ashley's seizures "had already ended." Tr. at 49. Nevertheless, Ms. Leary said, she "explained exactly" Ashley's behavior to the doctor. Tr. at 48. Ms. Leary related that the doctor believed that Ashley had suffered "probably a neurological reaction to" her DPT "immunization." Tr. at 49. However, according to Ms. Leary, the doctor suggested that "the worst" part of the

reaction was "probably over" because Ashley had "calmed down." *Id.* Ms. Leary offered that although she was "upset" by Ashley's seizures, she was not "particularly alarmed with the way" that Ashley appeared for the remainder of the evening on April 11, 1994. *Id.* Indeed, Ms. Leary described the rest of the night as "pretty normal." *Id.*

Ms. Leary testified that "two days later," Ashley exhibited a new type of seizure. Tr. at 63; *see also* Tr. at 50, 64, 69. Ms. Leary characterized the new type of seizure as a "jack knife" seizure. Tr. at 69. Ms. Leary elaborated that during the new type of seizure, Ashley "would draw up her arms and legs" in "a cluster." Tr. at 49; *see also* Tr. at 50, 52, 63-64, 69. Ms. Leary indicated that during the new type of seizure, Ashley "would cry," too, as if she were "upset." Tr. at 49; *see also* Tr. at 69. Ms. Leary stated that the new type of seizure was "traumatic." Tr. at 69; *see also* Tr. at 50, 52. Indeed, Ms. Leary related, she telephoned Dr. Ortega at approximately 7:00 a.m., on April 14, 1994, when she noticed that one "bout" of Ashley's new type of seizure involved "apnea." Tr. at 50-51; *see also* Tr. at 52. Ms. Leary recalled that Dr. Ortega wanted to examine Ashley "as soon as possible." Tr. at 52; *see also* Tr. at 51. Ms. Leary remembered that Ashley exhibited "some more" of the new type of seizure "in the car on the way" to Dr. Ortega's office. Tr. at 51. Ms. Leary recounted that after Dr. Ortega evaluated Ashley, he "recommended" that Ms. Leary admit Ashley into "the hospital for observation." Tr. at 53.

Ms. Leary recollected that upon admission into the hospital, Ashley underwent an EEG. Tr. at 53. Ms. Leary said that because the EEG revealed a "hypsarrhythmia pattern," Ashley's treating physicians prescribed "anticonvulsants." *Id.* Nevertheless, according to Ms. Leary, Ashley's seizures "got worse" while Ashley was in the hospital. *Id.*; *see also* Tr. at 55. Ms. Leary explained that Ashley's seizures became "more and more frequent," with "longer" apneic episodes. Tr. at 53. Therefore, Ms. Leary stated, Ashley's treating physicians transferred Ashley to "intensive care for about four or five days." *Id.*

Ms. Leary offered that she "continued to breast feed" Ashley during Ashley's ten-day hospitalization in April 1994. Tr. at 53. But, Ms. Leary asserted, she did not have the same "day-to-day" interaction with Ashley in the hospital that she had with Ashley at home. Tr. at 54; *see also* Tr. at 53, 55. Thus, Ms. Leary confessed, she did not observe changes in Ashley's developmental skills until Ashley had been discharged from the hospital. Tr. at 54; *see also* Tr. at 53, 55.

Ms. Leary depicted the period following Ashley's discharge from the hospital as "a very intense time." Tr. at 54. Ms. Leary related that although Ashley was "able to feed and drink," she "was very limp," Tr. at 56; *see also* Tr. at 54, exhibiting "no head control." Tr. at 54; *see also* Tr. at 56. Ms. Leary related also that Ashley was "very unresponsive," sleeping "a lot." Tr. at 56; *see also* Tr. at 54. And, according to Ms. Leary, one of Ashley's "debilitating" medications--ACTH--caused Ashley's face to swell so much at times that Ashley "couldn't open her eyes." Tr. at 54; *see also* Tr. at 56. Indeed, Ms. Leary declared, Ashley "was just kind of there, a body" following her discharge from the hospital. Tr. at 54; *see also* Tr. at 56.

Ms. Leary recalled that Ashley's "continual spasms" ceased "relatively quickly" after Ashley began ACTH therapy, though. Tr. at 55; *see also* Tr. at 69. In addition, Ms. Leary recalled, an EEG that Ashley underwent in "the first part of May" 1994 showed that the "hypsarrhythmia pattern had decreased." Tr. at 55. Further, Ms. Leary recalled, as treating physicians tapered Ashley's dose of ACTH, Ashley "started to smile again." *Id.* Nevertheless, Ms. Leary noted, Ashley exhibited still "some seizures," including "complex partial seizures." Tr. at 56; *see also* Tr. at 69-70. However, Ms. Leary said, the seizures were not "really aggressive." Tr. at 56; *see also* Tr. at 69-70. Ms. Leary recounted that Ashley's treating physicians prescribed "phenobarbital" to control the complex partial seizures. Tr. at 56. Then, according to Ms. Leary, Ashley's seizures "stopped" completely for "about a six-week period" in July 1994 and in August 1994.

Ms. Leary testified that beginning in August 1994, Ashley exhibited "startle" episodes again. Tr. at 56-57; *see also* Tr. at 70-72, 111-12. Ms. Leary described each startle episode as "an isolated event." Tr. at 113; *see also* Tr. at 71-72. Ms. Leary said that during each startle episode, Ashley "stiffened." Tr. at 57; *see also* Tr. at 72, 113. Ms. Leary added that during some of the startle episodes, Ashley "would throw her arms up even." Tr. at 113. Ms. Leary proclaimed that the startle episodes alarmed her because of her experience with Ashley's "infantile spasms." *Id.*; *see also* Tr. at 71.

Ms. Leary related that Ashley underwent another EEG. *See* Tr. at 57, 71. Ms. Leary stated that the EEG revealed "spike" activity similar to "hypsarrhythmia." Tr. at 57; *see also* Tr. at 71, 111-12. Ms. Leary recollected that Ashley's treating physicians prescribed "Tegretol." Tr. at 57; *see also* Tr. at 71, 112. Ms. Leary offered that Tegretol appeared to "control" Ashley's seizures. Tr. at 57; *see also* Tr. at 71, 112. But, then, according to Ms. Leary, Ashley developed again episodes associated with apnea. Tr. at 57; *see also* Tr. at 71-72, 112. Ms. Leary indicated that Ashley deteriorated rapidly, experiencing progressively frequent and longer seizures. *See* Tr. at 57-58. Ms. Leary remembered that Ashley's treating physicians "started adding all the other anticonvulsants" to Ashley's medication regimen. Tr. at 58. "It was a terrible, terrible time," Ms. Leary declared. *Id.*

Although Ms. Leary described Ashley as "a very healthy girl" now, Tr. at 58, Ms. Leary stated that Ashley "has not made great gains" in her overall development. Tr. at 60; *see also* Tr. at 59. Indeed, Ms. Leary indicated that Ashley displays only rudimentary gross motor and communication skills. *See* Tr. at 58-61. And, while Ms. Leary testified that Ashley's seizures have decreased, Ms. Leary noted that Ashley "is on three" different anticonvulsants. Tr. at 59.

Thomas A. Schweller, M.D. (Dr. Schweller)[17]

[17] Dr. Schweller testified for the Learys. Dr. Schweller is board-certified in pediatrics; in neurology, with a special competence in child neurology; and in electroencephalography. Tr. at 74; *see also* Pet. ex. 15 at 1. Dr. Schweller indicated that while he devotes most of his current medical practice to performing "various forms of disability evaluations" for California State agencies, he treats a small number of "seizure patients with severe disease." Tr. at 74-75; *see also* Tr. at 85. Dr.

Dr. Schweller stated that before her April 11, 1994 DPT vaccination, Ashley was normal, or, at least, "within the low range of normal." Tr. at 76; *see also* Tr. at 97, 100. However, Dr. Schweller acknowledged that before her April 11, 1994 DPT vaccination, Ashley suffered "a genetic disorder of metabolism," Tr. at 76, affecting the myelination of her brain. Tr. at 86, 97. Dr. Schweller described myelin as "insulation to the nerves in the brain." Tr. at 97. Dr. Schweller explained that myelin assists "messages" to "travel more quickly." *Id.* Dr. Schweller said that at birth, humans "lack myelin." *Id.* According to Dr. Schweller, the myelination process that occurs after birth is essential to the development of many skills, including controlling the head, supporting weight, sitting, standing and walking. Tr. at 81; *see also* Tr. at 97. In addition, Dr. Schweller acknowledged that before her April 11, 1994 DPT vaccination, Ashley exhibited "subtle signs" of her genetic disorder, such as "some changes in tone," Tr. at 76; *see also* Tr. at 80-81, 86, 95-96; questionable head control, Tr. at 81, 86, 96; and pinpoint lesions on her right thigh. Tr. at 86-87.

