

OFFICE OF SPECIAL MASTERS

No. 00-0183V

(Filed: February 15, 2002)

JACOB WESLEY DUNCAN, by his parents and *
natural guardians, WESLEY ERNEST DUNCAN *
and CHRISTY LYNN DUNCAN, *

Petitioners, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

Clifford Shoemaker, Vienna, VA for Petitioners.

Tammy Parker, U.S. Department of Justice, Washington, D.C. for Respondent.

DECISION ON ENTITLEMENT

French, Special Master

This matter is brought before the Special Master under the National Vaccine Injury Act of 1986, as amended.¹ Petitioners, Wesley and Christy Lynn Duncan, filed their petition on April 3, 2000 alleging that injuries to their son, Jacob Wesley Duncan (hereinafter, Jacob), were caused by an adverse reaction to a diphtheria-pertussis-tetanus (DPT) vaccination administered on April 7, 1997. Respondent filed its response arguing that Jacob suffers from a condition unrelated to the vaccine namely, Tourette’s Syndrome. For the reasons set forth below, the court finds that Petitioners evidence fails to establish the requisite legal link to the vaccine.

¹ Statutory provisions governing the Vaccine Program are found at 42 U.S.C §§ 300aa-1 through 300aa-33. This petition was filed after March 24, 1997, the effective date of the final rule most recently amending the regulations of the Vaccine Program, the claim is governed by the new regulations. See, 42 C.F.R. § 100.3 (c)(1).

PROCEDURAL MATTERS

On August 1, 2001, Petitioners filed the medical expert report of Dr. Carlo Tornatore. On August 7, 2001, Respondent filed the medical expert report of Dr. Russell Snyder. The hearing was held on October 30, 2001 in Washington, D.C. Petitioners presented the oral testimony of Christy Duncan and Wesley Duncan, Jacob's biological parents, and the expert testimony of Dr. Carlo Tornatore. Respondent presented the expert testimony of Dr. Russell Snyder.

FACTS²

Jacob Duncan was born full term on March 13, 1993. He weighed seven pounds, nine ounces. His prenatal course was unremarkable with one exception only, that his mother was placed on Progestin due to previous problems with miscarriages. During delivery, Ms. Duncan had a fever of 101 degrees and tested positive for Group B strep. Although the infant had a negative septic work-up, he was treated with antibiotics for seven days and kept in the intensive care unit for monitoring. Jacob's documented clinical course includes multiple infections and one documented adverse reaction to a covered vaccine. His clinical course will be presented here in detail.

Prior to May 4, 1993, no relevant information about Jacob's health and development appears in the record. On May 4, 1993, shortly before the age of two months, Jacob was given a DPT shot without apparent problems. A second DPT shot was given approximately three months later on July 13, 1993. On this occasion, Jacob had an adverse reaction including fever, sudden loss of head control, somnolence from which he could not be awakened, symptoms that the doctor found worrisome. An EEG revealed "frontal activity." He was taken to Dr. Zeller, a neurologist who then instructed Mr. and Mrs. Duncan that they should make sure that he would never again be given the Pertussis component of any future vaccination. See, Petitioners' Exhibit 6 at 11 (hereinafter, P. Ex.); Hearing Tr. at 24-27 (hereinafter, Tr. at).

On September 10, 1993, Jacob was seen for a checkup at Scott and White Hospital. The records for that date describe Jacob as developing normally, but reveal also that the child had certain abnormal conditions and illnesses as follows: Jacob demonstrated plagiocephaly, (asymmetry of the head), torticollis (a slight head tilt) to the left. A CT scan suggested a small arachnoid cyst in the left anterior/inferior middle cranial fossa, and a subsequent MRI scan noted possible benign external hydrocephalus with no other significant findings. Ten days later, on September 20, 1993, Jacob suffered an episode thought to be a petit mal seizure. P. Ex. 6 at 15. His head dropped down suddenly and he had a very confused look on his face. He slept for 40 to 50 minutes, then appeared to be fine. An EEG was performed, and was interpreted as abnormal due to independent epileptiform discharges. Anticonvulsant treatment was not recommended at that time, but Jacob's treating physician advised further monitoring. His parents sought a second opinion.

² The facts presented here are unchallenged. The court's narration of the facts is taken largely from Respondent's comprehensive Rule 4 Report. Filed on October 10, 2000.

