OFFICE OF SPECIAL MASTERS

(Filed: September 22, 2005)

ALINA CUSATI, as parent of, and as legal representative of the estate of, ERIC FERNANDEZ, Petitioner,	)	
v.	)	No. 99-0492V
	)	DO NOT PUBLISH
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	

DECISION[1]

Petitioner, Alina Cusati (Ms. Cusati), as the legal representative of the estate of her son, Eric Fernandez (Eric), seeks compensation under the National Vaccine Injury Compensation Program (Program).[2] Ms. Cusati alleges that Eric suffered an intractable seizure disorder that was related to a measles-mumps-rubella (MMR) immunization that he received on November 5, 1996. *See* Amended Petition (Am. Pet.). In addition, Ms. Cusati alleges that Eric died from his intractable seizure disorder. *See* Am. Pet. Ms. Cusati concedes that Eric's condition does not qualify for the statutory presumption of causation afforded by § 300aa-11(c)(1)(C)(i); § 300aa-13(a)(1)(A); the Vaccine Injury Table (Table), 42 C.F.R. § 100.3(a)(III); and the qualifications and aids to interpretation (QAI), 42 C.F.R. § 100.3(b)(2), that apply to the Table governing the petition. *See* Am. Pet. Thus, Ms. Cusati acknowledges that she must prove that Eric's November 5, 1996 MMR

[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

immunization caused actually Eric's intractable seizure disorder resulting in Eric's death. *See* Am. Pet.

THE LEGAL STANDARD

To prevail, Ms. Cusati must demonstrate by the preponderance of the evidence that (1) "but for" the administration of Eric's November 5, 1996 MMR immunization, Eric would not have sustained his intractable seizure disorder, and (2) Eric's November 5, 1996 MMR immunization was a "substantial factor in bringing about" Eric's intractable seizure disorder. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). In addition, Ms. Cusati must demonstrate by the preponderance of the evidence that Eric's death was the sequela, acute complication, or pathological consequence of Eric's intractable seizure disorder.[3] 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 mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove legal cause. *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *see also Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). Rather, Ms. Cusati must present "a medical theory," supported by "[a] reliable medical or scientific explanation," establishing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant*, 956 F.2d at 1148; *see also 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). Ms. Cusati's medical or scientific explanation need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. But, Ms. Cusati's medical or scientific explanation must be "logical" and "probable," given "the circumstances of the particular case." *Knudsen*, 35 F.3d at 548-49.

According to the United States Court of Appeals for the Federal Circuit (Federal Circuit), "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549. However, in most actual causation cases in the Program, petitioners are not able to adduce epidemiological evidence regarding a vaccination and an injury.

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[3] However, the parties do not dispute that Eric died probably from his intractable seizure disorder. *See, e.g.*, Transcript (Tr.) at 48, 64, 118-119.

As a result, some special masters have struggled over the years to articulate the proper method of analyzing actual causation cases that lack epidemiological evidence regarding a vaccination and an injury. *See e.g.*, *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001); *see also Pafford v. Secretary of HHS*, 64 Fed. Cl. 19 (2005), *appeal docketed* No. 05-5105 (Fed. Cir. Apr. 12, 2005). The Federal Circuit iterated recently that the actual causation standard requires a petitioner to adduce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also id.* at 1281 (Under the "court's well-established precedent," a petitioner must "provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes.").

BACKGROUND

Eric was born on October 26, 1995, at Lawrence Hospital in Bronxville, New York. *See generally* Petitioner's exhibit (Pet. ex.) 3. As an infant, Eric received routine, pediatric medical attention from physicians at Riverdale Pediatrics in Riverdale, New York, *see generally* Pet. ex. 4, and from physicians at Pediatric Associates in Bronx, New York. *See generally* Pet. ex. 5. Except for frequent "episodes of otitis media, which were treated with antibiotics," Eric was a well child, who achieved "[d]evelopmental motor milestones" at a "normal" rate. Pet. ex. 5 at 57. Before age one year, Eric received a full complement of childhood vaccinations, including diphtheria-pertussis-tetanus (DPT) vaccinations, hemophilus influenzae type-B vaccinations, and oral polio vaccine (OPV). *See* Pet. ex. 5 at 1.

On November 5, 1996, Eric presented to Pediatric Associates for his one-year physical examination. *See* Pet. ex. 5 at 3. He weighed 23 pounds, seven-and-one-half ounces. *See id.* He measured 30½ inches in length. *See id.* His head circumference was 49 centimeters. *See id.* The physician noted that Eric was "cruising." *Id.* In addition, the physician noted that Eric was able to say "a few words." *Id.* Eric received an MMR immunization. *See id.* The physician instructed Ms. Cusati to "R[eturn]T[o]C[linic]" with Eric in "3 mo[nth]s." *Id.*

Eric "was doing okay," Pet. ex. 6 at 14, until November 9, 1996, when he developed a "mild fever" of "102" degrees. Pet. ex. 6 at 2. At approximately 10:00 p.m., on November 9, 1996, he appeared to be "staring and unresponsive." *Id.*; *see also* Pet. ex. 6 at 14. Ms. Cusati administered "Tylenol." Pet. ex. 6 at 14.

