

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

Case No. 10-615V

Filed: March 7, 2014

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MELISSA DAVIS & CECIL DAVIS, SR., \*  
As the Parents and Natural Guardians of \*  
C.D.J., an Infant, \*  
\*  
Petitioners, \*  
\*  
v. \*  
\*  
SECRETARY OF HEALTH \*  
AND HUMAN SERVICES, \*  
\*  
Respondent. \*  
\* \* \* \* \*

**PUBLISHED**

Special Master Dorsey

Entitlement; Decision without a hearing; Ruling on the record; Pediarix; Prevnar; PedvaxHIB; RotaTeq; Encephalopathy; Seizures; Congenital disorder of glycosylation; Mutation of *PIGT* gene.

Mark Theodore Sadaka, Englewood, NJ, for petitioners;  
Justine Elizabeth Daigneault, U.S. Department of Justice, Washington, DC, for respondent.

### DECISION ON ENTITLEMENT<sup>1</sup>

#### **I. Introduction**

On September 14, 2010, Melissa Davis and Cecil Davis, Sr. (“petitioners”), as the parents and natural guardians of C.D.J., an infant, filed a petition for compensation under the National Vaccine Injury Compensation Program (“the Program”<sup>2</sup>), alleging that numerous vaccinations, including Pediarix,<sup>3</sup> Prevnar,<sup>4</sup> PedvaxHIB,<sup>5</sup> and RotaTeq<sup>6</sup> that C.D.J. received on September 26,

<sup>1</sup> This Decision was originally filed on February 19, 2014. On March 5, 2014, petitioners requested a redaction. The motion was granted in an Order filed on March 7, 2014. In the reissued version, the minor child’s birth date is redacted and this footnote is changed to reflect the redaction. The remainder of the Decision is unchanged.

<sup>2</sup> The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

<sup>3</sup> Pediarix consists of diphtheria-tetanus-acellular-petussis (“DTaP”), hepatitis B, and inactivated polio virus (“IPV”) vaccines. See Centers for Disease Control & Prevention, Pediarix Vaccine: Questions and Answers, <http://www.cdc.gov/vaccines/vpd-vac/combo-vaccines/pediarix/faqs-hcp-pediarix.htm>.

2007, caused him to suffer from epileptic seizures and hypotonia.<sup>7</sup> Petition at 1. The medical records and other information in the record, however, do not support a finding that petitioners are entitled to compensation under the Program.

Under the Program, petitioners may not receive compensation based solely upon their claims. In order to receive compensation, the petition must be supported by either medical records or by the opinion of a qualified physician proving a causal relationship. See § 300aa-13(a)(1). Here, the medical records do not support petitioners' claims, so a medical opinion is required. Id. Petitioners have offered the opinion of Dr. Garrett C. Burris, a pediatric neurologist. See Petitioners' Exhibit ("Pet'rs' Ex.") 13 at 1. But, as described in detail below, Dr. Burris' opinion fails to provide support for the elements necessary to prove causation. Additionally, petitioners have failed to provide any expert report or opinion addressing the fact that C.D.J. has been diagnosed with an inherited genetic disorder, which is a "congenital disorder of glycosylation<sup>8</sup> with two mutations in the *PIGT* gene." Pet'rs' Ex. 45 at 1.<sup>9</sup> For these reasons, and the reasons discussed below, petitioners have failed to demonstrate that they are entitled to compensation.

## II. Procedural History

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<sup>4</sup> Prevnar 13 is a pneumococcal conjugate vaccine, also known as PCV 13. See Centers for Disease Control & Prevention, Pneumococcal Vaccination, <http://www.cdc.gov/VACCINES/vpd-vac/pneumo/default.htm>.

<sup>5</sup> PedvaxHIB is a Haemophilus influenzae type b vaccine which prevents meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), epiglottitis (a severe throat infection), and other serious infections caused by a type of bacteria called Haemophilus influenza type b. See Centers for Disease Control & Prevention, Hib Vaccination, <http://www.cdc.gov/Vaccines/vpd-vac/hib/default.htm>.

<sup>6</sup> RotaTeq is a vaccine used to prevent severe rotavirus disease in infants and children. See Centers for Disease Control & Prevention, Statement Regarding Rotarix and RotaTeq Rotavirus Vaccines and Intussusception, <http://www.cdc.gov/vaccines/vpd-vac/rotavirus/intussusception-studies-acip.htm>.

<sup>7</sup> Hypotonia is "a condition of diminished tone of the skeletal muscles, so that they have diminished resistance to passive stretching and are flaccid." Dorland's Illustrated Medical Dictionary (32d ed. 2012) ("Dorland's") at 907.

<sup>8</sup> Glycosylation is "the formation of linkages with glycosyl groups." Dorland's at 794.