In addressing the medical meaning of the startle episodes that Ashley exhibited before her April 11, 1994 DPT vaccination, Dr. Schweller discussed differences between the Moro response and seizures. Dr. Schweller defined the Moro response as an immediate "reflex phenomenon," Tr. at 102-03; *see also* Tr. at 76, 81, 98, 104-05, 107, that occurs "classically" with "a quick change in the linear posture," Tr. at 107; *see also* Tr. at 76-77, 92, 102-03, of "a child whose brain is not fully myelinated yet." Tr. at 76. According to Dr. Schweller, the Moro response is "very noticeable in the newborn period," Tr. at 77, but disappears gradually between age three months and age five months as the brain matures. Tr. at 86; *see also* Tr. at 77, 81, 97. Dr. Schweller said that the Moro response is "benign in the sense" that the Moro response does not indicate "damage to the brain," like the "electrical misfiring" of the brain in seizures. Tr. at 96-97; *see also* Tr. at 78, 87, 92, 98. However, Dr. Schweller offered, "a persistent Moro response" may denote a problem with the myelination of the brain. Tr. at 97; *see also* Tr. at 86, 99.

Dr. Schweller stated that the Moro response and seizures can involve similar, "stereotyped movements." Tr. at 77. However, according to Dr. Schweller, seizures "are a reflection of what's happening in the brain." Tr. at 89-90. And, Dr. Schweller said, a primary, distinguishing feature of seizures is their "paroxysmal" character. Tr. at 77; *see also* Tr. at 87, 91-92, 98, 105, 107. Dr. Schweller elaborated that while the Moro response is a "provoked event," Tr. at 87; *see also* Tr. at 76-77, 92, 98, 102-03, 107, that "doesn't happen on its own as a rule," Tr. at 77; *see also* Tr. at 87, seizures are "spontaneous events," Tr. at 105; *see also* Tr. at 91-92, 107, that appear "to be coming out of the blue," Tr. at 77, without any stimulation. Tr. at 98; *see also* Tr. at 103, 105. Yet, Dr. Schweller testified that stimulation or movement may elicit seizures. Tr. at 108. Moreover, Dr. Schweller acknowledged that the onset of seizures--particularly infantile spasms--in newborns is so insidious that pediatricians misconstrue occasionally the initial symptoms of seizure activity. Tr. at 88, 90-91. Dr. Schweller explained that because an infant's motions "are fairly subtle" at "the typical time that infantile spasms arrive," the process leading to a diagnosis of infantile spasms usually begins only when "a clear marked change" in the "type of movements" has occurred, such

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Schweller indicated also that he participates frequently as a medical consultant in legal proceedings. Tr. at 75.

as "more dramatic" events like respiratory arrest or "a series" of "repetitive" gestures, and usually "requires" a specialist "more schooled in" evaluating children who suffer infantile spasms. Tr. at 88; *see also* Tr. at 100.

Although Dr. Schweller asserted that before her April 11, 1994 DPT vaccination, Ashley "was not having any obvious seizures," Tr. at 76; *see also* Tr. at 83, Dr. Schweller admitted eventually that he does not know the medical significance of the startle episodes that Ashley exhibited before her April 11, 1994 DPT vaccination. Tr. at 91; *see also* Tr. at 90, 99. In fact, Dr. Schweller declared, Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination may have been seizures. Tr. at 91; *see also* Tr. at 90. Nevertheless, in the absence of an EEG confirming "electrical discharges" during Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination, Tr. at 102; *see also* Tr. at 77-78, 88, 91, 98, 106, and based upon the assumption that all of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were provoked by movement, Tr. at 87; *see also* Tr. at 76, 102-103, 105, 107, Dr. Schweller said that he "perhaps leans toward" a conclusion that the startle episodes were simply a Moro response. Tr. at 92; *see also* Tr. at 76-78, 86-87, 90-91, 96, 98-99, 102, 105, 107. But, Dr. Schweller cautioned that even if Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were simply a Moro response, the increasing prominence of the startle episodes as Ashley aged would constitute another manifestation of Ashley's genetic disorder. *See, e.g.*, Tr. at 86, 96-97, 99, 106.

Dr. Schweller proclaimed that Ashley displayed "an abrupt change in her condition" when, he asserted, Ashley experienced "the first clear onset of infantile spasms" on "the evening of" her April 11, 1994 DPT vaccination. Tr. at 82-83. Thus, Dr. Schweller opined, Ashley's "extensive spasms in clusters" on April 11, 1994, heralded Ashley's decline. Tr. at 83. Dr. Schweller speculated that Ashley suffered seizures because "something" about her April 11, 1994 DPT vaccination somehow "interrupted or interacted with" her genetic disorder. Tr. at 82.

Dr. Schweller testified that Ashley exhibits currently profound delay "for her age." Tr. at 83; *see also* Tr. at 82. According to Dr. Schweller, Ashley "has not progressed a great deal beyond the" developmental stage that she had achieved by the time she received her April 11, 1994 DPT vaccination. Tr. at 83. Indeed, Dr. Schweller asserted, Ashley's "motor control," Ashley's "interaction," and Ashley's "language development" hover close to the developmental stage of a six-month old child. *Id.*

Dr. Schweller stated that he has never evaluated a patient with CDGS. Tr. at 85. Indeed, Dr. Schweller offered that he would defer "to individuals who study" CDGS. Tr. at 84; *see also* Tr. at 93. But, Dr. Schweller stated, he "looked at some of the" literature about CDGS. Tr. at 75; *see also* Tr. at 93-94. And, in expressing his "understanding" about the "spectrum" of CDGS, Dr. Schweller questioned anyone's ability to predict accurately the course of Ashley's genetic disorder. Tr. at 83-84. Based upon his belief that Ashley's seizures began after Ashley's April 11, 1994 DPT vaccination, Dr. Schweller wondered openly if Ashley was destined "necessarily" to "progress to the more severe form of" her genetic disorder. Tr. at 84; *see also* Tr. at 93. Yet, Dr. Schweller agreed that all patients with CDGS display neurologic impairment and developmental delay. Tr. at 94.

Moreover, Dr. Schweller agreed that Ashley's neurologic impairment and developmental delay are consistent with CDGS. Tr. at 95. Finally, Dr. Schweller agreed that there is no medical literature that supports a proposition that DPT vaccine can actually significantly aggravate CDGS. Tr. at 94.

Peter R. Kollros, M.D., Ph.D. (Dr. Kollros)[18]

Dr. Kollros agreed that absent a "concurrent EEG," he cannot state "with certainty" that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were seizures. Tr. at 116; *see also* Tr. at 126. However, based upon his understanding of the evolution of Ashley's condition, Dr. Kollros opined that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were "much more likely" seizures than a persistent Moro response. Tr. at 125; *see also* Tr. at 116-17, 119, 121, 124-26, 132. In addition, Dr. Kollros attributed Ashley's current condition solely to CDGS. Tr. at 121-23; *see also* Tr. at 124, 130-31. Dr. Kollros reviewed the bases for his conclusions.

Dr. Kollros depicted the Moro response simply as a reflex that neonates display "with a sudden lack of head support" or other, similar movement. Tr. at 118. Dr. Kollros said that the Moro response "should become less prominent, more difficult to elicit, and less frequent through the second month" of age. Tr. at 133; *see also* Tr. at 117-18. Indeed, Dr. Kollros asserted, an increasing presence of the Moro response after age two months suggests "a problem with neurological development." Tr. at 133; *see also* Tr. at 117.

Dr. Kollros described the onset of infantile spasms as insidious, presenting frequently as "just a brief head nod," a "single jerk," Tr. at 118, or "repetitive[,] funny startles." Tr. at 129; *see also* Tr. at 119. In fact, Dr. Kollros proclaimed, many "general" physicians confuse symptoms of the "early stages of infantile spasms" with "some kind of reflex or some kind of colic." Tr. at 118. According to Dr. Kollros, the "hypsarrhythmia pattern" peculiar to infantile spasms on EEG "is activated by sleep and drowsiness." Tr. at 119. In addition, according to Dr. Kollros, the "very distinct pattern of hypsarrhythmia" on EEG "takes some time to develop." *Id.* Dr. Kollros indicated that following the onset of infantile spasms, children fail commonly to "progress," and maybe even regress. Tr. at 128-29. However, Dr. Kollros stated, the individual child's ability to achieve milestones following the onset of infantile spasms "depends on the severity of the spasms." Tr. at 128. Thus, Dr. Kollros asserted that, during the "very early stage" of infantile spasms, a child may "make some developmental progress for a short period of time." Tr. at 129.

Dr. Kollros testified that Ashley showed "signs and symptoms" of CDGS, such as "the dimples on the skin" and "abnormalities of tone," before her April 11, 1996 DPT vaccination. Tr.