At approximately 9:15 a.m., on November 10, 1996, Eric exhibited "jerky movement" in his " [left] upper and lower extremities," accompanied by "eye deviation to the [right]" and "[increased] salivation." Pet. ex. 6 at 14. The episode lasted four minutes. *Id.* Ms. Cusati transported Eric to the Bronx Lebanon Hospital Center Emergency Room. *See* Pet. ex. 6 at 2. While he was in the emergency room, Eric suffered a "witnessed seizure" involving "stiffness [and] clonic movements"

in his "[right] leg," accompanied by "head [and] eye" deviation to the left. Pet. ex. 6 at 20. The episode lasted three minutes. *Id.*

An emergency room physician described Eric's "[i]nterictal exam" as "non-focal." Pet. ex. 6 at 20. According to the physician, Eric appeared "awake" and "responsive." *Id.* The physician "loaded" Eric "with phenobarbital." Pet. ex. 6 at 10. The physician obtained a "C[omputed]T[omography]" scan of Eric's head. Pet. ex. 6 at 20. The CT was "negative." *Id.* In addition, the physician performed a "L[umbar]P[uncture]." *Id.* The LP was negative. *See* Pet. ex. 6 at 10. The physician determined to "admit" Eric into the "P[ediatric]I[ntensive]C[are]U[nit]." Pet. ex. 6 at 20. The physician planned to obtain an "E[lectro]E[ncephalo]G[ram]." *Id.* In addition, the physician requested a "neuro[logy] consult[ation]." *Id.*

In PICU, Eric did "fine." Pet. ex. 6 at 10. The consulting pediatric neurologist concluded that Eric had experienced the "probable new onset" of a "seizure disorder." Pet. ex. 6 at 32. The consulting pediatric neurologist recommended maintaining Eric "on phenobarbital." *Id.* On November 11, 1996, Eric underwent an EEG. *See, e.g.*, Pet. ex. 6 at 31. The EEG was "negative." Pet. ex. 6 at 10.

Medical personnel discharged Eric from the hospital on November 12, 1996, with a "diagnosis" of "atypical febrile seizures." Pet. ex. 6 at 10. Medical personnel instructed Ms. Cusati to administer "30 milligrams" of "phenobarbital" to Eric "orally twice a day for two weeks." Pet. ex. 6 at 11. In addition, medical personnel instructed Ms. Cusati to "followup with the pediatrician in one week." *Id.*

On November 14, 1996, Eric presented to Pediatric Associates. *See* Pet. ex. 5 at 3. The physician reviewed details of Eric's hospitalization. *See id.* The physician concluded that Eric had suffered a "febrile seizure." *Id.*

Shlomo Shinnar, M.D., Ph.D. (Dr. Shinnar), Director of the Epilepsy Management Center at Montefiore Medical Center in Bronx, New York, evaluated Eric on November 25, 1996. *See* Pet. ex. 5 at 78. According to Dr. Shinnar, Ms. Cusati reported that Eric had "been cranky and sleepier than usual since he began phenobarbital" during his mid-November 1996 hospitalization for seizures. *Id.* Indeed, Dr. Shinnar observed that Eric "was somewhat fussy but easily comforted by his mom." Pet. ex. 5 at 79. However, Dr. Shinnar detected nothing remarkable during Eric's physical examination. *See id.*

Dr. Shinnar concluded that Eric had experienced "one episode of complex febrile seizure activity." Pet. ex. 5 at 79. Dr. Shinnar commented that Eric was possibly "at slightly higher than average risk of recurrence" based upon the "relatively early onset" of Eric's seizure and Eric's "low fever" when Eric's "seizures occurred." *Id.* Nevertheless, given Eric's "mild behavioral changes," Dr. Shinnar "recommended that [Ms. Cusati] taper" Eric's "phenobarbital." *Id.* Dr. Shinnar planned to "repeat an EEG" after Eric was "off the phenobarbital." *Id.*

As Ms. Cusati began to taper Eric's phenobarbital, Eric's seizures recurred during the "weekend" of November 29, 1996. Pet. ex. 5 at 76. Eric exhibited "four episodes of left arm twitching" without "fever or intercurrent illness." *Id.* Each episode lasted "ten seconds or less." *Id.*

On December 2, 1996, Dr. Shinnar examined Eric during "an emergency followup" appointment. Pet. ex. 5 at 76. Dr. Shinnar reviewed his initial decision to taper Eric's phenobarbital based upon his impression that Eric had suffered "one seizure a week after an MMR vaccine" that "could have been related to the vaccine and the fever." *Id.* However, with the recurrence of Eric's seizures, Dr. Shinnar determined to "treat" Eric's condition "as a new onset focal seizure disorder." *Id.* While Dr. Shinnar believed still apparently that Eric's "MMR may have been the trigger for the first" seizure, Dr. Shinnar proclaimed that Eric's seizure disorder "clearly" was "not causally related" to Eric's MMR immunization. *Id.* Dr. Shinnar reinstituted Eric's anticonvulsant medication. *Id.*

Eric's seizures persisted, necessitating a five-day hospitalization in December 1996, *see* Pet. ex. 7 at 1-55; an 11-day hospitalization in February/March 1997, *see* Pet. ex. 7 at 56-172; and a 45-day hospitalization in March/April/May 1997. *See* Pet. ex. 7 at 173-547. By late May 1997, Ms. Cusati began expressing concerns about Eric's development. *See, e.g.*, Pet. ex. 5 at 48-63. In June 1997, Eric underwent a developmental evaluation. *See* Pet. ex. 5 at 49-62. Eric exhibited delays in all "[f]unctional [d]omains." Pet. ex. 5 at 51.