<sup>9</sup> Petitioners have filed another petition for compensation on behalf of their other child, C.D., in which they allege that the same vaccines C.D.J. received caused the same injuries C.D. suffered. See Davis v. Sec'y of Health & Human Servs., No. 09-684V. A similar Decision has issued in that case. See Davis v. Sec'y of Health & Human Servs., No. 09-684V, Decision, filed February 19, 2014.

Petitioners filed their action for compensation on September 14, 2010, and the case was initially assigned to Special Master Gary Golkiewicz. Petitioners filed numerous medical records related to C.D.J.'s birth and medical care on November 23, 2010. The case was reassigned to Special Master Dee Lord on December 7, 2010. Respondent filed her Report pursuant to Vaccine Rule 4(c), in which she stated that the medical personnel of the Division of Vaccine Injury Compensation had reviewed the petition and medical records and concluded that petitioners had not proven that C.D.J.'s injury had been caused by the vaccine(s), and that the case was therefore not appropriate for compensation under the Program. Respondent's Report ("Resp't's Rep't"), filed February 22, 2011, at 2.

On August 11, 2011, and February 1, 2012, petitioners filed the expert report and supplemental expert report of Dr. Garrett Burris. Pet'rs' Ex. 13; Pet'rs' Ex. 18. On June 11, 2012, respondent filed the expert report of Dr. Gerald V. Raymond. Respondent's Exhibit ("Resp't's Ex.") A.

Petitioners were ordered to file an amended petition to clarify their allegations, Order, filed July 13, 2012, which they did on August 3, 2012. In their amended petition, petitioners allege that C.D.J. "developed vaccine-induced encephalopathy resulting in epileptic seizures and hypotonia after receiving second doses of Pediarix, Prevnar, PedvaxHIB and Rotateq on September 26, 2007." Amended Petition ("Am. Pet.") at 1. Petitioners further allege that C.D.J. was assessed as a "well child" prior to the stated vaccines but that he had an "undiagnosed condition . . . generally termed as a 'metabolic disorder'" and that persons with "metabolic disorders" are more susceptible to vaccine-related injury. Id. at 3. Petitioners allege that PedvaxHIB "contains antigens that induce the body to produce antibodies to the disease." Id. These antibodies can "cross-react with antigens similar to what is contained in the vaccine." Id. at 4.

Petitioners allege that C.D.J. had his first seizure on October 1, 2007, about six days after receiving the vaccinations at issue. Id. His seizure activity consisted of "severe jerking of his upper and lower extremities." Id. Then, in December 2007, C.D.J. had jerking in his face. Id. In January 2008, C.D.J. was hospitalized with "pneumonia and status epilepticus." Id. As a result of receiving vaccinations on September 26, 2007, petitioners allege that C.D.J. suffered a regression of his motor skills, constant seizures, encephalopathy, epilepsy, and a decrease in his muscle tone. Id. at 4.

Notwithstanding the submission of Dr. Burris' expert report and supplemental expert report, counsel for petitioners indicated during a November 29, 2012, status conference that they would likely be switching experts in the near future. Order, filed Nov. 30, 2012, at 1. On January 28, 2013, petitioners filed a status report stating that although they had made "continuous efforts," they had been unable to find a new expert. See Status Report, filed Jan. 28, 2013, at 1.

On February 22, 2013, the case was reassigned to the undersigned, and a status conference was held on March 28, 2013. During the status conference, petitioners were ordered to file an expert report by May 31, 2013. Order, filed Mar. 28, 2013, at 1-2. Additional medical records were filed on March 29, 2013. On May 31, 2013, petitioners filed an unopposed motion for an extension of time until July 30, 2013, to file an expert report. That motion was granted.

Order, filed May 31, 2013. On July 30, 2013, petitioners filed another motion for an extension of time in which to file an expert report, until August 29, 2013. Again, that motion was granted. Order, filed July 30, 2013, at 1. Meanwhile, petitioners were also investigating the results of genetic testing that had been performed on C.D.J., so that the results of such testing could be obtained and filed. See Status Report, filed Aug. 16, 2013, at 1. Petitioners did not file an expert report by August 29, 2013, as ordered.

A subsequent status conference was held on September 3, 2013. During the status conference, counsel for petitioners stated that petitioners intended to file a motion for a decision on the record. The issue of genetic test results was again discussed and the petitioner was ordered to obtain and file all records from the National Institutes of Health (“NIH”) and all results regarding any genetic testing. See Order, filed Sept. 18, 2013, at 1. A motion for judgment on the administrative record was filed on October 17, 2013, and a letter from the NIH Undiagnosed Diseases Program, reporting on C.D.J.’s genetic tests results, was filed on October 31, 2013. Pet’rs’ Ex. 45. Petitioners also filed a status report stating that petitioners had been informed that both C.D.J. and C.D. had received a confirmed diagnosis of a “congenital disorder of glycosylation with two different mutations in the *PIGT* gene. This diagnosis is an inherited autosomal recessive disease.” Status Report, filed Oct. 31, 2013, at 1.