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[18] Dr. Kollros testified for respondent. Dr. Kollros is a "child neurologist" in an "academic pediatric neurology practice" at the Jefferson Medical College of Thomas Jefferson University in Philadelphia, Pennsylvania, and at the A.I. DuPont Institute in Wilmington, Delaware. Tr. at 115. He is board-certified in pediatrics and in neurology, with a special competence in child neurology. *Id.*; *see also* Respondent's exhibit (R. ex.) B at 2.

at 121. And, Dr. Kollros maintained, Ashley's "unusual startles" before Ashley's April 11, 1994 DPT vaccination "were consistent with," *id.*, if not "very typical of," Tr. at 119, infantile spasms. Dr. Kollros noted that many of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination occurred as Ashley "was being put down to sleep." Tr. at 118; *see also* Tr. at 119, 125-26. In addition, Dr. Kollros noted that Ashley's "initial EEG" on April 14, 1994, showed clearly hypsarrhythmia. Tr. at 119. Further, Dr. Kollros noted that Ashley's medical records do not reflect reports of a "continuing isolated [M]oro response" after Ashley displayed definite seizures. Tr. at 125. Finally, Dr. Kollros noted that the other two identified cases with Ashley's particular type of CDGS involve infantile spasms. Tr. at 117; *see also* Tr. at 122, 125, 132. Therefore, Dr. Kollros urged that, in context, Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination constituted seizures. Tr. at 117, 125-26, 132.

Dr. Kollros offered that he has difficulty separating his knowledge about Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination from his knowledge that Ashley suffers "infantile spasms," as well as other "neurological abnormalities" related to her "genetic metabolic disorder." Tr. at 117. Thus, Dr. Kollros acceded that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination could have been possibly a Moro response. *Id.*; *see also* Tr. at 124, 132-33. Nevertheless, Dr. Kollros insisted that if Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were merely a Moro response, then the frequency and the prominence of the episodes when Ashley was age three months and age four months signaled that Ashley's preexisting metabolic encephalopathy "was worsening in its manifestations." Tr. at 117; *see also* Tr. at 132-133.

Dr. Kollros acknowledged that Ashley's "symptoms became more clear cut" after Ashley's April 11, 1994 DPT vaccination. Tr. at 124; *see also* Tr. at 121. However, Dr. Kollros declined to characterize Ashley's condition as worse following Ashley's April 11, 1994 DPT vaccination. *See* Tr. at 124; *see also* Tr. at 121. Indeed, although he recognized that the medical community has limited experience with the "range of biological variability of" Ashley's type of CDGS, Dr. Kollros asserted that "all" of the children "have infantile spasms." Tr. at 125; *see also* Tr. at 117, 122, 131-32. Thus, Dr. Kollros considered Ashley's infantile spasms to be "part and parcel" of her metabolic disorder. Tr. at 121; *see also* Tr. at 122, 130-31. Moreover, Dr. Kollros asserted, CDGS "causes severe developmental delay" in many cases. Tr. at 126. And, Dr. Kollros said that, as they age, "most children" who experience infantile spasms "tend to" exhibit "severe neural developmental problems" consistent with "the underlying cause" of their infantile spasms. Tr. at 122. Therefore, in Dr. Kollros's view, DPT did not change "in any way" Ashley's "potential" or Ashley's "disease." Tr. at 124; *see also* Tr. at 122, 130-31.

Dr. Krasnewich[19]

[19] The Learys attempted initially to retain Dr. Krasnewich as their expert witness. Tr. at 136-37. However, because of her status as a Federal employee, Dr. Krasnewich could not testify for the Learys. Tr. at 137. Instead, Dr. Krasnewich testified for respondent. *Id.* Dr. Krasnewich works at the National Human Genome Research Center--a division of the National Institutes of Health (NIH)--where she evaluates "patients with genetic disorders" and where she performs "basic science

Dr. Krasnewich testified that CDGS is a rare, inherited, metabolic disorder. *See* Tr. at 137, 143-44, 157. According to Dr. Krasnewich, "the underlying basis of" CDGS is the "defective synthesis of N-linked oligosaccharides." Tr. at 137; *see also* Tr. at 143. Dr. Krasnewich described N-linked oligosaccharides as "complex" structures of "sugar units." Tr. at 137. Dr. Krasnewich explained that "as they are placed on proteins and on the outside of cells," N-linked oligosaccharides "have physiologic and biologic function." *Id.* Dr. Krasnewich indicated that the effect of "abnormal glycocholation" of proteins in CDGS is "multisystemic." Tr. at 137; *see also* Tr. at 160.

Dr. Krasnewich related that CDGS is marked by a "specific pattern of the transferrin protein on isoelectric focusing" of "sera." Tr. at 138. Dr. Krasnewich identified "four known types of CDGS," labeled as Type I, Type II, Type III and Type IV. *Id.* Dr. Krasnewich said that each type of CDGS is defined by a "distinctive" isoelectric focusing pattern. Tr. at 139; *see also* Tr. at 149, 159. Dr. Krasnewich said that each type of CDGS is defined also by "clinical criteria." Tr. at 139; *see also* Tr. at 159.

Dr. Krasnewich offered that people with CDGS display "a fairly wide variation" of symptoms. Tr. at 139. Indeed, Dr. Krasnewich declared, "not all systemic problems show up in all cases" of CDGS. Tr. at 140. For example, Dr. Krasnewich stated, some people within each type of CDGS have seizure disorders. Tr. at 139. And, Dr. Krasnewich stated, some people with CDGS exhibit other serious medical conditions, such as "failure to thrive," Tr. at 137, "liver disease," Tr. at 140; *see also* Tr. at 137, 146, "coagulation problems," Tr. at 146; *see also* Tr. at 137, 140, or "cardiac problems." Tr. at 140; *see also* Tr. at 137, 146. However, Dr. Krasnewich emphasized, "all" people with CDGS "have significant developmental delay." Tr. at 140; *see also* Tr. at 137, 139.

Dr. Krasnewich recounted that, "as part of a protocol in which [she] was seeing children with CDGS," she examined Ashley "at NIH." Tr. at 137; *see also* Tr. at 136. Dr. Krasnewich testified that since Ashley's "transferrin reflects a Type IV pattern" on isoelectric focusing, Tr. at 149, Ashley "is a Type IV CDGS." Tr. at 140; *see also* Tr. at 149. Moreover, Dr. Krasnewich noted, many of Ashley's current clinical characteristics are similar to clinical characteristics in other reported cases of Type IV CDGS, including Ashley's "microcephaly," Tr. at 141; Ashley's dysmorphic features, *id.*; Ashley's low tone, *id.*; Ashley's "seizure disorder," Tr. at 148; *see also* Tr. at 141; and Ashley's "developmental delay." Tr. at 148; *see also* Tr. at 141. Yet, Dr. Krasnewich indicated, Ashley's initial clinical course was different from the initial clinical course in other reported cases of Type IV CDGS. Tr. at 146-47; *see also* Tr. at 150-51; *but see* Tr. at 145. Dr. Krasnewich elaborated that while grave manifestations of neurologic injury appeared "very early" in other reported cases of Type IV CDGS, Tr. at 148; *see also* Tr. at 146-47, Ashley exhibited only "some hints" of CDGS before her April 11, 1994 DPT vaccination. Tr. at 147; *see also* Tr. at 157. Dr. Krasnewich cited specifically Ashley's "one inverted nipple," Ashley's "dimpling," and Ashley's questionable "tone

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research in carbohydrate disorders." Tr. at 135. Dr. Krasnewich offered that she possesses "specific expertise in biochemical genetics," with a particular "interest in" CDGS. *Id.* Indeed, Dr. Krasnewich has written several articles on CDGS. Tr. at 136. She represented that she is board-certified in pediatrics and in biochemical genetics. Tr. at 135.

at the four-month checkup." Tr. at 156; *see also* Tr. at 142. Indeed, Dr. Krasnewich asserted, Ashley did not experience any "documented[,] medically[-]recognized problems" during her "first four months of life," Tr. at 147; *see also* Tr. at 141-42, 148, including "seizures." Tr. at 153. Therefore, Dr. Krasnewich proclaimed, Ashley suffered a new condition after the April 11, 1994 DPT vaccination, when she received "a very serious diagnosis of seizure disorder." *Id.*; *see also* Tr. at 144, 156. But, Dr. Krasnewich acknowledged, the medical significance of Ashley's startle episodes before the April 11, 1994 DPT vaccination is a primary issue in this case. *See* Tr. at 156. And, Dr. Krasnewich deferred to Dr. Schweller and to Dr. Kollros based upon their "expertise in pediatric neurology." Tr. at 156. Regardless, Dr. Krasnewich expressed that, even if Ashley's startle episodes before the April 11, 1994 DPT vaccination represented just a persistent Moro response, the presence of a Moro response "into the third and fourth month" is "a red flag." Tr. at 157.