At some point, Douglas R. Nordli, Jr., M.D. (Dr. Nordli), Director of the Epilepsy Monitoring Unit at The Columbia-Presbyterian Medical Center in New York, New York, assumed management of Eric's seizure disorder. *See, e.g.*, Pet. ex. 9. In August 1997, Dr. Nordli admitted Eric into the Pediatric Epilepsy Monitoring Unit at The Columbia-Presbyterian Medical Center "for further characterization of seizures and evaluation for possible surgery." Pet. ex. 9 at 7. Eric "underwent continuous C[losed]C[ircuit]T[ele]V[ision]/EEG monitoring." *Id.*

Dr. Nordli depicted Eric's "monitoring session" as "abnormal." Pet. ex. 9 at 10. According to Dr. Nordli, Eric's EEG "recording" showed "multiple complex partial seizures" arising from "the left posterior temporal region." *Id.* Dr. Nordli elaborated that his "findings" were "consistent with a focal structural lesion in the left temporal region, superimposed on diffuse or multifocal cerebral dysfunction." *Id.* Dr. Nordli commented that a previous "monitoring session" indicated that Eric's "seizures" commenced "in the right hemisphere" of Eric's brain, suggesting "multifocal disease." *Id.* Dr. Nordli diagnosed "[l]ocalization-related epilepsy." *Id.*

In September 1997, Dr. Nordli referred Eric for a "P[ositron]E[mission]T[omography] Brain Scan." Pet. ex. 13 at 1. The scan reflected "a large region of hypometabolism involving the entire left temporal lobe and posterior left parietal lobe." *Id.* The physician who interpreted the scan deemed the area of hypometabolism as "suspicious for seizure focus." *Id.*

In November 1997, a pediatric neurosurgeon and a "neurosurgeon specializing in resection of brain tissue for intractable seizures" performed a "craniotomy" on Eric. Pet. ex. 8 at 16. The

surgeons removed "epileptogenic brain tissue" from Eric's left temporal lobe. *Id.* In addition, the surgeons accomplished a "resection" of "epileptogenic brain tissue in the occipital lobe." Pet. ex. 8 at 16.

A neuropathologist reviewed several tissue specimens from Eric's craniotomy. *See* Pet. ex. 23. The neuropathologist identified "prominent subpial fibrillary astrocytosis in some areas of the cortex." Pet. ex. 23 at 2. In addition, the neuropathologist identified "occasional heterotopic neurons" in "[t]he white matter." *Id.* According to the neuropathologist, the heterotopic neurons were "within normal limits for the temporal lobe." *Id.* The neuropathologist diagnosed "Chaslin's marginal sclerosis." *Id.*

Following his "epilepsy surgery," Eric experienced "a dramatic reduction in the frequency and intensity of seizures." Pet. ex. 15 at 14. Regardless, Eric's seizures "continued." *Id.* In addition, Eric remained profoundly mentally retarded. Pet. ex. 15 at 22; *see also* Pet. ex. 14 at 1-14.

Upon returning home "from shopping" on September 10, 1999, Ms. Cusati "found" Eric "not responding [and] not breathing." Pet. ex. 20 at 1. Ms. Cusati transported immediately Eric to the Bronx Lebanon Hospital Center Emergency Room. *See id.* Medical personnel were not able to revive Eric. *See* Pet. ex. 20 at 2. Medical personnel "pronounced" Eric "dead" at 3:46 p.m. on September 10, 1999. *Id.* The medical examiner who prosecuted Eric's autopsy attributed Eric's death to a "seizure disorder." Pet. ex. 21 at 1.

THE MEDICAL TESTIMONY

Dr. Kinsbourne[4]

Dr. Kinsbourne acknowledged that "technically," Eric suffered "one" seizure on "Day 4" after his November 5, 1996 MMR immunization, followed by "one" seizure on "Day 5" after his November 5, 1996 MMR immunization. Tr. at 68; *see also* Tr. at 43. Dr. Kinsbourne commented that Eric "had begun to have fever" when he experienced his first seizure. Tr. at 68; *see also* Tr. at 45. Dr. Kinsbourne characterized Eric's seizures as "focal." Tr. at 43; *see also* Tr. at 46-47, 53-54, 82. Dr. Kinsbourne explained that a focal seizure "is not symmetrical" like a "benign febrile seizure." Tr. at 53-54; *see also* Tr. at 46. Rather, according to Dr. Kinsbourne, "the jerking" with a focal seizure appears on "one side of the body." Tr. at 54. Thus, Dr. Kinsbourne characterized Eric's seizures as "complex febrile seizures." Tr. at 43; *see also* Tr. at 47, 81-82. Dr. Kinsbourne stated that, as with a "substantial minority" of children who exhibit complex febrile seizures, Eric