Respondent filed a response to petitioners’ motion for judgment on the administrative record on January 17, 2014. Respondent argues that Dr. Burris’ “opinion regarding the genetic nature of [C.D.J.]’s condition is simply incorrect” and that “there is no reliable evidence that any of [C.D.J.]’s clinical manifestations were caused or exacerbated by any of the immunizations that he received.” Respondent’s Response to Petitioner’s Motion for a Decision on the Record (“Resp’t’s Resp.”), filed Jan. 17, 2014, at 16. Rather, respondent claims that all of C.D.J.’s “symptoms . . . are presentations of [his] . . . genetic disorder.” Id. at 14. Thus, respondent asserts that, “[o]n the present record, petitioners have clearly failed to meet their burden of proving by preponderant evidence that C.D.J.’s vaccinations either caused his injury or significantly aggravated his preexisting condition.” Id. at 1.

The case is now ripe for a ruling on petitioners’ motion for judgment on the administrative record.

### **III. Summary of Relevant Medical Records and Other Filed Exhibits**

C.D.J. was born on [redacted], at thirty-one weeks gestation. Pet’rs’ Ex. 2 at 41-42. He was apneic<sup>10</sup> at birth and required ventilation by bag and mask and ventilator. Pet’rs’ Ex. 11 at 525. His Apgar scores were 4, 5 and 7 at 1, 5, and 10 minutes, respectively. Id. C.D.J. was unresponsive to tactile stimulation, jittery, and had significant tremors of his lower extremities. Pet’rs’ Ex. 2 at 43. C.D.J. was admitted to the neonatal intensive care unit (“NICU”) from the date of his birth until he was discharged on June 27, 2007. Pet’rs’ Ex. 2 at 41. During this admission, he was diagnosed with numerous problems, including respiratory distress syndrome, prematurity, suspected sepsis, apnea, and feeding difficulties. Id. C.D.J.’s family history was significant in that he had a one-year-old sister, C.D., who had been diagnosed with a metabolic disorder and significant cognitive and motor developmental delay. Id. at 42. C.D. also had a

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<sup>10</sup> Apnea is a “cessation of breathing.” Dorland’s at 116.

complex epilepsy disorder and a suspected mitochondrial disorder, but there was no specific diagnosis for her condition. Id. at 42.

C.D.J.'s physical exam in the NICU was significant in that he had dysmorphic facial characteristics and prominent gum ridges. Id. at 44. He had myoclonic<sup>11</sup> jerks and jitteriness with immature motor control. Id. He also had periodic tremors in his hands and clonus<sup>12</sup> of his ankles. Id. C.D.J. had cardiac abnormalities, including dilated right atrium, atrial septal defect<sup>13</sup> with a left to right shunt, atrial septal aneurysm,<sup>14</sup> and dysplastic tricuspid valve.<sup>15</sup> Id. at 43. C.D.J. had poor feeding with periods of apnea during feedings. Id. On C.D.J.'s discharge from the NICU, a genetics consult was recommended. Id. at 46. C.D.J. was suspected to have a mucopolidosis disorder. Id.; Pet'rs' Ex. 35 at 7.

On July 2, 2007, C.D.J. was referred to the Arkansas infant and toddler program, First Connections, for premature birth, possible developmental delay, and an occupational therapy evaluation. Pet'rs' Ex. 5 at 62-63. On August 6, 2007, when C.D.J. was 2 months and 21 days old, an occupational therapy ("OT") evaluation was done by Ms. Carly Hill, OTR/L, which revealed slight delays in fine motor skills, prematurity, low muscle tone, and tremors. Id. at 93, 96. C.D.J. was also noted to have frequent tremors and jitteriness of his extremities. Id. at 94. C.D.J. had limited range of motion, generalized hypotonia, poor head control, delayed visual behaviors, and was unable to track objects. Id. at 94-95.

At his two-month well child visit on July 9, 2007, C.D.J.'s pediatrician, Dr. Carl Engmann, noted abnormal findings on physical examination, including heart murmur, "coarse features," tremors and jitteriness, and clicks in the hips and right shoulder. Pet'rs' Ex. 32 at 1. Dr. Engleman's assessment was "? metabolic disorder." Id.

At a subsequent visit on July 25, 2007, C.D.J.'s mother was concerned that he was sleeping too much. Id. at 2. At that visit, C.D.J. received his first doses of Pediarix, Prevnar, PedvaxHIB and RotaTeq. Id.

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<sup>11</sup> Myoclonus is "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." Dorland's at 1222.

<sup>12</sup> Clonus is an "alternate muscular contraction and relaxation in rapid succession." Dorland's at 373.