Dr. Krasnewich projected that any individual with Type IV CDGS "will have serious developmental problems and seizures." Tr. at 150; *see also* Tr. at 141. However, Dr. Krasnewich admitted readily that, because so few cases of Type IV CDGS have been reported, she cannot "completely predict the exact degree" of symptoms or range of conditions that any individual with Type IV CDGS will experience. Tr. at 150; *see also* Tr. at 141, 149, 152. Moreover, Dr. Krasnewich admitted that she cannot conclude that Ashley's April 11, 1994 DPT vaccination did not alter Ashley's clinical course. *See* Tr. at 155; *see also* Tr. at 143. Indeed, based upon her assumption that Ashley's April 11, 1994 DPT vaccination and Ashley's seizures following Ashley's April 11, 1994 DPT vaccination were associated, Dr. Krasnewich speculated that Ashley's April 11, 1994 DPT vaccination and Ashley's seizures following Ashley's April 11, 1994 DPT vaccination "may very well have altered" somehow Ashley's "metabolic status." Tr. at 144-45; *see also* Tr. at 142-43, 155. Regardless, Dr. Krasnewich stressed, Ashley's "inability to correct[ly] produc[e] N-linked oligosaccharides" was "defined by" Ashley's "DNA" at Ashley's conception. Tr. at 143-44. Given her understanding of "glycobiology," Dr. Krasnewich asserted that CDGS represents "abnormal glycocholation in the whole person." Tr. at 160. And, Dr. Krasnewich maintained, individuals with CDGS "will have the clinical features reflective of" the "impact" of CDGS "on their biologic system." *Id.* Thus, Dr. Krasnewich insisted, Ashley's CDGS will ultimately cause Ashley "to have developmental problems." Tr. at 144.

CDGS

First reported by Jaek Jaeken in 1980, CDGS is family of autosomal recessive genetic disorders characterized by "the abnormal synthesis of N-linked glycosylation of cell structures." R. ex. X at 1-2. CDGS affects embryologic development. *Id.* Thus, the "physiological consequences" of CDGS are multisystemic. *Id.* "Affected patients are initially seen in infancy with severe CNS involvement." *Id.*; *see also* R. ex. X at 3.

Certain "clinical findings" in infancy, such as hypotonia, developmental delay, inverted nipples, and seizures, suggest a diagnosis of CDGS. R. ex. X at 10-11. However, a "specific biochemical finding, the presence of abnormally glycosylated serum proteins, typically transferrin, detected by cathodal migration on serum isoelectric focusing," confirms the diagnosis of CDGS. *Id.*

Additional "typing" of CDGS depends upon "both clinical features and distinctive transferrin isoelectric focusing patterns." R. ex. X at 14.

THE STATUTORY SCHEME

Congress desired specifically to extend the Program's compensation provisions to people with "possible minor events in" their "past medical history" who experience "serious cases of illness" related to vaccination. H.R. Rep. No. 99-908, pt. 1, at 15 (1986). Thus, Congress developed the concept of "significant aggravation." *Id.*; *see also* §§ 300aa-11(c)(1)(C); 300aa-14(a); 300aa-33(4). According to the United States Court of Appeals for the Federal Circuit, the concept of significant aggravation is "one of the most slippery and difficult to apply" in Program practice. *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1105 (Fed. Cir. 1996)(*Whitecotton II).*

The Learys may pursue potentially three significant aggravation theories. The Learys may present what is commonly referred to as a Table case. The Act contains the Vaccine Injury Table that lists vaccines covered by the Act and certain injuries and conditions that may stem from the vaccines. § 300aa-14. If the Learys establish by the preponderance of the evidence that following her April 11, 1994 DPT vaccination, Ashley suffered the onset of the significant aggravation of an injury listed on the Table, within the time period provided by the Table, then the Learys are entitled to a presumption that the vaccine caused the significant aggravation of the injury. §§ 300aa-11(c)(1)(C)(i); 300aa-13(a)(1)(A).[20]

In the alternative, the Learys may show based upon traditional tort standards that Ashley's April 11, 1994 DPT vaccination caused actually the significant aggravation of a condition that is listed on the Table for DPT vaccine, but that occurred outside the period provided in the Table, § 300aa-11(c)(1)(C)(ii)(II); or that Ashley's April 11, 1994 DPT vaccination caused actually the significant aggravation of a condition that is not listed on the Table for DPT vaccine. § 300aa-11(c)(1)(C)(ii)(I). The burden under the traditional tort standard for actual causation is "heavy." *Whitecotton*, 81 F.3d at 1102. The mere temporal coincidence between a vaccination and the significant aggravation of an injury, and the absence of other obvious etiologies for the significant aggravation of the injury, are patently insufficient to prove actual causation. *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Wagner v. Secretary of HHS,* No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). Instead, the Learys must establish "a logical sequence of cause and effect showing that the vaccination was the reason for the [significant aggravation of

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[20] The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See, e.g.*, *Thornton v. Secretary of HHS,* 35 Fed. Cl. 432, 440 (1996); *see also In re Winship,* 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring), *quoting* F. James, CIVIL PROCEDURE 250-51 (1965). Mere conjecture or speculation will not meet the preponderance of the evidence standard. *Snowbank Enter. v. United States,* 6 Cl. Ct. 476, 486 (1984); *Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612 (1995), *aff'd*, 73 F.3d 381 (Fed. Cir. 1995).

the] injury." *Grant*, 956 F.2d at 1148. The Learys must support the logical sequence of cause and effect with a "sound and reliable medical or scientific explanation." *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994), citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993). "The analysis undergirding" the medical or scientific explanation must "fall within the range of accepted standards governing" medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

Special masters apply routinely a two-part test to analyze actual causation cases. *See, e.g.*, *Crockett v. Secretary of HHS*, No. 94-0015V, 1997 WL 702559 (Fed. Cl. Spec. Mstr. Sept. 30, 1997); *Housand v. Secretary of HHS*, No. 94-0441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996); *Guy v. Secretary of HHS*, No. 92-0779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. Mar. 18, 1994). First, special masters determine if a specific vaccine *can* cause the significant aggravation of a particular injury. *See, e.g.*, *Crockett v. Secretary of HHS*, No. 94-0015V, 1997 WL 702559 (Fed. Cl. Spec. Mstr. Sept. 30, 1997). Then, special masters determine if the vaccine more likely than not *did* cause the significant aggravation of a particular injury in the individual case. *Id.* The evidence in a case "must affirmatively demonstrate that the [significant aggravation of an] injury . . . was caused by the vaccine." *Grant*, 956 F.2d at 1147-48 (quoting H.R. REP. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6356) (emphasis omitted); *see also Hodges v. Secretary of HHS*, 9 F.3d 958, 961 n.4 (Fed. Cir. 1993) ("That the DPT vaccine may cause death is not proof that it did in a particular case." (quoting *Hodges v. Secretary of HHS*, No. 90-0551V, 1991 WL 169397, *4 (Cl. Ct. Spec. Mstr. Aug. 14, 1991))); *Bunting v. Secretary of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991)(A petitioner's burden is "to show causation in the particular case," not a "generalized 'cause and effect relationship' with [Table injuries]"). Under the actual causation standard, the Learys establish legal cause by proving that the vaccine was the "but for" cause of the significant aggravation of Ashley's injury, as well as a "substantial factor" in causing the significant aggravation of Ashley's injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Governed by traditional tort standards for actual causation, respondent may rebut a *prima facie* Table significant aggravation case or a *prima facie* actual significant aggravation case with a preponderance of the evidence that the significant aggravation was "due to factors unrelated to the administration of" a vaccine. § 300aa-13(a)(1)(B); *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994). The phrase "'factors unrelated to the administration of'" a vaccine "may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing" the significant aggravation. § 300aa-13(a)(2)(B). However, the phrase "'factors unrelated to the administration of'" a vaccine "does not include any idiopathic, unexplained, unknown, hypothetical, or undocumented cause, factor, injury, illness, or condition." § 300aa-13(a)(2)(A).

DISCUSSION

This case presents an array of complicated legal, factual and medical issues that are among the most difficult that the special master has encountered in his tenure. The special master must address initially respondent's legal defense that the Learys may not pursue a Table significant aggravation claim. The special master's ruling on respondent's legal defense is dispositive potentially because the Learys acknowledge a paucity of evidence supporting a *prima facie* actual significant aggravation case. *See, e.g.* Tr. at 9. However, regardless of the special master's ruling on respondent's legal defense, the parties request that the special master address comprehensively the Learys' Table significant aggravation claim and respondent's factors unrelated defense. The analysis of the Learys' Table significant aggravation claim and of respondent's factors unrelated defense involves particularly the careful deliberation of the factual evidence and of the medical evidence regarding startle episodes that Ashley exhibited before her April 11, 1994 DPT vaccination. The special master must address finally evidence of actual significant aggravation.