Dr. Robert Zeller, a pediatric neurologist, noted a small fluid collection in the left middle cranial fossa but noted also that Jacob was otherwise normal in development. In December of 1993, at nine months of age, the child was hospitalized for two days due to congestion, fever of 103 degrees Fahrenheit, abdominal petechia and irritability. His diagnosis was an upper respiratory viral infection and croup. A nasopharyngeal culture grew influenza A. Pet. Ex. 6 at 66. Other mild childhood illnesses were noted on December 27, 1993 and February 7, 1994.

Jacob was seen again on March 17, 1994, for his four-month well-child examination. It was recorded that he still had hydrocele, which was repaired in April of the same year, and over the course of the next two years, Jacob experienced frequent episodes of otitis, diarrhea, bronchitis, and pneumonia. It was during that period, on July 11, 1994, that Jacob received his first measles-mumps-rubella (MMR) vaccination along with the third injection of the oral polio vaccine (OPV). No adverse reactions to the vaccinations are noted in the records, but he was seen again on July 23, 1994 with complaints of fever elevated to 104 degrees, loose stools, and pharyngitis. Jacob was subsequently treated thereafter with pneumostomy tubes placed in the eardrums.

On March 19, 1997, Jacob was evaluated for speech and language developmental concerns. He was four years old at the time. Mrs. Duncan reported that Jacob had difficulty in paying attention, and was easily distracted. The examiner felt that his language skills were in the high range of average, but that he had some articulation problems. Therapy was recommended.

On April 9, 1997, an event occurred that is considered by Petitioners' expert to be highly relevant to this case. This event is documented in the medical records and described also in the oral testimony of Jacob's mother. Jacob was due for his 4-year well baby visit. He was described as "a well child" at that time and he received several vaccines on that day. Unfortunately, and contrary to Mrs. Duncan's request, office personnel insisted that the child be given a DtaP vaccination. The nurse corroborated Mrs. Duncan's fear that the vaccine did in fact contain the Pertussis component and although arguments pursued, the vaccine was administered. Mrs. Duncan had tried to prevent the vaccination based on Dr. Zeller's earlier instructions that the Pertussis should not be given but to no avail.³

One week later, on April 16, 1997, Jacob was taken again to Dr. Wong for a rash which had spread throughout his body. On May 13, 1997, the onset of neurological symptoms had become apparent to all and included obvious facial tics, tongue darting and eye twitching. According to Mr. and Mrs. Duncan, these represented new symptoms they had not observed before. Dr. Wong referred

³ Dr. Wong's own documents contain evidence that she either knew, or should have known, that Jacob had "an allergy to pertussis" because it was written in her notes. It appears that she had initially written "no known drug allergies (NKDA)" which was apparently erased and crossed out. In addition, a consent form for a DPT vaccine had a handwritten notation that says "allergy" next to the printed "DT" in the consent form. Despite this documentation and mother's firm request, a DPT vaccine was administered apparently in error. P. Ex. 15 at unnumbered page 4.

Jacob back to Dr. Zeller for evaluation. Dr. Zeller observed the symptoms and concluded that Jacob was suffering from “motor tics.” He suggested observation. By October 21, 1999, Dr. Zeller had reconsidered Jacob’s continuing motor movements, his history of facial and vocal tics, and compulsive behavior. He amended his diagnosis as Tourette’s Syndrome. His tics have never fully disappeared. Recently, for example, a tic, (shaking his head back and forth), became so disturbing and frequent that he had to be taken out of school. P. Ex. at 25.

STATUTORY PROVISIONS

Table case Method of Proof: A petitioner who files a claim under the Vaccine Act may establish causation in one of two ways. Petitioner may establish a Table case by proving 1), that the individual sustained an injury set forth in the Vaccine Injury Table (§14 of the Act) or 2), sustained a significant aggravation of a preexisting injury set forth in the Table, and 3), that the first manifestation of onset of symptoms of that Table injury or the significant aggravation of a preexisting injury, occurred within a prescribed time period. If successful, a petitioner enjoys a rebuttable presumption that the injury or aggravation was caused by the vaccine.

Causation- in- Fact Method of Proof: If Petitioners are unable to establish an on-table case, a second method of proof is available. Petitioners may pursue a method described as “actual causation” or “causation in fact.” This method of proof is analogous to the method of proof required in traditional tort claims litigation. The standard of proof, is a preponderance of evidence. In other words, applying the statutory provisions, Petitioners here, must establish that the vaccine more likely than not, actually caused Jacob’s condition. “These requirements are based upon long-standing Federal Circuit precedence. Petitioners’ burden of showing [actual] causation is heavy.”⁴ Petitioners are required to establish that the vaccine “in fact” caused Jacob’s symptoms, and that his persisting neurological condition is related to the vaccine.