<sup>13</sup> An atrial septal defect is a congenital cardiac anomaly where there is a persistent patency of the atrial septum due to failure of fusion between either the septum secundum or the septum primum and the endocardial cushions. Dorland's at 476.

<sup>14</sup> An atrial septal aneurysm is "a rare malformation of the interatrial septum in which the sac protrudes into one of the atria." Dorland's at 82.

<sup>15</sup> Dysplastic tricuspid valve means abnormal development of the tricuspid valve of the heart. See Dorland's at 1965.

C.D.J. returned to his pediatrician for his four-month visit on September 26, 2007. Id. at 3. At that visit, C.D.J. was noted to have tightness in his muscles and, again, the family expressed concerns about the fact that he was sleeping a lot, was fussy, and cried a lot. Id. At that visit, C.D.J. received his second doses of Pediarix, Prevnar, PedvaxHIB, and RotaTeq. Id.

Based upon a history given by C.D.J.'s mother to Gretchen A. Golas, C.R.N.P., on May 19, 2009, at the NIH, C.D.J. began having jerking of his arms and legs on October 1, 2007, one week after receiving his second set of vaccinations, when he was about five months old. Pet'rs' Ex. 11 at 526, 529. There are no contemporaneous medical records that document the events of October 1, 2007.

On December 12, 2007, at about seven months of age, C.D.J. presented to his pediatrician with cold and cough symptoms. Pet'rs' Ex. 32 at 4. He was diagnosed with an upper respiratory illness. Id. In the notes for that visit there is no reference to the events of October 1, 2007, regarding C.D.J. having jerking of his arms and legs.

On December 19, 2007, the pediatrician's office notes document that C.D.J. had six seizures on the previous day, and that he had rhinorrhea,<sup>16</sup> hypotonia, and motor delay. Id. at 5. The office records from that visit state that "Mom has noticed some twitching ... of his upper limbs as well as dropping his head." Id. at 6. C.D.J. was diagnosed with a possible seizure disorder. Id. C.D.J. received his third doses of Pediarix, Prevnar, and RotaTeq at that visit. Id. at 5. On December 20, 2007, an EEG was performed, which was interpreted as normal, although it was noted that the study was technically difficult. Pet'rs' Ex. 41 at 1.

Moving forward to 2008, on January 4, 2008, C.D.J. was noted to have hypotonia, jerking movements of both upper and lower extremities, an absent walking reflex, and moderate to severe delay in his gross motor skills. Pet'rs' Ex. 5 at 88-91. In February 2008, C.D.J. had an EEG, which was abnormal and consistent with generalized epilepsy. Pet'rs' Ex. 11 at 526. On March 8, 2008, C.D.J. presented to the emergency department at North West Medical Center with seizures and a temperature of 102.7°F. Pet'rs' Ex. 6.1 at 104. Physical examination was significant for mild microcephaly.<sup>17</sup> Pet'rs' Ex. 6.2 at 112. Past history was notable for "congenital developmental delay ... and mitochondrial abnormality." Id.

On May 20, 2008, C.D.J. received his one-year vaccinations, including MMR, Varicella, Hepatitis A, and Prevnar. Pet'rs' Ex. 32 at 11. A barium swallow test performed in June 2008 revealed that C.D.J. had a weak suck, delayed swallow, and incoordination of suck and swallow. Pet'rs' Ex. 8.1 at 163. In August 2008, when C.D.J. was 14 months old, he was noted to have had no progression in his development since age five months. Pet'rs' Ex. 11 at 526. He was not able to sit, roll or track objects. Id. His diagnosis was intractable myoclonic epilepsy and developmental delay. Id. He was also noted to have "coarse features similar to his sibling's." Id.

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<sup>16</sup> Rhinorrhea is "the free discharge of a thin nasal mucus." Dorland's at 1640.

<sup>17</sup> Microcephaly is "abnormal smallness of the head, usually associated with mental retardation." Dorland's at 1157.

On August 6, 2008, Dr. Rolla Shbarou, pediatric neurologist, diagnosed C.D.J. with “intractable myoclonic epilepsy, developmental delay, visual impairment, [and] coarse facial features.” Pet’rs’ Ex. 14.4 at ACH 332. In December 2008, C.D.J. was hospitalized for status epilepticus, pneumonia, respiratory failure, and increased seizures. Pet’rs’ Ex. 11 at 526. At that time, C.D.J. required intubation and ventilation. Id. at 527; Pet’rs’ Ex. 8.2 at 197. A chest x-ray showed cardiomegaly<sup>18</sup> and an echocardiogram showed a large left to right shunt through the atrial septal defect, along with other abnormalities. Pet’rs’ Ex. 11 at 527. In January 2009, C.D.J. had a gastrostomy tube placed for feeding due to his history of aspiration and pneumonia. Id.; see also Pet’rs’ Ex. 8.9 at 286.