[4] Dr. Kinsbourne received his medical degree from Oxford University in England. Pet. ex. 25 at 1. He is a Member of the Royal College of Physicians. *Id.* In addition, he is certified by the American Board of Pediatrics. *Id.* He belongs to the American Neurological Association and to the Child Neurology Society. *Id.* at 4. He is a Professor of Psychology at New School University in New York, New York. *Id.* at 2.

developed "epilepsy and other neurological problems," Tr. at 54; *see also* Tr. at 44, 47, 58, 81, including "quite severe mental retardation." Tr. at 44; *see also* Tr. at 47. Dr. Kinsbourne observed "a clear continuity" between Eric's "first two focal seizures" and Eric's "death." Tr. at 47; *see also* Tr. at 44-45, 58-59. Dr. Kinsbourne noted that medical personnel "attributed" Eric's death to Eric's "seizure disorder." Tr. at 45. Dr. Kinsbourne opined that Eric's November 5, 1996 MMR immunization "was the cause or trigger or precipitating factor for" Eric's condition leading to Eric's death. Tr. at 45; *see also* Tr. at 47-48, 64, 68.

Dr. Kinsbourne asserted that it is "obvious," Tr. at 80, that MMR vaccine is "capable of causing seizures." Tr. at 45; *see also* Tr. at 80. Dr. Kinsbourne offered two scenarios. First, Dr. Kinsbourne said that seizures can occur as "a non[-]specific effect of" the "rise in temperature" related to "viremia that follows the administration of the vaccine." Tr. at 45-46; *see also* Tr. at 68. Second, Dr. Kinsbourne said that seizures, and "a variety of" other "neurological manifestations," can occur "by some mechanism" related to "an actual attack of the vaccine virus on the brain." Tr. at 46; *see also* Tr. at 49, 83. According to Dr. Kinsbourne, the "time frame" for either scenario coincides with the increase of viremia, "most typically" during "the second week after vaccination." Tr. at 45; *see also* Tr. at 55-58, 68. However, Dr. Kinsbourne maintained that the "time frame" for either scenario may be "earlier or later less frequently." Tr. at 45; *see also* Tr. at 56-58, 68. Indeed, Dr. Kinsbourne advanced that medical literature demonstrates a consistent "distribution" of cases along a "curve," Tr. at 56; *see also* Tr. at 57, 68, "with the probability dropping" farther on each side of the peak of incidents in "the middle of the second week" following immunization. Tr. at 68; *see also* Tr. at 56-58.

Dr. Kinsbourne insisted that an Institute of Medicine (IOM)[5] report endorses the proposition that MMR vaccine can cause seizure disorders like Eric's seizure disorder. *See* Tr. at 62-63, 76-79. Dr. Kinsbourne elaborated that based upon medical literature "'evidence'" indicating "'that acute seizures are possible sequelae of immunization with measles and mumps vaccine,'" the IOM recognized that "'it is biologically plausible that there is a connection between immunization'" and seizure disorders. Tr. at 62, quoting Pet. ex. 30 at 52 (IOM Report at 145). Dr. Kinsbourne acknowledged that the IOM concluded that medical literature "evidence is inadequate to accept or reject the causal relation between measles vaccine and" seizure disorders. *See* Tr. at 77, citing Pet. ex. 30 at 52 (IOM Report at 145). Nevertheless, Dr. Kinsbourne declared that the IOM's conclusion "certainly doesn't contradict" his "opinion." Tr. at 77; *see also* Tr. at 76. Dr. Kinsbourne contended that the IOM expressed its conclusion "at the level of scientific certainty." Tr. at 77. And, Dr. Kinsbourne contended that the IOM reserved judgment regarding the causal association between measles vaccine and seizure disorders because the IOM could not exclude "'the possibility'" that

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[5] The IOM is an august division of the National Academy of Sciences (NAS) that Congress designated to canvass scientific and medical evidence regarding adverse consequences of routine childhood vaccines. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, §§ 312-13, 100 Stat. 3779-82 (1986); Kathleen R. Stratton, *et al*., INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY (National Academy Press 1994) (IOM Report).

some of the seizures "'described in the literature'" were benign febrile seizures. Tr. at 62-63, quoting Pet. ex. 30 at 52 (IOM Report at 145); *see also* Tr. at 79. Dr. Kinsbourne explained that benign febrile seizures progress rarely to seizure disorders. Tr. at 63; *see also* Tr. at 46, 52-53. Therefore, Dr. Kinsbourne proclaimed that since Eric's initial seizures were "not benign febrile seizures," the IOM report "applies directly to Eric." Tr. at 63; *see also* Tr. at 46, 53.