THE EXPERT OPINION

Respondent presented the expert testimony of Dr. Russell Snyder.⁵

Dr. Snyder testified that during his thirty some years of practice he has dealt with many kinds of neurological diseases, including Tourette’s Syndrome. Based on the records of Jacob’s clinical course and on his own observations of the child as seen on video tape, Dr. Snyder believes that Jacob had early signs of neurologic involvement before his April 7, 1997 immunization and that the

⁴ Whitecotton v. Sec’y of HHS, 81 F.3d 1009, 1102 (Fed. Cir. 1996)

⁵ Dr. Snyder, is widely published and has years of experience as a Professor of Pediatrics and Neurology since 1959 beginning at the University of Colorado. His present office is Department of Neurology, University of New Mexico School of Medicine, in Albuquerque, New Mexico. He was Board Certified in Pediatrics in 1965, Neurology in 1969, and Neurology with Special Competence in Child Neurology, also in 1969.

vaccine is not the cause of his present condition. Those signs include torticollis or wryneck, which seems to have been a transient event, he notes, but is an event that involves the same part of the brain as is thought to be involved in Tourette's Syndrome (hereinafter, TS).⁶ Jacob had trouble with his vocalizations before the immunizations in question, and the first manifestation that the family noted involved Jacob's early oral musculature. Dr. Snyder is of the opinion that the medical records and a review of the early video tapes suggest the presence of motor tics prior to the vaccination that were simply not recognized.

Dr. Snyder argues that alternative causes of TS exist that have not been ruled out. For example, TS is considered to be hereditary, and is now believed to be associated with genetic causes. No evidence of TS appears in Jacob's family history, but a genetic cause cannot be ignored or ruled out because "many cases remain undiagnosed or "wrongly attributed to hyperactivity, nervousness, habits, allergies, asthma and other conditions."⁷

Dr. Snyder testified that the medical community has provided evidence in case studies and research, that suggests that a causal relationship between TS and Streptococcus infection is likely. A considerable number of articles have been published providing sufficient evidence to have convinced many experts that such relationship exists.⁸ Unfortunately, Dr. Snyder explains, due to failure of the treating physicians to follow up on Jacob's numerous infections that plagued him (beginning early in his life, and continued to show up in the medical records thereafter), one might suspect that Jacob may have sustained a Streptococcus infection which was never tested and thus could not be ruled out. Moreover, such infections are frequently subclinical. He insists that if Jacob's condition was related to an infection, as Petitioners' expert alleges, it would be more likely that the child could very well have sustained a subclinical Streptococcus infection which is well known to be associated with the very injuries Jacob acquired.

Further, Dr. Snyder points to the fact that many experts now believe that Streptococcus is associated with TS in many cases, (See, e.g., the PANDA cases, R. Exs. C, D and E.). None of the case studies however, has ever indicated an association with any infectious agent other than the Streptococcus-- to be specific-- the A beta-hemolytic streptococcus. No other infection has yet to be associated with a vaccine.

In summary, based on Jacob's clinical course and suspicious movements observed on the video tape, Dr. Snyder believes that Jacob was already suffering from Tourette's Syndrome before

⁶ Torticollis and shoulder rotation, which Dr. Snyder believes appear in the video, are described as dystonic tics, and are symptoms of TS. P. Ex. 29, N Engl J Med, Vol. 345, No. 16 October 18, 2001 at 1184.

⁷ Id.

⁸ Both experts in this case accept that theory as likely, and several articles supporting the theory have been filed in this case by both parties.

he received his April 7, 1999 vaccinations. Sudden exacerbations are frequent events in TS.⁹ It is Dr. Snyder's firm opinion that the child was exhibiting subtle evidence of motor tics, prior to the vaccination, and the abrupt onset of obvious and recognizable symptoms, which by then were being diagnosed by his doctors as Tourette's Syndrome, was merely an expected evolution of his previously unidentified Tourette's Syndrome. Waxing and waning of symptoms is well known during the natural course, of TS,¹⁰ and sudden exacerbations such as that observed following his April 7, 1997 vaccinations, are not uncommon events in TS.