At age 2, from May 18 to 22, 2009, C.D.J. was admitted to the NIH Undiagnosed Disease Program for evaluation by Gretchen A. Golas, C.R.N.P., and Dr. William A. Gahl. They documented that his “[c]oarse features and tapered fingers suggest a storage disorder or other syndrome.” Pet’rs’ Ex. 11 at 515. C.D.J. was noted to have bilateral corneal clouding, high triglycerides, aminoaciduria,<sup>19</sup> osteopenia,<sup>20</sup> and immunoglobulin A (“IgA”) deficiency. Id. at 519. C.D.J. was also diagnosed with “profound global developmental delay,” “epileptic encephalopathy,” atrial septal defect with “significant left to right shunt with right cardiomegaly,” hypotonia, and dysmorphic features. Pet’rs’ Ex. 11 at 519. On discharge, genetic tests were pending. Id.

On July 21, 2009, C.D.J. had closure of his atrial septal defect by Dr. Paul Seib. Pet’rs’ Ex. 14.13 at 940. C.D.J. continued to have severe progressive encephalopathy. C.D.J.’s condition continued to progressively worsen over time. Moving forward to 2011, an MRI performed on April 7, 2011, showed “cerebellar and possibly brainstem atrophy.” Pet’rs’ Ex. 14.1 at 7. On June 20, 2011, Dr. Tonya Balmakund documented that C.D.J., at that time age 4, had a neurodegenerative disease and intractable epilepsy with a markedly abnormally EEG. Pet’rs’ Ex. 14.1 at 83-84.

Genetic testing with a final report date of February 12, 2013, identified that C.D.J. had 49 “clinically novel” genes. Pet’rs’ Ex. 37 at 2. “A clinically novel gene is a previously undescribed gene, not currently known to underlie a genetic condition.” Id. The results indicated that “the underlying cause of the patient’s clinical symptoms has not been discovered.” Id. Phosphatidylinositol glycan anchor biosynthesis, class T (*PIGT*) was one of the novel genes identified. Id. at 3.

Neurology clinic notes dated June 6, 2013, by Dr. Balmakund, describe C.D.J. as a “6-year-old little boy with a history of intractable epilepsy and significant encephalopathy and hypotonia related to an underlying neurodegenerative disorder of uncertain etiology.” Pet’rs’ Ex. 38 at 3. Dr. Balmakund noted that the family history is “remarkable for a sibling with a similar disease.” Id. On July 20, 2011, C.D.J. was seen by Dr. Jerie B. Karkos, for rehabilitative

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<sup>18</sup> Cardiomegaly is “abnormal enlargement of the heart from either hypertrophy or dilatation.” Dorland’s at 294.

<sup>19</sup> Aminoaciduria is “an excess of amino acids in the urine.” Dorland’s at 61.

<sup>20</sup> Osteopenia is “any decrease in bone mass below the normal.” Dorland’s at 1347.

services, who noted that C.D.J. had microcephaly with a head circumference in the 2% range. Pet'rs' Ex. 14.1 at 31. On July 25, 2011, Dr. Balmakund and C.D.J.'s mother corresponded by email, and Dr. Balmakund explained that C.D.J.'s and C.D.'s conditions were not due to any alternative acquired disease, and that the "children are word for word out of texts for several metabolic and neurodegenerative diseases." Id. at 75-76.

On October 29, 2013, petitioners received a letter from Ms. Golas and Dr. Cynthia J. Tift, Director of the NIH Pediatric Undiagnosed Diseases Program. Pet'rs' Ex. 45. The letter states, in pertinent part, the following:

This letter is to confirm our recent phone conversation regarding the molecular diagnosis of a congenital disorder of glycosylation with two different mutations in the *PIGT* gene for both your children, [C.D.] and [C.D.J.] . . . Both [C.D. and C.D.J.] have inherited an autosomal recessive disease called a congenital disorder of glycosylation involving mutations in the *PIGT* gene. The complex pathway of glycosylation involves many different genes participating in the biochemical process of adding and removing sugars to/from proteins. *PIGT* is a gene that has been only very recently identified (May 2013) in the medical literature as an additional cause of a type of congenital disorders of glycosylation with the feature of intellectual disability.

Id. at 1.