Dr. Kinsbourne stated that Eric's initial seizures were "complex febrile seizures" marked by "focal" motor activity. Tr. at 43; *see also* Tr. at 46-47, 53-54. As a consequence, Dr. Kinsbourne testified that he "can infer safely" that Eric's initial seizures "arose from an abnormally functioning local place in the brain." Tr. at 46; *see also* Tr. at 47, 54. In Dr. Kinsbourne's view, Eric's November 5, 1996 MMR immunization "caused or contributed to the abnormal functioning of a particular part of [Eric's] brain" by "setting up" Eric's seizure disorder, or by "triggering and bringing into chemical reality" an "underlying susceptibility" to a seizure disorder. Tr. at 47; *see also* Tr. at 45. Dr. Kinsbourne conceded that Eric's medical records do not contain evidence suggesting that MMR vaccine virus infected directly Eric's brain. Tr. at 84. Moreover, Dr. Kinsbourne agreed that Eric did not sustain an acute encephalopathy, "in terms of the definitions that" medical personnel "use," related to his November 5, 1996 MMR immunization. Tr. at 69; *see also* Tr. at 85-86. Instead, Dr. Kinsbourne urged that Eric's November 5, 1996 MMR immunization produced naturally viremia, causing characteristic fever, resulting in Eric's initial seizures, leading to Eric's epilepsy and death. Tr. at 68; *see also* Tr. at 45.

According to Dr. Kinsbourne, Eric's fever associated with Eric's initial seizures was "within the period of time during which the MMR" vaccine produces naturally viremia. Tr. at 45; *see also* Tr. at 56, 65, 68. In addition, according to Dr. Kinsbourne, Eric's clinical course following Eric's initial seizures was similar to the clinical courses of many children who suffer complex febrile seizures. *See* Tr. at 44, 47, 54, 81. Finally, according to Dr. Kinsbourne, Eric's treating physicians did not discover other "specific causes" for Eric's condition, despite "routine" testing and a "temporal lobectomy." Tr. at 51-52. Thus, Dr. Kinsbourne asserted that he possesses "no evidence or reason to believe" that, with "the absence of" the administration of Eric's November 5, 1996 MMR immunization, Eric would have suffered his seizure disorder and his death. Tr. at 64; *see also* Tr. at 45, 68.

Dr. Kohrman[6]

Dr. Kohrman testified that Eric suffered an "unprovoked febrile seizure," Tr. at 100; *see also* Tr. at 94, 109-10, "about four days after" his November 5, 1996 MMR immunization. Tr. at 99; *see also* Tr. at 100, 117. Dr. Kohrman defined an unprovoked febrile seizure as "an event that begins with fever" as its "only cause." Tr. at 110. Dr. Kohrman classified Eric's unprovoked febrile seizure as "complex" because Eric "had two events within the same 24 hours." Tr. at 94. According to Dr. Kohrman, Eric's unprovoked complex febrile seizure was "multi-focal." Tr. at 95; *see also* Tr. at 112-13, 139. Dr. Kohrman explained that Eric's first "two seizures" following the November 5, 1996 MMR immunization "were actually different." Tr. at 94. Dr. Kohrman elaborated that one of Eric's seizures originated "from the left side" and one of Eric's seizures originated "from the right side." Tr. at 94-95; *see also* Tr. at 113. Dr. Kohrman said that Eric's unprovoked complex febrile seizure "led to catastrophic epilepsy." Tr. at 109; *see also* Tr. at 97-98, 118-19, 140. Dr. Kohrman agreed that Eric's death was "[m]ost likely" related to Eric's epilepsy. Tr. at 118; *see also* Tr. at 119. Nevertheless, Dr. Kohrman disputed that Eric's November 5, 1996 MMR immunization "precipitated" Eric's "seizure disorder" resulting in Eric's death. Tr. at 119; *see also* Tr. at 94, 100, 124, 143.

Dr. Kohrman noted that the pathology report from Eric's left temporal lobectomy in November 1997 revealed "some heterotopic cells." Tr. at 96; *see also* Tr. at 111-12, 136-37. Dr. Kohrman stated that "heterotopic cells are normal cells that have not migrated to the normal place" during fetal development. Tr. at 111-12; *see also* Tr. at 96, 136-37. In addition, Dr. Kohrman stated that "heterotopic cells are the basic component of cortico dysgenesis or cortico malformations or migratory malformations." Tr. at 96; *see also* Tr. at 111. Based upon the presence of the heterotopic cells, Dr. Kohrman suggested that Eric suffered a "migration abnormality." Tr. at 111-12; *see also* 96-97, 136-37. Thus, Dr. Kohrman insisted that Eric "had the propensity to convulse and was going to convulse." Tr. at 142-43. In Dr. Kohrman's view, Eric's "clinical course" was "no different" from the clinical courses of many "other children with unprovoked complex febrile seizures." Tr. at 97; *see also* Tr. at 98, 109, 119, 140.