Respondent's Legal Defense

Citing § 300aa-11(c)(1)(C)(i); § 300aa-14(a)(I)(B); § 300aa-14(b); § 300aa-14(b)(3)(A) and § 300aa-14(b)(3)(B), respondent contends that the Act's unequivocal language prevents the Learys from mounting a Table significant aggravation case. *See* Respondent's Post-Hearing Brief (R. Brief), filed January 23, 1998. According to respondent, § 300aa-11(c)(1)(C)(i) requires the Learys to demonstrate that Ashley "sustained, or had significantly aggravated, any illness, disability, injury or condition set forth in the Vaccine Injury Table in association with" a vaccine listed in the Table, and that "the first symptom or manifestation of the onset or of the significant aggravation for such illness, disability, injury or condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table," in order to receive a statutory presumption of causation. R. Brief at 3-4. Respondent acknowledges that § 300aa-14(a)(I)(B) lists encephalopathy as a Table injury associated with the DPT vaccine. R. Brief at 2. In addition, respondent acknowledges that § 300aa-14(a)(I)(B) provides that the first symptom or manifestation of onset of a significant aggravation of an encephalopathy must occur within three days after the administration of a DPT vaccine for the significant aggravation of the encephalopathy to qualify for a statutory presumption of causation. R. Brief at 3-4. However, respondent asserts that the special master must construe § 300aa-14(a)(I)(B) in conjunction with § 300aa-14(b), entitled "Qualifications and aids to interpretation" (QAI), which "shall apply to the Vaccine Injury Table." R. Brief at 8. In respondent's view, § 300aa-14(b)(3)(A) defines generally a Table encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." R. Brief at 2-3. But, respondent's insists, § 300aa-14(b)(3)(B) modifies specifically the general definition of a Table encephalopathy. R. Brief at 3. Respondent notes that § 300aa-14(b)(3)(B) states: "If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances[,] the encephalopathy shall not be considered to be a condition set forth in the table." R. Brief at 3. Respondent notes also that § 300aa-14(b)(3)(B) instructs: "In determining whether or not an encephalopathy is a condition set

forth in the table, the court shall consider the entire medical record." R. Brief at 9. Respondent reasons that because the Learys concede that Ashley suffered an encephalopathy that was caused by her CDGS before her April 11, 1994 DPT vaccination, and that because § 300aa-14(b)(3)(B) mandates that an encephalopathy related to a metabolic disturbance is not to be "considered to be a condition set forth in the table," Ashley's preexisting metabolic encephalopathy fails to meet the definition of a Table encephalopathy. R. Brief at 3. Thus, respondent concludes that the Learys cannot "avail themselves of a presumption of vaccine causation for the events that transpired after" Ashley's April 11, 1994 DPT vaccination. R. Brief at 4. Rather, respondent offers, as "Ashley's preexisting condition is *not* set forth in the Table," the Learys are limited to proof of actual causation. R. Brief at 3 (emphasis in original).

The Learys grant that respondent's "interpretation of § 300aa-14(b)(3)(B) is plausible." Petitioners' Post-Hearing Memorandum (P. Brief), filed February 13, 1998, at 5. Nevertheless, relying upon legislative history, the Learys urge that § 300aa-14(b)(3)(B) is merely "a restatement of the rule governing factors unrelated to the administration of the vaccine" contained in §300aa-13(a). *Id.* Thus, the Learys maintain that § 300aa-14(b)(3)(B) "does not restrict the nature of prevaccination encephalopathies upon which a petitioner may base a significant aggravation case." P. Brief at 9.

The Program represents a waiver of sovereign immunity. *See, e.g.*, *Mass v. Secretary of HHS*, 31 Fed. Cl. 523, 528 (1994). Thus, the special master must apply strictly Program provisions. *Id.* When interpreting the Act, the special master must confer a literal meaning to clear, unambiguous language, avoiding any construction that renders portions of the Act redundant. *See, e.g.*, *Hellebrand v. Secretary of HHS*, 999 F.2d 1565 (Fed. Cir. 1993). Indeed, "[t]he 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). Therefore, the special master should not consult legislative history unless the plain language of the Act yields absurd consequences. *See Hellebrand*, 999 F.2d at 1569. Moreover, if there are multiple "plausible" interpretations of a statutory provision, then the special master "must choose the interpretation that produces the more limited" effect. *Burch v. Secretary of HHS*, No. 99-0946V, 2001 WL 180129, at *7 (Fed. Cl. Spec. Mstr. Feb. 8, 2001).

In *Whitecotton II*, the Federal Circuit confirmed that under § 300aa-11(c)(1)(C)(i), a "[p]etitioner must show that [petitioner] suffered the first symptom or manifestation of the significant aggravation *of a table injury* within the table time following [petitioner's] vaccination." *Whitecotton*, 81 F.3d at 1103 (emphasis added). Of course, the Table lists encephalopathy as an injury associated with DPT vaccine. § 300aa-14(a)(I)(B). If the Table--§ 300aa-14(a)--stood in isolation, the accepted medical definition of the term "encephalopathy" in § 300aa-14(a)(I)(B) would control both the initial onset and the significant aggravation of an encephalopathy following vaccination. *See Abbott v. Secretary of HHS*, 27 Fed. Cl. 792, 794 (1993)("Congress intended this statute to be understood--and to be applied--as it would be by a medical professional."). But, the Table does not stand in isolation. Rather, § 300aa-14 contains also the QAI. § 300aa-14(b). And,

by employing obviously compulsory language, Congress intended special masters to apply § 300aa-14(b) to a petitioner's proof that petitioner sustained the initial onset or the significant aggravation of a Table injury. Congress's intent simply could not be clearer. For instance, in the original Table, Congress provided compensation for an injury called "residual seizure disorder." § 300aa-14(a)(I)(D); § 300aa-14(a)(II)(C). Yet, "residual seizure disorder" is a term of art, lacking a definition in common medical parlance. Therefore, Congress directed specifically the application of the definition of "residual seizure disorder" contained in § 300aa-14(b)(2). § 300aa-14(a)(I)(D); § 300aa-14(a)(II)(C). Likewise, the special master must refer to § 300aa-14(b)(3) to determine *at the outset* if a petitioner presents with either the initial onset of a Table encephalopathy or the significant aggravation of a Table encephalopathy. Indeed, according to the Federal Circuit: "Section 300aa-14(b)(3)(B) applies *only* when determining whether there is a Table injury. Once a Table injury is established, the Secretary may rebut the presumption pursuant to section 300aa-13(a)(2)." *Hanlon v. Secretary of HHS*, 191 F.3d 1344, 1348 (Fed. Cir. 1999)(emphasis added).

Section 300aa-14(b)(3)(A) defines "[t]he term 'encephalopathy'" in § 300aa-14(a)(I)(B) as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." Section 300aa-14(b)(3)(B) provides that if "the entire record" reveals "that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances[,] the encephalopathy *shall not be considered to be a condition set forth in the table*." (emphasis added). The special master determines that clear statutory language necessitates the ineluctable conclusion that any encephalopathy "caused by infection, toxins, trauma or metabolic disturbances" before the administration of a vaccine is not a Table injury that can be significantly aggravated under § 300aa-11(c)(1)(C)(i).

The Learys arguments countering the special master's interpretation of § 300aa-14(b)(3)(B) fail on many grounds. First, the Learys recognize that the special master's interpretation of § 300aa-14(b)(3)(B) is "plausible." P. Brief at 5. *Burch* demands that the Learys submit to the more restrictive of plausible interpretations of § 300aa-14(b)(3)(B). Second, the special master's interpretation does not yield unintended or absurd results. The special master's interpretation of § 300aa-14(b)(3)(B) limits surely the type of preexisting encephalopathies that can qualify for a statutory presumption of aggravation. Yet, it does not strain credulity to believe that when Congress designed the significant aggravation concept to compensate a petitioner for the exacerbation of "possible minor events" that occurred before vaccination, H.R. Rep. No. 99-908, pt. 1, at 15 (1986), Congress understood that some preexisting encephalopathies--such as encephalopathies related to metabolic disturbances--were such severe conditions that the encephalopathies did not warrant a statutory presumption of aggravation. Moreover, the special master's interpretation of § 300aa-14(b)(3)(B) does not prohibit completely the Learys from pursuing Program compensation. The Learys may still proffer evidence that Ashley's April 11, 1994 DPT vaccination caused actually the significant aggravation of Ashley's preexisting metabolic encephalopathy. § 300aa-11(c)(1)(C)(ii)(I). Third, the Learys' proposed construction of § 300aa-14(b)(3)(B) violates well-established canons of statutory interpretation. The Learys suggest that § 300aa-14(b)(3)(B) is merely a "restatement" of § 300aa-13(a). P. Brief at 5. However, the special master must strive to adopt

an interpretation of § 300aa-14(b)(3)(B) that does not make the provision redundant. *Hellebrand*, 999 F.2d at 1571.

In this case, the evidence establishes overwhelmingly that Ashley suffered a metabolic encephalopathy related to CDGS before her April 11, 1994 DPT vaccination. Under the special master's interpretation of § 300aa-14(b)(3)(B), Ashley's metabolic encephalopathy before her April 11, 1994 DPT vaccination is not "a condition set forth in the table." Therefore, the special master's interpretation of § 300aa-14(b)(3)(B) forecloses the Learys from seeking under § 300aa-11(c)(1)(C)(i) a legal presumption that Ashley's April 11, 1994 DPT vaccination aggravated significantly Ashley's preexisting metabolic encephalopathy.