Petitioners subsequently filed a copy of a medical article referenced in the above letter.<sup>21</sup> The article reports on the "novel autosomal recessive syndrome, characterised by distinct facial features, intellectual disability, hypotonia and seizures, in combination with abnormal skeletal, endocrine, and ophthalmologic findings." Pet'rs' Ex. 46 at 1. The authors examined four patients with a similar phenotype, using whole exome sequencing and identified a "homozygous mutation, c.547A>C . . . in *PIGT*." Id. at 1. Further study revealed that this mutation was the cause of a "novel autosomal recessive intellectual disability syndrome." Id. Patients with *PIGT* mutations have clinical findings which include hypotonia, mild microcephaly, impaired motor and cognitive development, severe motor and intellectual disability, abnormal brain imaging, seizures, initially normal EEG with subsequent development of seizures, impaired vision, renal abnormalities, skeletal abnormalities, cardiac abnormalities, mild dysmorphic facial features, and global cerebral atrophy. Id. at 2-3. The authors conclude that they have found "strong evidence that a syndrome of intellectual disability, hypotonia, seizures, and skeletal and ophthalmologic findings seen in the patients of this study is caused by mutations in *PIGT*." Id. at 7.

#### **IV. Expert Opinion**

On August 11, 2011, petitioners filed the expert report of Dr. Garrett C. Burris, a child neurologist. Pet'rs' Ex. 13. In his report, Dr. Burris provided a brief summary of medical facts beginning with C.D.J.'s birth and ending with a short paragraph about C.D.J.'s admission to the

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<sup>21</sup> Pet'rs' Ex. 43, Malin Kvarnung, et al., "A novel intellectual disability syndrome caused by GPI anchor deficiency due to homozygous mutations in *PIGT*," 50 J. MED. GENETICS 8, 521-28 (August 2013).

NIH in May 2009. Id. at 1-2. Dr. Burris omitted from his report pertinent facts, such as C.D.J.’s “[c]oarse features and tapered fingers [which] suggest a storage disorder or other syndrome,” or his bilateral corneal clouding, high triglycerides, aminoaciduria, osteopenia, and IgA deficiency. See Pet’rs’ Ex. 11 at 515, 519. Dr. Burris failed to note that when C.D.J. was discharged from the NIH, genetic tests were pending. Id. at 519. Dr. Burris also failed to reference any records after 2009, although his report is dated August 9, 2011. Most notably, there is no reference to C.D.J.’s genetic mutation in Dr. Burris’ report.

Dr. Burris opined that within a reasonable degree of medical certainty, C.D.J. had vaccine induced acute encephalopathy, consisting of “seizures and decreased consciousness lasting for longer than 24 hours . . . . occur[ring] within 5 days after the administration of vaccines.” Pet’rs’ Ex. 13 at 567. Dr. Burris also opined that C.D.J. had chronic encephalopathy, “severe global developmental retardation” and refractory seizures. Id. Dr. Burris concluded that “[t]he presence of acute encephalopathy and developmental regression with chronic encephalopathy following administration of vaccine is consistent with vaccine induced encephalopathy. There are no other causes of encephalopathy in this case.” Id.

In a supplemental expert report, Dr. Burris opined that C.D.J. had a metabolic disorder which made him more susceptible to developing an abnormal immune response to the vaccinations. Pet’rs’ Ex. 18 at 1. Dr. Burris stated that metabolic disorders produce a chronic inflammatory state. Id. Dr. Burris further stated that antigens, which are foreign substances that cause an immune response, elicit the production of antibodies, and that “[v]accinations are specifically designed to elicit this immune response resulting in the production of antibodies.” Id. The risk of developing an autoimmune disease increases when vaccines are given to a “patient with a chronic inflammatory condition caused by metabolic disorders,” like C.D.J.’s. Id.

Dr. Burris identified four theories of autoimmunity: “molecular mimicry, bystander activation, persistent viral infections and fertile field.” Id. Generally, Dr. Burris believed that there are two causal pathways of autoimmune epilepsy and encephalopathy – one is “that the body produces auto-antibodies for specific proteins necessary for proper neurological function.” Id. at 2. The second is that an “increased number of antibodies can trigger seizures and encephalopathy.” Id. Dr. Burris did not know which causal pathway might be relevant in C.D.J.’s case. Id. But he concluded that the “record clearly shows the development of seizures within days after vaccination and both children suffer from chronic inflammation caused by metabolic disorder.” Id.

Respondent filed the expert report of Dr. Gerald V. Raymond, a neurologist and clinical geneticist, and the Director of Neurogenetics Research at the Johns Hopkins School of Medicine. Resp’t’s Ex.s A and B at 1. Dr. Raymond has an active clinical practice evaluating children with genetic disorders, including those with “progressive neurodegenerative disorders.” Resp’t’s Ex. A at 4.