Dr. Kohrman conceded that MMR immunization "clearly causes seizures." Tr. at 118; *see also* Tr. at 98, 119-20. However, Dr. Kohrman maintained that "good case literature," Tr. at 98; *see also* Tr. at 118, 120, associates MMR immunization and seizures only in the context of acute

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[6] Dr. Kohrman received his medical degree from Rush Medical College in Chicago, Illinois. Respondent's exhibit (R. ex.) B at 1. He is certified by the American Board of Pediatrics and by the American Board of Psychiatry and Neurology with Special Competence in Child Neurology, among others. *Id.* at 2. He belongs to the American Academy of Neurology, to the Child Neurology Society and to the American Epilepsy Society. *Id.* at 3-4. He is an Associate Professor of Clinical Pediatrics and Neurology at the University of Chicago. *Id.* at 1. He is "one of four members of the Comprehensive Epilepsy Center at the University of Chicago," where he concentrates his practice on "epilepsy and sleep." Tr. at 93. He treats children with complex febrile seizures "[v]ery frequently." Tr. at 93-94.

encephalopathy "followed by a chronic presentation." Tr. at 118; *see also* Tr. at 98, 102, 114-15, 119-20. Dr. Kohrman asserted that Eric did not exhibit an acute encephalopathy when he suffered the onset of his seizure disorder following his November 5, 1996 MMR immunization. *See* Tr. at 95, 98, 102-03, 114-15, 120, 139; *see also* Tr. at 140-41.

Dr. Kohrman acknowledged that MMR vaccine, like "viremia from any [source]," does "cause fever." Tr. at 121; *see also* Tr. at 94, 100, 122. Indeed, Dr. Kohrman proclaimed that "[f]ever is common with MMR during the viremic period." Tr. at 100. In addition, Dr. Kohrman acknowledged that "fever is a trigger for seizures of any type." Tr. at 111; *see also* Tr. at 121. Moreover, according to Dr. Kohrman, "fever will make those seizures much worse" in children who "have an underlying migrational abnormality." Tr. at 111. Although Dr. Kohrman identified Eric's November 5, 1996 MMR immunization "as a cause for fever" leading to Eric's initial unprovoked complex febrile seizure, Tr. at 94, *see also* Tr. at 100, 124-25, 143, Dr. Kohrman declared that there exists "no cause and effect relationship" between Eric's November 5, 1996 MMR immunization and Eric's fever leading to Eric's initial unprovoked complex febrile seizure. Tr. at 100; *see also* Tr. at 144-45. Dr. Kohrman advanced that "the incidence of background fever in children" during the "four-to-five day period" following MMR immunization "is higher than the incidence of MMR related fever at Day 4 to Day 5 after vaccination." Tr. at 144-45; *see also* Tr. at 100, 142, 150. Regardless, Dr. Kohrman contended that medical studies "done to date" do not demonstrate an "association between febrile seizures," whether "complex or simple," and Eric's type of seizure disorder: temporal lobe epilepsy. Tr. at 109; *see also* Tr. at 108.

DISCUSSION

Describing the Vaccine Act as a "technically elaborate" statute, *Abbott v. Secretary of HHS*, 27 Fed. Cl. 792, 794 (1993), *aff'd in part, rev'd in part and remanded* 19 F.3d 39 (Fed. Cir. 1994), that contains "words of specialization drawn from the vocabulary of the field of medicine," *id.* at 793, the United States Court of Federal Claims (and, implicitly, the Federal Circuit) have counseled that "Congress intended [the Act] to be understood--and to be applied--as it would be by a medical professional." *Id.* at 794; *see also Shyface*, 165 F.3d at 1349. Yet, the Federal Circuit has invoked also traditional tort principles, adopting the Restatement (Second) of Torts as "a uniform approach" to analyzing "causation" in Program cases. *Shyface*, 165 F.3d at 1351-52. From the special master's perspective, the instant case underscores the perpetual tension in Program cases between "medical cause" and "legal cause."

Through Dr. Kinsbourne, Ms. Cusati advances a seemingly simple argument. At the outset, Ms. Cusati asserts that Eric's November 5, 1996 MMR immunization generated a fever. Next, Ms. Cusati asserts that Eric's fever from Eric's November 5, 1996 MMR immunization prompted a complex febrile seizure involving focal motor activity. Then, Ms. Cusati asserts that Eric is among the percentage of children, as reflected in medical literature, who develop epilepsy after experiencing a complex febrile seizure. Thus, Ms. Cusati concludes that but for the administration of Eric's November 5, 1996 MMR immunization, Eric would not have experienced a fever leading to his first

complex febrile seizure that resulted in epilepsy; and that Eric's November 5, 1996 MMR immunization was a substantial factor in bringing about a fever leading to Eric's first complex febrile seizure that resulted in epilepsy. Finally, Ms. Cusati asserts that Eric's epilepsy induced Eric's death.