Table Significant Aggravation

For purposes of discussion only, the special master assumes that Ashley's metabolic encephalopathy related to Ashley's CDGS before Ashley's April 11, 1994 DPT vaccination qualifies as a Table encephalopathy. In *Whitecotton II*, the Federal Circuit promulgated a legal standard governing the Learys' *prima facie* Table significant aggravation claim. In crafting the standard, the Federal Circuit acknowledged specifically that an inherent dilemma "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 v. Secretary of HHS*, 23 Cl. Ct. 322, 327 (1991). After examining several attempts by the United States Court of Federal Claims to "formulate a legal construct for deciding claims of significant aggravation," *Whitecotton*, 81 F.3d at 1105, and after considering "the meaning of the statute," *id.* at 1107, the Federal Circuit rejected soundly a "framework" that included as part of a petitioner's *prima facie* case any comparison between an individual's objective condition after vaccination with an individual's "predicted condition had the vaccine not been administered." *Id.* at 1104. The Federal Circuit reasoned that such a framework "improperly" placed a burden on a petitioner to establish ultimately "that petitioner's significant aggravation was not caused by a pre-existing injury." *Id.* at 1106. Therefore, the Federal Circuit articulated a test which "hoves close to the statutory mandate." *Id.* at 1107. The test dictates only seemingly rudimentary "factual assessments and determinations." *Id.* at 1108; *see also Haley v. Secretary of HHS*, No. 90-2727V, 1999 WL 476272 at *18 (Fed. Cl. Spec. Mstr. June 21, 1999)(*Whitecotton II* test is not "stringent"). Under the test, the special master must evaluate Ashley's condition before Ashley's April 11, 1994 DPT vaccination; evaluate Ashley's current condition; and decide if Ashley's current condition constitutes a "significant aggravation" of Ashley's condition before vaccination. *Id.* "The term significant aggravation means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). If the special master decides that Ashley's current condition constitutes a significant aggravation of Ashley's condition before vaccination, then the special master must decide if the first symptom or manifestation of the significant aggravation occurred within the Table period. *Whitecotton*, 81 F.3d at 1107.

Ashley was within normal limits of development before her April 11, 1994 DPT vaccination. Pet. ex. 2 at 4; Tr. at 76, 97, 100. Regardless, Ashley was born with CDGS. Tr. at 143-44. Indeed, before her April 11, 1994 DPT vaccination, Ashley exhibited distinct physical features associated with her CDGS, including possible "eversion" of a "nipple," Pet. ex. 11 at 1-2, and "pinpoint lesions," Pet. ex. 2 at 1, or "pitting," Pet. ex. 11 at 1-2, on her "right thigh," Pet. ex. 2 at 1, suggesting "some atrophy of the underlying fat." Pet. ex. 11 at 1-2. And, before her April 11, 1994 DPT vaccination, Ashley exhibited symptoms of an encephalopathy associated with her CDGS, including questionable head control, Pet. ex. 3 at 1; *see also* Tr. at 39-40, 65-66, 68-69; "fair" tone in her legs, Pet. ex. 2 at 4; *see also* Pet. ex. 2 at 5; and "some startle episodes" beginning in February 1994, Pet. ex. 3 at 1, 8; *see also* Pet. ex. 8 at 2, 65-66; Tr. at 40-43, 62-63, 65, 68, representing either a persistent Moro response, *see e.g.*, Tr. at 86, 96-97, 99, 106, 117, 133, or infantile spasms. *See, e.g.*, Tr. at 166-67, 119, 121, 124-26, 132. While the special master's factual ruling regarding the medical characterization of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination does not affect greatly the special master's analysis of Ashley's condition before Ashley's April 11, 1994 DPT vaccination, the special master's factual ruling regarding the medical characterization of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination is critical to respondent's factors unrelated defense.

None of Ashley's medical records describes substantively the startle episodes that Ashley exhibited before her April 11, 1994 DPT vaccination. Few of Ashley's medical records even refer to the episodes. When he admitted Ashley into Rockford Memorial Hospital in April 1994, Dr. Ortega indicated only that Ms. Leary related for the first time that preceding the April 11, 1994 DPT vaccination, Ashley had experienced "some startle episodes" that "resolved spontaneously." Pet. ex. 3 at 1; *see also* Pet. ex. 3 at 8. And, during Ashley's December 1994 hospitalization at the University of Chicago Hospitals, Dr. Tonsgard remarked simply that Ashley displayed a "startle" twice between age two months and age four months. Pet. ex. 8 at 2.

At hearing, Ms. Leary testified about Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination. Ms. Leary asserted that each of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination occurred with some "movement," Tr. at 42, such as "dressing," Tr. at 40, or being placed into a "bassinet" at night. Tr. at 42; *see also* Tr. at 43, 62. According to Ms. Leary, Ashley "stiffened," Tr. at 41; *see also* Tr. at 40, 62, extending her arms "out," Tr. at 40; *see also* Tr. at 41, 62, 68, and her legs "straight," Tr. at 42; *see also* Tr. at 62-63, during each startle episode before her April 11, 1994 DPT vaccination. In addition, according to Ms. Leary, Ashley's "eyes got a little big," Tr. at 41; *see also* Tr. at 44, as if Ashley were "scared," Tr. at 41; *see also* Tr. at 40, 62, during each startle episode before her April 11, 1994 DPT vaccination. Further, according to Ms. Leary, Ashley exhibited a "gasp" during each startle episode before her April 11, 1994 DPT vaccination. Tr. at 68.

Dr. Schweller conceded that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination may have been seizures. Tr. at 91; *see also* Tr. at 90. Nevertheless, Dr. Schweller advocated that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were more likely manifestations of a persistent Moro response reflecting only delayed myelination associated

with Ashley's CDGS. Tr. at 76-78, 86-87, 90-91, 96-99, 102, 105-07. Dr. Schweller relied essentially upon two factors to support his view: Ms. Leary's testimony that "movement" prompted each of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination, Tr. at 87; *see also* Tr. at 76, 102-03, 105, 107, and the absence of an EEG documenting that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination involved seizure "discharges." Tr. at 102; *see also* Tr. at 77-78, 88, 91, 98, 106.

In contrast, Dr. Kollros advanced that, despite the absence of a definitive, "concurrent EEG," Tr. at 116; *see also* Tr. at 126, Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination "were consistent with," Tr. at 121, if not "very typical of," Tr. at 119, the insidious nature of infantile spasms. *See, e.g.*, Tr. at 118-19, 129. Dr. Kollros based his opinion upon the evolution of Ashley's condition presented in Ashley's medical records. *See* Tr. at 116-17, 119, 121, 124-26, 132. Commenting that Ashley's medical records do not contain reports of a "continuing isolated [M]oro response" following the diagnosis of infantile spasms in April 1994, Tr. at 125, Dr. Kollros urged that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination constituted subtle seizures in the early stage of infantile spasms that progressed to obvious seizures after Ashley's April 11, 1994 DPT vaccination. Tr. at 117, 125-26, 132. Moreover, Dr. Kollros asserted that the clear hypsarrhythmic pattern on Ashley's "initial EEG" just three days after Ashley's April 11, 1994 DPT vaccination would have taken "some time to develop." Tr. at 119. Thus, Dr. Kollros suggested that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination correlated well with emerging hypsarrhythmia. *See id.*

The special master has considered exhaustively Ashley's medical records, Ms. Leary's testimony, Dr. Schweller's testimony and Dr. Kollros's testimony. The special master concludes that Dr. Kollros offers the more rational, supported and persuasive interpretation of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination. Therefore, the special master determines that Ashley's symptoms of an encephalopathy associated with Ashley's CDGS before Ashley's April 11, 1994 DPT vaccination included infantile spasms.

At the outset, the special master cannot discern any difference between Ms. Leary's description of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination and the description in Ashley's medical records of at least two startle episodes in August 1994 that heralded the reappearance of hypsarrhythmia on EEG. One startle episode occurred as Ms. Leary "went to pick [Ashley] up" for feeding. Pet. ex. 2A at 25; *see also* Pet. ex. 2A at 10. Another startle episode occurred as Ms. Leary "went to lay [Ashley] down" after feeding. Pet. ex. 2A at 25; *see also* Pet. ex. 2A at 10. Thus, Ashley's August 1994 startle episodes--identified clinically as seizures--arose with movement exactly like movement that Ms. Leary claimed precipitated all of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination. In addition, during one August 1994 startle episode, Ashley "threw [her] arms out." Pet. ex. 2A at 25. The depiction of Ashley's arm gesture during the August 1994 startle episode is remarkably similar to Ms. Leary's depiction of Ashley's arm gesture during each of Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination. In the special master's view, Dr. Schweller failed in any attempt to distinguish Ashley's

startle episodes before Ashley's April 11, 1994 DPT vaccination from Ashley's startle seizures in August 1994.

Moreover, two, if not three, of Ashley's treating physicians expressed some measure of concern about Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination. In his April 14, 1994 notation regarding Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination, Dr. Ortega seemed surprised--perhaps even dismayed--that Ms. Leary had not reported the startle episodes during any of Ashley's previous examinations. *See* Pet. ex. 3 at 1; *see also* Pet. ex. 3 at 8.[21] In late 1994, Dr. Tonsgard believed possibly that Ashley's startle episodes before Ashley's April 11, 1994 DPT vaccination were seizures. Pet. ex. 8 at 2; *see also* Pet. ex. 8 at 65-6. And, labeling the development of a "hypsarrhythmia pattern [on EEG] within just three days of [a DPT] vaccine" as "unusual," Dr. Campbell was "suspicious" plainly that Ashley had exhibited "seizure activity" before April 11, 1994. Pet. ex. 8 at 9-10. Dr. Campbell's view is consonant certainly with Dr. Kollros's opinion.