In his report, Dr. Raymond noted that C.D.J. demonstrated motor abnormalities as documented in his NICU stay after birth, and that he also had “dysmorphic facies,” including “prominent gum ridges.” Id. at 1. After discharge from the NICU, he was referred to the Infant and Toddlers Program and in August 2007, where Ms. Hill, OTR/L, noted that C.D.J. had frequent tremors and jitteriness. Id. C.D.J. had other abnormalities including limited range of

motion, generalized hypotonia, and poor head control. Id. at 1. In addition, he had “delayed visual behaviors and would not track any objects.” Id. C.D.J. subsequently developed seizures, on or about October 1, based upon family recollection. Id. at 2. Dr. Raymond described C.D.J.’s history of seizures, abnormal EEG findings, hypotonia and severe global developmental delay. Id. at 2-3. He noted that C.D.J. was evaluated by Dr. Andrea Gropman, who documented C.D.J.’s “course features” and tapered fingers, which were “suggestive of a storage disease.” Id. at 3. Dr. Raymond also noted that C.D.J. had microcephaly, and that an MRI showed cerebellar and brainstem atrophy. Id. at 4.

Dr. Raymond explained that C.D.J. and his sister have a genetic disorder, which is probably autosomal recessive. Id. at 5. Dr. Raymond described the basis for his opinions, and provided a brief overview of autosomal recessive genetic disorders and how they occur. Id. He recommended that C.D.J. have whole exome sequencing testing to determine a genetic diagnosis. Id. at 6. Dr. Raymond concluded that “to a reasonable degree of medical certainty” C.D.J. has a “genetic epileptic encephalopathy with dysmorphic features that were present at the time of birth.” Id. at 6. Dr. Raymond rejected the notion that C.D.J.’s injuries were caused by or exacerbated by vaccinations. Id. at 6-7.

Dr. Raymond disagreed with the opinions set forth by Dr. Burris. First, Dr. Raymond stated that C.D.J. did not have acute encephalopathy because he did not have any “alteration of consciousness at the time of onset of seizures beyond the brief events themselves.” Id. at 6. Second, Dr. Raymond opined that C.D.J. does not have various metabolic disorders; rather, he has a single genetic condition. Id. Third, C.D.J. has demonstrated many times that he responds appropriately to infections and that he does not have an “abnormal immune response.” Id. Fourth, there was no evidence or documentation to suggest that C.D.J. has had any adverse reaction to vaccines. Id. None of C.D.J.’s treating physicians has diagnosed him with a vaccine-related disorder and, in fact, his treating physicians have continued to administer vaccinations to C.D.J.. Id. Fifth, while Dr. Raymond agreed that there are neurological conditions caused by antibodies, such conditions would not explain C.D.J.’s congenital abnormalities and dysmorphic features. Id. Dr. Raymond opined that “there is substantial evidence that he has exactly the same [genetic] condition as his older sister.” Id.

## **V. Standards for Adjudication – Causation**

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” Rooks v. Sec’y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

To establish causation in fact, a petitioner must show by a preponderance of the evidence that but for the vaccination, the petitioner would not have been injured, and that the vaccination was a substantial factor in bringing about the injury. Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Proof of actual causation must be supported by a sound and reliable “medical or scientific explanation that pertains specifically to the petitioner’s case,

although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (medical theory must support actual cause). “[A] petitioner must demonstrate the reliability of any scientific or other expert evidence put forth to carry this burden . . . . Expert testimony, in particular, must have some objective scientific basis in order to be credited by the Special Master.” Jarvis v. Sec’y of Health & Human Servs., 99 Fed. Cl. 47, 54-55 (2011) (citing Moberly, 592 F.3d at 1322; Cedillo, 617 F.3d at 1339; Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

Causation is determined on a case-by-case basis, with “no hard and fast per se scientific or medical rules.” Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and “close calls” regarding causation must be resolved in favor of the petitioner. Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

To receive compensation under the Program, petitioners must prove either: (1) that C.D.J. suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that C.D.J. suffered an injury that was actually caused by the vaccine (or vaccines) he received. See §§ 300aa-13(a)(1)(A) and 11(c)(1); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioners must show that a vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because petitioners do not allege that C.D.J. suffered a Table injury, they must prove that a vaccine C.D.J. received caused his injury. To do so, they must establish, by preponderant evidence: (1) a medical theory causally connecting a vaccine and C.D.J.’s injury (“Althen Prong One”); (2) a logical sequence of cause and effect showing that a vaccine was the reason for his injury (“Althen Prong Two”); and (3) a showing of a proximate temporal relationship between a vaccinee and his injury (“Althen Prong Three”). Althen, 418 F.3d at 1278; § 300aa-13(a)(1) (requiring proof by a preponderance of the evidence).