Dr. Kinsbourne and Dr. Kohrman concur fundamentally on predominant aspects of the case. Dr. Kinsbourne and Dr. Kohrman agree that Eric did not sustain an acute encephalopathy following his November 5, 1996 MMR immunization. *See* Tr. at 69, 95, 98, 102-03, 114-15, 120, 139.[7] Likewise, Dr. Kinsbourne and Dr. Kohrman agree that the record does not contain evidence that MMR vaccine virus infected Eric's brain. *See* Tr. at 84, 110-11. Dr. Kinsbourne and Dr. Kohrman agree that before his November 5, 1996 MMR immunization, Eric was predisposed probably to suffer seizures. *See* Tr. at 47, 96-97, 111-12, 136-37, 142-43. Dr. Kinsbourne and Dr. Kohrman agree that MMR vaccine causes fever. *See* Tr. at 45-46, 68, 94, 100, 121-22. Dr. Kinsbourne and Dr. Kohrman agree that fever causes seizures. *See* Tr. at 45-46, 68, 111, 121. In fact, Dr. Kohrman declared that fever in a child who is susceptible to seizures will make the child's seizures "much worse." Tr. at 111. Dr. Kinsbourne and Dr. Kohrman agree that Eric's November 5, 1996 MMR immunization was a logical source of Eric's fever associated with Eric's initial complex febrile seizure. *See* Tr. at 45, 68, 94, 100, 124-25, 143; *but see* Tr. at 100, 144-45. Dr. Kinsbourne and Dr. Kohrman agree that a child who suffers a complex febrile seizure has a greater chance of developing epilepsy. *See* Tr. at 44, 47, 54, 58, 81, 97-98, 109, 118-19, 140. As a consequence, Dr. Kinsbourne and Dr. Kohrman agree that Eric's initial complex febrile seizure and Eric's subsequent intractable seizure disorder were related. *See* Tr. at 44, 47, 54, 58, 81, 97-98, 109, 118-19, 140. Dr. Kinsbourne and Dr. Kohrman agree that Eric died from his intractable seizure disorder. *See* Tr. at 48, 64, 118-119. Dr. Kinsbourne and Dr. Kohrman diverge merely on the role of Eric's November 5, 1996 MMR immunization in Eric's clinical condition. Dr. Kinsbourne views Eric's November 5, 1996 MMR immunization as "the cause or trigger or precipitating factor" for Eric's intractable seizure disorder. Tr. at 45; *see also* Tr. at 47-48, 64, 68. Dr. Kohrman views Eric's November 5, 1996 MMR immunization solely, if at all, "as a cause for fever" leading to an unprovoked complex febrile seizure. Tr. at 94; *see also* Tr. at 100, 124-25, 143-45.

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[7] Indeed, Dr. Kinsbourne was exquisitely careful to distinguish his use of certain literature describing encephalopathy following MMR immunization for the "pattern of timing of onset" *only*. Tr. at 55-56. As Dr. Kinsbourne elaborated, the literature shows that "there is a latent period" between the administration of an MMR immunization and whatever "clinical abnormality" may ensue. Tr. at 56. Nevertheless, in briefing, Ms. Cusati argues that certain literature describing encephalopathy following MMR immunization supports directly the proposition that Eric's November 5, 1996 MMR immunization "was the likely cause of Eric's seizures and death." Petitioner's Posthearing Memorandum (P. Memo) at 24. According to Ms. Cusati, certain literature demonstrates that "'a causal relationship between measles vaccine and encephalopathy may exist as a rare complication of measles immunization.'" *Id.*, citing P. ex. 26 at 383. While certain literature may establish that MMR vaccine may cause encephalopathy in certain circumstances, the literature is inapposite really to most of Ms. Cusati's case because Eric did not suffer clinically an encephalopathy as described in the literature. Thus, the special master considers Ms. Cusati's broad citation of the literature to be rather disingenuous.

At hearing, respondent depicted the IOM report as "the gorilla that's in the room." Tr. at 24. Respondent is wrong. The "gorilla" is the appropriate legal standard in Program proceedings.

The special master suspects that, as a very frequent witness for petitioners in Program cases, Dr. Kinsbourne knows well the differences between "medical cause" and "legal cause." Indeed, based upon his experience assessing many times Dr. Kinsbourne's testimony, the special master would daresay that Dr. Kinsbourne does not believe that Eric's November 5, 1996 MMR immunization was the "medical cause" of Eric's neurologic condition and Eric's death. Rather, based upon his experience assessing many times Dr. Kinsbourne's testimony, the special master would daresay that Dr. Kinsbourne believes that an unidentified "abnormally functioning local place in [Eric's] brain" that Eric's November 5, 1996 MMR immunization brought "into chemical reality" was the "medical cause" of Eric's neurologic condition and Eric's death. Tr. at 46-47. But, the Act does not require Ms. Cusati to prove "medical cause." Rather, the Act requires Ms. Cusati to prove "legal cause" under the preponderance of the evidence standard. *See Shyface*, 165 F.3d at 1352; *Althen*, 418 F.3d at 1278. Moreover, American tort jurisprudence assigns liability even when "a physical condition of the other which is neither known or should be known to the actor makes the injury greater than that which the actor as a reasonable man should have foreseen as a probable result of his conduct." Restatement (Second) of Torts § 461 (1965); *see also McMurry v. Secretary of HHS*, No. 95-0682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. June 27, 1997).