Finally, Dr. Schweller acknowledged that an infant's motions may be so "subtle" at "the typical time that infantile spasms arrive" that some observers misconstrue the initial symptoms of seizure activity. Tr. at 88, 90-91. Indeed, Dr. Schweller stated, the process leading to the diagnosis of infantile spasms by a specialist "schooled" in evaluating children who suffer infantile spasms begins often only when "a clear marked change" in the "type of movements" has occurred. Tr. at 88; *see also* Tr. at 100. Ashley's clinical course, as recounted in Ashley's medical records and in Ms. Leary's testimony, mirrors perfectly Dr. Schweller's account of the medical profession's common experience with infantile spasms. Between age two months and age four months, Ashley exhibited several, transient "startle episodes" that did not appear serious. Pet. ex. 3 at 1; *see also* Tr. at 42. Then, at age four months, Ashley exhibited several dramatic clusters of startle movements leading quickly to hospitalization and to the diagnosis of infantile spasms by a neurologist. *See* Pet. ex. 3 at 8, 34; Tr. at 46-48, 53, 63-65, 68-69.

The parties do not dispute that Ashley is currently devastated neurologically. Tr. at 58-61, 82-83, 141, 148. Since infancy, Ashley has achieved few developmental milestones. Tr. at 59-60. In addition, Ashley suffers an intractable seizure disorder. Tr. at 59. The simple comparison between Ashley's symptoms of an encephalopathy associated with Ashley's CDGS before Ashley's April 11, 1994 DPT vaccination and Ashley's current encephalopathy prescribed by *Whitecotton II* compels surely the conclusion that Ashley has suffered a significant aggravation of her encephalopathy before vaccination as defined by § 300aa-33(4).

Within three days after her April 11, 1994 DPT vaccination, Ashley suffered a noticeable increase in the frequency, and in the duration, of her infantile spasms. Indeed, within three days after

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[21] Based upon *Cucuras v. Secretary of HHS*, 993 F.2d 1525 (Fed. Cir. 1993), the special master finds that Dr. Ortega's contemporaneous record from 1994 undermines Ms. Leary's current recollection that she discussed Ashley's startle episodes with Dr. Ortega, who assured her that the activity was "a normal reflex." Tr. at 44; *see also* Tr. at 72.

her April 11, 1994 DPT vaccination, Ashley entered Rockford Memorial Hospital, where Dr. Sheikh diagnosed conclusively infantile spasms based upon an EEG demonstrating marked hypsarrhythmia. *See generally* Pet. ex. 3. In Dr. Schweller's view, Ashley's "clusters" of spasms beginning on April 11, 1994, signaled "an abrupt change in [Ashley's] condition." Tr. at 82-83. Dr. Schweller offered that seizures "are a reflection of what's happening in the brain." Tr. at 89-90. Thus, Dr. Schweller implied that Ashley's obvious seizures within three days after Ashley's April 11, 1994 DPT vaccination indicated the onset of the decline in Ashley's neurologic condition associated with Ashley's CDGS. Tr. at 82-83. Based upon his opinion that Ashley's infantile spasms before Ashley's April 11, 1994 DPT vaccination and Ashley's infantile spasms after Ashley's April 11, 1994 DPT vaccination were "part and parcel" of Ashley's CDGS, Tr. at 121; *see also* Tr. at 122, 130-31, and based upon his understanding that CDGS "causes severe developmental delay" in many cases, Tr. at 126, Dr. Kollros disputed that Ashley's infantile spasms after Ashley's April 11, 1994 DPT vaccination represented the onset of a deterioration in Ashley's neurologic condition associated with Ashley's CDGS. *See* Tr. at 121, 124. However, Dr. Kollros acceded that Ashley's "symptoms" of her CDGS "became more clear cut" following the April 11, 1994 DPT vaccination. Tr. at 124; *see also* Tr. at 121.

Under the *Whitecotton II* test, the Learys are not required to offer any explanation regarding how, or why, Ashley's April 11, 1994 DPT vaccination may have affected Ashley's encephalopathy associated with Ashley's CDGS before Ashley's April 11, 1994 DPT vaccination to lead to Ashley's current, significantly aggravated encephalopathy. Thus, Dr. Schweller's conjecture that Ashley's April 11, 1994 DPT vaccination "interrupted or interacted with" Ashley's CDGS is not relevant to the Learys' Table significant aggravation claim. Tr. at 82. Rather, to obtain a statutory presumption of causation under the *Whitecotton II* test, the Learys must show only that the first symptom of Ashley's current, significantly aggravated encephalopathy occurred within three days after Ashley's April 11, 1994 DPT vaccination. *Whitecotton*, 81 F.3d at 1107; § 300aa-14(a)(I)(B). Asserting that Ashley's clinical course before Ashley's April 11, 1994 DPT vaccination; Ashley's clinical course after Ashley's April 11, 1994 DPT vaccination and Ashley's current condition are compatible entirely with Ashley's CDGS, Dr. Kollros maintained emphatically that Ashley's April 11, 1994 DPT vaccination did not change "in any way" Ashley's condition. Tr. at 124; *see also* Tr. at 122, 130-31. Nevertheless, Dr. Kollros acknowledged that Ashley's symptoms of an encephalopathy associated with Ashley's CDGS "became more clear cut" when Ashley's brief infantile spasms before Ashley's April 11, 1994 DPT vaccination segued to clusters of continuous infantile spasms within three days after Ashley's April 11, 1994 DPT vaccination. Tr. at 124; *see also* Tr. at 121. Thus, regardless of whether Dr. Kollros would attribute Ashley's clusters of continuous infantile spasms within three days after Ashley's April 11, 1994 DPT vaccination to Ashley's April 11, 1994 DPT vaccination, or whether Dr. Kollros would argue that Ashley's clusters of continuous infantile spasms within three days after Ashley's April 11, 1994 DPT vaccination were merely coincidental to Ashley's April 11, 1994 DPT vaccination, the testimony supports a factual conclusion that Ashley's condition worsened within three days after Ashley's April 11, 1994 DPT vaccination. *Whitecotton II* demands no more. As a consequence, the special master finds that the Learys have established a *prima facie* Table significant aggravation claim. Thus, the Learys receive a statutory

presumption that Ashley's April 11, 1994 DPT vaccination caused Ashley's current, significantly aggravated encephalopathy.

Factors Unrelated

Respondent may rebut the Learys' statutory presumption of causation by establishing by the preponderance of the evidence that Ashley's current, significantly aggravated encephalopathy "is due to factors unrelated to" Ashley's April 11, 1994 DPT vaccination. § 300aa-13(a)(1)(B). Factors unrelated to vaccination include, but are not limited to, "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing" an individual's condition. § 300aa-13(a)(1)(B). However, factors unrelated to vaccination do not encompass "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, illness or condition." § 300aa-13(a)(2)(A).

Traditional tort standards for actual causation control clearly respondent's proof regarding factors unrelated to vaccination. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). Yet, neither the United States Court of Federal Claims, nor the Federal Circuit, has addressed directly respondent's factors unrelated defense in a Table significant aggravation case since at least 1994, when the Federal Circuit announced in *Whitecotton v. Secretary of HHS*, 17 F.3d 374 (Fed. Cir. 1994)(*Whitecotton I*), that statutory language excludes even legitimate, preexisting conditions as factors unrelated to vaccination if the conditions are idiopathic. *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 377 (Fed. Cir. 1994)(citing *Koston v. Secretary of HHS*, 974 F.2d 157, 160-61 (Fed. Cir. 1992);[22] *see also Gruber v. Secretary of HHS*, 1998 WL 928423 (Fed. Cl. Spec. Mstr. Dec. 22, 1998)(adopting *Whitecotton I*, special master ruled that although medical community agrees that a diagnosis of severe myoclonic epilepsy (SME) presages very serious neurological deficits, child's SME with onset before vaccination did not qualify as a factor unrelated capable of defeating presumption of causation because child's preexisting SME was "idiopathic"). However, because the United States Supreme Court reversed and remanded *Whitecotton I*, the precedential value of *Whitecotton I* is highly questionable. *Shalala v. Whitecotton*, 514 U.S. 268 (1995). Indeed, in a concurring opinion, Justice O'Connor signaled that the Federal Circuit's "approach" to the "factor unrelated" defense prohibiting respondent from relying upon "an underlying condition that predated use of a vaccine and obviously caused a claimant's ill health, if the cause of that underlying condition is unknown," merited possibly consideration "in the future." *Whitecotton*, 514 U.S. at 278-79. Moreover, while the Federal Circuit did not review fully on remand its previous ruling that a preexisting "brain disorder of unknown origin" does not "constitute the basis of a 'factor unrelated' defense" because the Federal Circuit deemed that respondent had "waived" the defense in the case, *Whitecotton*, 81 F.3d at 1107, n. 13, the Federal Circuit relented apparently in its insistence that respondent must identify the cause of a preexisting condition to prevail upon a factors unrelated defense in a Table significant aggravation case. *Id.* at 1107. Rather, according to the Federal

[22] The Federal Circuit did not analyze *Whitecotton I* as a significant aggravation claim.