Petitioners presented the expert testimony of Dr. Carlo Tornatore:¹¹

Dr. Tornatore is of the opinion that the onset of Jacob's motor tics was caused by a vaccine related injury. His reasoning follows. 1) The evidence shows that Jacob was continuing to develop normally and "by all accounts, continued to do well from a neurologic standpoint." He had no documented problems through 1997. His only developmental problem of note was a mild problem with articulation, evaluated by a speech pathologist in March 19, 1997. Dr. Zeller told his parents "you have a normal child." Tr. at 25.

2) The close temporal relationship (within seven days) suggests an association between the April 9, 1997 vaccinations and the onset of his uncontrollable motor tics. These symptoms had never been observed before. A close temporal relationship is legally insufficient to establish a causal relationship although it is a consideration. 3) Dr. Tornatore notes, incidently, that Jacob received multiple vaccinations including Measles, Mumps, and Rubella (MMR), Diphtheria, Pertussis, and Tetanus (DPT), and Oral Polio vaccine (OPV), seven vaccines all at the same time. Tr. at 113. Dr. Tornatore is of the opinion that the administration of seven vaccines, in a case in which the child had already demonstrated an allergic reaction or adverse response,¹² probably caused a synergistic event identifiable by the development of hives, a severe rash, in which his immune system attacked the

⁹ See, e.g. The New England Journal of Medicine, Vol. 345, No. 16 October 18, 2001 at 1184; P. Ex. 29.

¹⁰ "Tourette's syndrome. . . is now recognized as a relatively common, biologic, genetic disorder with a spectrum of neurobehavioral manifestations that wax and wane during its natural course. The marked fluctuations in the severity and frequency of symptoms. . . . contribute to frequent misdiagnosis." P. Ex. 29 at 1184.

¹¹ Dr. Tornatore is an Assistant Professor, Department of Neurology, Georgetown University Medical Center in Washington, D.C. He is Section Chief of Molecular Therapeutics, and is a neuroscientist of molecular medicine. He is published widely in neuropathology and immunology. A list of his publications and reviews from 1990 to the present, cover several pages in his curriculum vitae.

¹² Dr. Tornatore is referring to the adverse reaction to pertussis in 1993 at age two months. The child's pediatrician cautioned his parents that he should not again be given the pertussis vaccine.

skin. 4)The severe rash, he explains, provides further evidence of an autoimmune process that caused a very dramatic change, triggering the onset of new symptoms.

5) Dr. Tornatore disagrees with Dr. Snyder's opinion that Jacob demonstrated motor tics prior to April 7, 1997. Dr. Tornatore reviewed the same medical records, observed the same video tape, and found no evidence of early tics. He concludes that no involuntary movements can be identified as early motor tics. Any such claim, he insists, is strictly speculation. Movements which Dr. Snyder believes to be evidence of tics, according to Dr. Tornatore, can just as easily be viewed as normal movements.

Dr. Tornatore is of the strong opinion that the mistakenly given pertussis vaccine is the cause of Jacob's present condition. He maintains that the central nervous system is susceptible to an allergic response not only to streptococcus, but also to other bacterial antigens. He argues that the bacterial protein in the pertussis vaccine, not only can, but in this case did result in triggering Jacob's neurological condition. He explains the mechanism of injury as a brisk immune response that triggered an autoimmune response to antigens affecting the neurons within the Central Nervous System (CNS.) The inflammatory response leads to neuronal dysfunction and the development of the tics and compulsive disorders. Thereafter, in Jacob's case, the full spectrum of Tourette's disease developed within the next two years following the vaccination. This mechanism he claims, is recognized as a possible etiology for Tourette's disease.

Dr. Tornatore believes that the large body of literature that supports the Streptococcus etiology of TS supports his theory. Antigens other than Streptococcus, he asserts, can also cause similar symptoms-- the antigen, in this case, is the Pertussis vaccine. He believes that the Pertussis antigen is clearly implicated in Jacob's case and demonstrates a clear association of Tourette's disease/obsessive compulsive behavior with an autoimmune response as demonstrated in Jacob's symptoms caused here by a bacterial agent that was administered to him by mistake. ¹³

DISCUSSION

The association between motor tics, Tourette Syndrome, OCD and Streptococcus¹⁴ has been well studied and published in medical literature. Dr. Snyder and Dr. Tornatore are both well acquainted with the medical literature and the hypothetical construct known as the "PANDAS" cases. PANDAS is an acronym for a spectrum of childhood neurobehavioral disorders, namely, Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal infection. According to case studies and animal research, it appears that Tourette's Syndrome, motor and vocal tics, and OCD have been associated temporally with an adverse immune response following a

¹³ See, Immune mechanisms in pediatric neuropsychiatric disorders: Tourette's syndrome, OCD and PANDAS, Trifiletti et.al., Child Adolesc Psychiatr (Clin N. Am 1999, 8(4): 767-75. Singer et.al. Infection: a stimulus for tic disorders, *Pediatr. Neurol* 2000 May 22 (5): 380-3.