The preponderance of the evidence standard is "very hospitable." *McClendon v. Secretary of HHS*, 24 Cl. Ct. 329, 333 (1991). Indeed, the Federal Circuit instructs that the "preponderance standard" contemplates specifically "the use of circumstantial evidence" and promotes "the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280, citing *Knudsen*, 35 F.3d at 549. The Federal Circuit instructs also that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280.

Regardless, Ms. Cusati has constructed a solid premise evincing not just a logical sequence between Eric's November 5, 1996 MMR immunization and Eric's death, but legal cause and effect between Eric's November 5, 1996 MMR immunization and Eric's death. Ms. Cusati has provided more than preponderant evidence that MMR vaccine causes fever. Ms. Cusati has provided more than preponderant evidence that fever causes seizures. Ms. Cusati has provided more than preponderant evidence that Eric's fever and Eric's initial complex febrile seizure occurred within an appropriate temporal relationship to Eric's November 5, 1996 MMR immunization. Ms. Cusati has provided more than preponderant evidence that Eric's initial complex febrile seizure and Eric's subsequent intractable epilepsy were associated. Therefore, Ms. Cusati has shown by more than preponderant evidence that but for the administration of Eric's November 5, 1996 MMR immunization, Eric would not have experienced a fever leading to his first complex febrile seizure that resulted in epilepsy; and that Eric's November 5, 1996 MMR immunization was a substantial factor in bringing about a fever leading to Eric's first complex febrile seizure that resulted in

epilepsy. And, Ms. Cusati has provided more than preponderant evidence that Eric's intractable seizure disorder led to Eric's death.

Respondent has failed to identify a pertinent, alternative cause for Eric's fever leading to Eric's initial complex febrile seizure that resulted in epilepsy. *See* § 300aa-13(a)(1)(B); *see also Althen*, 418 F.3d at 1281-82. In briefing, respondent acknowledges that Dr. Kohrman submitted "multiple reports." Respondent's Post-Hearing Submission (R. Memo) at 1. *Yet, Dr. Kohrman never suggested in his "multiple reports" that Eric's fever following Eric's November 5, 1996 MMR immunization was attributable to "background fever" instead of immunization. See* R. ex. A; R. ex. D; Tr. at 100, 142, 144-45, 150. And, as petitioner's counsel noted at hearing, Dr. Kohrman proffered no support at hearing for a proposition that Eric's fever following Eric's November 5, 1996 MMR immunization was attributable to "background fever" instead of immunization. Tr. at 144-45; *see also* GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM at 8 ("[T]he court often frowns upon evidence introduced once proceedings are underway if that evidence was available" earlier.). Regardless, the special master does not need to consider seriously Dr. Kohrman's contention that Eric's fever following Eric's November 5, 1996 MMR immunization was attributable to "background fever" instead of immunization. Eric's medical records reflect that Eric's treating physicians believed that Eric's MMR immunization triggered Eric's initial complex febrile seizure. *See, e.g.*, Pet. ex. 5 at 76.[8] Respondent appreciates certainly the "'dangerous precedent'" of "'[s]econd-guessing, during litigation, medical judgments made contemporaneously to treatment.'" R. Memo at 17 (citations omitted). Moreover, Dr. Kohrman implicated Eric's November 5, 1996 MMR immunization as the cause of Eric's fever. *See* Tr. at 94, 100, 124-25, 143.

In addition, the special master is not satisfied that Dr. Kohrman explained adequately either in an exceptionally cursory statement regarding particular medical literature in his "multiple reports," *see* R. ex. D at 2, or in exceptionally cursory testimony regarding particular medical literature during hearing, *see* Tr. at 108-09, the application of the literature to respondent's defense of the case. However, the special master infers that the literature supports somehow respondent's thrust that Eric's November 5, 1996 MMR immunization was not the "medical cause" of Eric's intractable seizure disorder and death. *See, e.g.*, R. ex. D at 1 ("[T]here is no evidence for *medical causation in fact* for Eric's seizure disorder by the MMR vaccine.") (emphasis added); *see also* R. ex. A at 2. As such, Dr. Kohrman's reports and testimony, and the medical literature, do not assist the special master in evaluating Ms. Cusati's "legal cause" claim.

CONCLUSION

[8] The special master recognizes that Eric's treating physicians did not relate Eric's subsequent seizure disorder to Eric's November 5, 1996 MMR immunization. *See, e.g.*, Pet. ex. 5 at 76. However, it appears that Eric's treating physicians based their views upon concepts of "medical cause," rather than "legal cause."

The special master has considered exhaustively the record as a whole. He determines that Ms. Cusati has established by the preponderance of the evidence that Eric's November 4, 1996 MMR immunization was the legal cause of Eric's intractable seizure disorder that provoked Eric's death. In addition, he determines that there is not a preponderance of the evidence that Eric's intractable seizure disorder that provoked Eric's death was due to factors unrelated to Eric's November 5, 1996 MMR immunization. Therefore, the special master rules that Ms. Cusati is entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment in Ms. Cusati's favor for $250,000.00.

The clerk of court shall send Ms. Cusati's copy of this decision to Ms. Cusati by overnight express delivery.

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John F. Edwards
Special Master