#### A. Althen Prong One

Petitioners failed to submit any expert opinion addressing a theory of how the vaccinations at issue could cause the alleged injuries in a patient with C.D.J.’s established genetic mutations; that is, mutations in the *PIGT* gene. These genetic mutations have been identified in the medical literature as a cause of congenital disorders of glycosylation with the feature of intellectual disability. Pet’rs’ Ex. 46 at 6. The *PIGT* gene functions to make a specific protein that helps other proteins attach to a sugar-fat structure called a glycolipid (“GPI”). Id. at 4. GPI is found in all cells of the body and is “essential for life.” Id. at 4. A study of four other patients with the same genetic mutation revealed that this mutation was the cause of a “novel autosomal recessive intellectual disability syndrome.” Id. at 1. Patients with *PIGT* mutations have hypotonia, mild microcephaly, impaired motor and cognitive development, severe motor and intellectual disability, seizures, impaired vision, skeletal abnormalities, cardiac abnormalities, mild dysmorphic facial features, and global cerebral atrophy. Id. at 5-7. The authors of the study concluded that there is “strong evidence that a syndrome of intellectual

disability, hypotonia, seizures, and skeletal and ophthalmologic findings seen in the patients of this study is caused by mutations in *PIGT*.” Id. at 7.

Petitioners’ expert, Dr. Burris, opined that C.D.J. has a metabolic disorder that produced a chronic inflammatory state. Pet’rs’ Ex. 18 at 1. Dr. Burris stated that the risk of developing an autoimmune disease increases when vaccines are given to a “patient with a chronic inflammatory condition caused by a metabolic disorder,” like C.D.J.’s. Id. But Dr. Burris did not identify any metabolic disorder(s), nor did he set forth facts relevant to this case to support his opinion that a metabolic disorder was at play here. Likewise, Dr. Burris did not cite any facts or evidence from the medical records to show that C.D.J. has a chronic inflammatory condition.

Dr. Burris identified four theories of autoimmunity: “molecular mimicry, bystander activation, persistent viral infections, and fertile field.” Id. Generally, Dr. Burris believes that there are two causal pathways of autoimmune epilepsy and encephalopathy – one is “that the body produces auto-antibodies for specific proteins necessary for proper neurologically function.” Id. at 2. The second is that an “increased number of antibodies can trigger seizures and encephalopathy.” Id. Dr. Burris has not explained how or whether these theories might apply to patients with genetic mutations.

Even if the undersigned were to assume that Dr. Burris’ theories of causation satisfied Althen’s Prong One, Dr. Burris’ reports are deficient as to Prongs Two and Three of Althen, as discussed below.

## **B. Althen Prong Two**

Althen Prong Two requires petitioners to show by a preponderance of the evidence that the vaccinations caused C.D.J.’s injuries consistent with the medical theory or theories proposed by Dr. Burris. Because Dr. Burris did not address C.D.J.’s genetic disorder or point to factual support from C.D.J.’s medical records to support his opinions, petitioners have failed to meet their burden.

Dr. Burris opined that C.D.J. had a metabolic disorder which produced a chronic inflammatory state. Id. at 1. Dr. Burris stated that the risk of developing an autoimmune disease increases when vaccines are given to a “patient with a chronic inflammatory condition caused by a metabolic disorder,” like C.D.J.’s. Id. Dr. Burris did not, however, refer to facts from C.D.J.’s medical records or provide any other basis to support his opinion that C.D.J. had a metabolic disorder or a chronic inflammatory condition. Therefore, his opinions are without foundation. “An expert opinion is no better than the soundness of the reasons supporting it.” Perreira v. Sec’y of Health and Human Servs., 33 F.3d 1375, 1377 fn. 6 (Fed. Cir. 1994).

Moreover, although Dr. Burris identified four mechanisms of autoimmunity, he failed to articulate how these theories apply to a patient with C.D.J.’s genetic mutations. Dr. Burris’ report does not discuss any logical sequence of cause and effect showing that C.D.J.’s vaccinations were the reason for his injuries.

Whether or not C.D.J. is presumed to have a genetic mutation, Dr. Burris' opinions fail Althen Prong Two because they lack factual support or other foundation. Thus, petitioners have failed to provide preponderant evidence of actual causation under Althen Prong Two.

### C. Althen Prong Three

Petitioners also failed to prove Althen Prong Three because Dr. Burris' reports are deficient on this issue. Dr. Burris does not address the issue of a proximate temporal relationship between the vaccinations and injury other than to make a conclusory statement that C.D.J. had acute encephalopathy five days after the administration of the vaccines. Dr. Burris fails to cite any medical facts or evidence to support his conclusion that there existed a proximate temporal relationship between C.D.J.'s vaccines and his alleged encephalopathy. As such, petitioners have failed to provide preponderant evidence of a proximal temporal relationship between the vaccines and any alleged injury.

## VI. Conclusion

For the reasons discussed above, the undersigned finds that petitioners have not established entitlement to compensation and their petition must be dismissed. **Therefore, this case is dismissed for failure to make a prima facie case. The Clerk shall enter judgment accordingly.**<sup>22</sup>

**IT IS SO ORDERED.**

s/ Nora Beth Dorsey  
Nora Beth Dorsey  
Special Master

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<sup>22</sup> Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.