¹⁴ Obsessive Compulsive Behavior (OCD).

streptococcus infection affecting the nervous system with resulting symptoms that mirror Tourette's Syndrome, or tics. The issue to be determined is whether it is scientifically reasonable to extrapolate a similar association with a vaccine antigen. Dr. Tornatore believes that if the Streptococcus can cause these symptoms, it is reasonable to suspect that another antigen of similar characteristics can also cause the same symptoms. He believes it to be equally likely. Dr. Snyder argues that such theory has not been studied and, as yet, enjoys no evidence to support Dr. Tornatore's theory. Under these circumstances, he argues, Petitioner's claim remains hypothetical only.

The court agrees with Dr. Snyder. Dr. Tornatore himself acknowledges that the mechanism he has described is theoretical and as yet has never been applied to vaccines or other infections. Dr. Tornatore may be on the cutting edge of the medical science in this regard. Dr. Tornatore has satisfied the court that his theory of causation is perhaps biologically possible. He has not established that it is probable. The Vaccine statute does not require scientific certainty, but without further scientific or medically supported evidence that would suggest a stronger causal link between the vaccine and TS, the court cannot assume a similar consequence following other environmental factors other than the Streptococcus. Until a theory of causation has been tested and subjected to peer review and publication, such theory remains speculative and should be further studied "or viewed with scepticism."¹⁵ Petitioners are required to affirmatively establish their claim in a causation in fact case by a preponderance of the evidence. Petitioners have failed to meet the required standard of proof.

The court has consideration the nearly equal credentials and expertise of both experts. Dr. Tornatore is perhaps more up to date in the more recent science. Nonetheless, the court is persuaded that the evidence supports Respondent's position. Both experts have been subject to a certain amount of speculation. For example, the question of whether the video tape shows early motor tics, cannot be satisfied either way with any measure of confidence. The court does not rely upon Respondent's arguments in that regard because either position is plausible. The court's decision relies instead on legal requisites, not hypothetical evidence. Moreover, if Petitioners had argued "significant aggravation"¹⁶ they would have still failed because the evidence has shown that Jacob's condition is more likely than not progressing through its normal course.

At the risk of being redundant, the court adds the following: Petitioner's theory of causation, no matter how reasonable it sounds, must fail. The hypothesis of a link between Jacob's neurological symptoms presents a rational and hopeful possibility that is not only appealing, but would greatly benefit the medical community and those who seek relief from a worrisome

¹⁵ See, *Trojanowicz v. Secretary of H.H.S*, No. 95-215V, (Office of Special Masters) July 1, 1998)(One cannot extrapolate shared similarities in pathogenesis to a conclusion of shared etiologies.)

¹⁶ 42 U.S.C. § 300aa-33(4)(1997). Petitioners have not argued significant aggravation as an alternative cause for Jacob's illness. Petitioners believe that "this child had the onset of a tick disorder after [the DPT] vaccination, not [an] exacerbation." Tr. at 265 (emphasis supplied).

neurological condition. Petitioners, however, have not provided the measure of proof required to prevail. The court acknowledges the remarkable expertise and current knowledge of “cutting edge” medical science. It does not, however, meet the requirements for establishing actual causation. That burden is indeed a difficult one. Petitioners have established the possibility of a link to the vaccine, based on the theory that science suspects a link with one particular antigen, A beta hemolytic Streptococcus. No evidence exists however to suggest that other antigens or other infections would have a similar same effect. Without further scientific or medically supported evidence of a causal link, the court cannot assume a similar consequence following other environmental antigens.

CONCLUSION

The court concludes that Petitioners have not met their burden of proof for establishing an causation-in-fact case. Under these circumstances, Petitioners are not entitled to an award in this case. This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith. Petitioners, however, filed their claim in good faith and had a reasonable basis. They are entitled to compensation for attorney’s fees and costs. Petitioners, therefore, shall file an application before the six month deadline.

IT IS SO ORDERED.

E. LaVon French
Special Master