Circuit, "once a petitioner has made a *prima facie* case [of significant aggravation], the government may still prevail if it can show, to a preponderance of the evidence, that the pre-existing condition was, in fact, the cause of the individual's post-vaccination significant aggravation." *Id.* Thus, in significant aggravation cases, respondent may present apparently two theories under the factors unrelated defense. Respondent may show that an event contemporaneous with vaccination, such as an intercurrent illness or a coincident trauma, caused the individual's post-vaccination significant aggravation. In the alternative, respondent may show that the preexisting condition was responsible for the individual's current state.

One solid, rational construction of respondent's burden in proving by the preponderance of the evidence that "the pre-existing condition was, in fact, the cause of an individual's post-vaccination significant aggravation," entails a comparison of an individual's predicted condition absent vaccination with an individual's current condition. *Whitecotton*, 81 F.3d at 1107. Using evidence of an individual's clinical presentation *before* vaccination, respondent would have to project based upon medical principles an individual's future condition absent vaccination. If the special master credited respondent's prediction of an individual's condition absent vaccination, then the special master would have to compare the predicted condition absent vaccination with the individual's current condition. The logical structure yields two distinct possibilities. First, if the special master's comparison of the predicted condition absent vaccination with the individual's current condition were to establish that the individual's current condition is worse than the predicted condition absent vaccination, then respondent would not defeat the presumption of causation, because at most, respondent's evidence of the individual's predicted condition absent vaccination would demonstrate that the individual's preexisting condition was responsible for only some measure of the individual's current condition.[23] Second, if the special master's comparison of the predicted condition absent vaccination with the individual's current condition were to establish that the individual's current condition mirrors the predicted condition absent vaccination, then respondent's evidence of the individual's predicted condition absent vaccination would demonstrate that the individual's preexisting condition caused the individual's current condition. Respondent's burden would not be easy. Under the scheme, respondent would prevail only in cases where an individual's condition before vaccination is sufficiently defined to enable respondent to predict accurately an individual's condition absent vaccination *and* where an individual's preexisting condition portends generally a devastating prognosis, rather than varied prognoses ranging from normal to guarded to catastrophic. If respondent succeeded in either scenario, then the burden would shift presumably again to petitioner to establish that the vaccine caused actually an individual's entire, significantly aggravated condition. *See Whitecotton*, 81 F.3d at 1106, citing *O'Connor v. Secretary of HHS*, 24 Cl. Ct. 428, 429 n.2 (1991), *aff'd* 975 F.2d 868 (Fed. Cir. 1992) and *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 527-28 (1993).

Dr. Krasnewich maintained that because CDGS affects "glycocholation in the whole person" from conception, Tr. at 160; *see also* Tr. at 143-44, people with CDGS "will have the clinical features reflective of" the "impact" of CDGS "on their biologic system." Tr. at 160. Indeed, Dr.

[23] However, respondent would be able to advocate the apportionment of damages.

Schweller, Dr. Kollros and Dr. Krasnewich agreed that CDGS causes neurologic impairment and developmental delay. Tr. at 94, 126, 137, 139-40. And, Dr. Schweller, Dr. Kollros and Dr. Krasnewich agreed that Ashley's current condition is consistent certainly with Ashley's CDGS. Tr. at 95, 117, 122, 124, 130-31, 141, 144, 150. In fact, based upon her extensive research regarding CDGS, Dr. Krasnewich opined forcefully that she would expect Ashley to exhibit "serious developmental problems and seizures" associated with her Type IV CDGS as she matured. Tr. at 150; *see also* Tr. at 137, 139, 140-41. Thus, each expert's testimony supports fairly a conclusion that Ashley's CDGS alone would render Ashley drastically neurologically compromised.

Nevertheless, the special master acknowledges two equivocal aspects of the medical testimony that may undermine respondent's ability to project reasonably Ashley's condition absent vaccination. First, both Dr. Schweller and Dr. Krasnewich assumed that Ashley did not suffer seizures until *after* her April 11, 1994 DPT vaccination. *See* Tr. at 84, 93, 142-45, 153, 155-56. Dr. Schweller questioned whether Ashley would proceed ultimately to a "more severe form" of her CDGS had she not developed infantile spasms. Tr. at 84; *see also* Tr. at 93. Dr. Krasnewich implied that the onset of infantile spasms contributed perhaps to greater manifestations of Ashley's underlying CDGS by altering somehow Ashley's "metabolic status." Tr. at 144-45; *see also* Tr. at 142-43, 155. Yet, the special master has ruled that Ashley experienced infantile spasms *before* her April 11, 1994 DPT vaccination. Therefore, the special master determines that the portions of Dr. Schweller's testimony and of Dr. Krasnewich's testimony that are predicated upon an incorrect factual basis are not probative.

Second, Dr. Schweller, Dr. Kollros and Dr. Krasnewich recognized that CDGS is so rare that the medical community possesses limited exposure to the potential scope of the disorder. Tr. at 83-84, 125, 141, 149, 150, 152. Thus, Dr. Schweller doubted that anyone could predict reliably the course of Ashley's CDGS absent vaccination. Tr. at 83-84. Moreover, Dr. Krasnewich conceded without hesitation that she cannot state to an "exact degree" the impact of Ashley's CDGS upon Ashley's overall development absent vaccination. Tr. at 150; *see also* Tr. at 141, 149, 152. However, respondent's burden under a factors unrelated defense is not medical certainty or medical exactitude. Rather, respondent's burden under a factors unrelated defense is the lesser preponderance of the evidence. Therefore, in this case, respondent must show only that, based upon what is known about CDGS, a particular outcome absent vaccination is more likely than not.

The special master determines that the record as a whole--comprised of Ashley's medical records, the medical literature and the medical testimony--demonstrates adequately that Ashley's diagnosis of CDGS foreboded overwhelmingly disastrous neurological consequences. Indeed, when Dr. Lubinsky tested Ashley for CDGS in 1995, he cautioned that "severe developmental delay," Pet. ex. 11 at 2, is "typical" in the disorder. Pet. ex. 12 at 1. Medical literature is replete with references that confirm Dr. Lubinsky's assessment. And, Dr. Krasnewich--one of the nation's, and possibly, one of the world's, foremost authorities on CDGS--maintained that "all" people with CDGS "have significant developmental delay." Tr. at 140; *see also* Tr. at 137, 139.

Before her April 11, 1994 DPT vaccination, Ashley displayed symptoms--including infantile spasms--of her CDGS. Ashley is now profoundly delayed. Based upon his finding that the prognosis for CDGS is frequently calamitous, the special master finds that Ashley's predicted condition absent vaccination is not different from Ashley's current condition. Thus, the special master rules that CDGS--a factor unrelated to Ashley's April 11, 1994 DPT vaccination--caused Ashley's current condition. Therefore, respondent rebuts the Learys' statutory presumption of causation.

Actual Causation

Although respondent has prevailed upon a factors unrelated defense, the Learys may receive still Program compensation by establishing that Ashley's April 11, 1994 DPT vaccination actually aggravated significantly Ashley's CDGS. The special master discusses, albeit briefly, the Learys' proof of actual causation. According to Dr. Schweller, Ashley suffered the onset of infantile spasms after her April 11, 1994 DPT vaccination because "something" about her April 11, 1994 DPT vaccination somehow "interrupted or interacted with" her CDGS. Tr. at 82. In addition, Dr. Krasnewich believed that the onset of Ashley's infantile spasms after Ashley's April 11, 1994 DPT vaccination may have affected Ashley's clinical course by changing Ashley's "metabolic status." Tr. at 144-45; *see also* Tr. at 142-43, 155. Dr. Schweller and Dr. Krasnewich did not elaborate upon their statements. Moreover, the special master has decided previously that Ashley suffered the onset of infantile spasms *before* her April 11, 1994 DPT vaccination. Thus, the special master discounts Dr. Schweller's testimony and Dr. Krasnewich's testimony regarding actual causation to the extent that Dr. Schweller and Dr. Krasnewich based the testimony upon the erroneous assumption that Ashley experienced the onset of a new condition--infantile spasms--after her April, 11, 1994 DPT vaccination. Further, in their opening statement at hearing, the Learys conceded essentially that they cannot adduce sufficient evidence to meet their burden under a theory that Ashley's April 11, 1994 DPT vaccination actually aggravated significantly Ashley's CDGS. Tr. at 9. The special master agrees. Thus, the Learys have not shown that Ashley's April 11, 1994 DPT vaccination actually aggravated significantly Ashley's CDGS.

CONCLUSION

The special master is exceedingly sympathetic about Ashley's tragic circumstances. However, the special master must apply the law as he interprets the law. Therefore, the special master is constrained to hold that the Learys are not entitled to Program compensation. In the absence of a motion for review under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The special master's secretary shall provide a courtesy copy of this decision to the parties by facsimile.

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John F. Edwards
Special Master