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ERIC LASSITER, AN INCOMPETENT, BY HIS MOTHER AND NEXT FRIEND, MARY LASSITER, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.

90-2036V

UNITED STATES COURT OF FEDERAL CLAIMS

1996 U.S. Claims LEXIS 216

December 17, 1996, Filed

CORE TERMS: autism, symptom, disorder, encephalopathy, onset, shot, vaccine, autistic, medical records, unrelated, brain, metabolic, diagnosis, dysfunction, deposition, disease, skill, medical history, etiology, seizure, doctor, neurological, brain damage, encephalopathic, developmental, preponderance, autistic-like, inoculation, retardation, causation

COUNSEL: [*1] Clifford J. Shoemaker, Vienna, Virginia for petitioner.

Caroline Elmendorf, U.S. Department of Justice, Washington, D.C., for respondent.

JUDGES: FRENCH, Special Master

OPINION BY: FRENCH

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OFFICE OF SPECIAL MASTERS

French, Special Master.

DECISION ON ENTITLEMENT

This case arises under the National Vaccine Injury Compensation Program (hereinafter Vaccine Act, Act, or Program) found at 42 U.S.C.A. §§ 300aa 1 - et seq. (West 1991 & Supp. 1995). Petitioner's mother, Mrs. Mary Lassiter, filed this claim on behalf of her son on September 28, 1990 alleging that as a result of the administration of a diphtheria-pertussis-tetanus (DPT) shot on April 19, 1972, petitioner sustained an injury set forth on the Vaccine Injury Table (§ 14 of the Act) namely, an encephalopathy, with permanent neurological damage. Respondent defends by arguing that because no contemporaneous medical records exist that document conclusively that the onset of the injury occurred within the requisite time frame, petitioner has not established a Table injury. Respondent argues further, that petitioner's condition, more likely than not, is due to autism and is unrelated to the DPT vaccine. Following [*2] a careful review of the record in its entirety, the court concludes that Eric Lassiter is entitled to compensation.

PROCEDURAL BACKGROUND

A hearing to consider facts only was held on April 5, 1994 in Arlington, Virginia. On September 30, 1994, a second hearing was held in which petitioner presented the testimony of Dr. Peter Lichtenfeld, a neurologist, who believes that petitioner's present neurological deficits are the result of his DPT shot. Dr. Lichtenfeld bases his opinion on his examination of the medical records, telephone conversations with both petitioner's mother and his maternal aunt, a detailed medical history narrated by petitioner's mother, and his personal examination of Eric Lassiter.

On April 7, 1995, the deposition of respondent's expert, Dr. Alfred Spiro, was recorded and thereafter filed. The record was held open for an extended period during which time additional evidence was filed in the form of medical articles, learned treatises, reports, and argument.

ISSUES

The controversy can be framed by two questions: First, is the evidence sufficiently reliable to establish the onset of encephalopathic symptoms within the specified time frame (three [*3] days)? If the answer to this question is in the affirmative, petitioner enjoys a presumption of causation. If not, petitioner must establish his case by the causation in fact method required in traditional tort litigation. Second, is a diagnosis of idiopathic autism sufficient to establish a factor unrelated thereby defeating petitioner's claim? The evidence supports an affirmative answer to the first question and a negative answer to the second.

FACTS

The following is a brief narration of the facts. Eric was born on September 15, 1970, the apparently healthy product of an uncomplicated pregnancy and delivery. Until his DPT booster shot given at 19 months of age, he was progressing very well and reaching developmental milestones as expected. Medical records of well baby checks at Morningside Health Station, a neighborhood clinic, verify that he was "doing well." Fact witnesses claim that at 12 months he was "very smart," walking, eating well, had a good vocabulary, and played games with his cousin. By fifteen to eighteen months he was fully potty trained and was a happy, pleasant child.

Everything changed after his DPT booster shot administered on April 19, 1972. Office [*4] records for that visit note "no problems," and his physical examination showed "a well developed, well nourished male who was active and alert." Petitioner's Exhibit (hereinafter P.Ex.) 17 at 4. Approximately four hours after the inoculation, he began to convulse, foam at the mouth, and roll his eyes back in his head. 1 For several days Eric exhibited bizarre symptoms; he developed fever, screamed "off and on" for extended periods, would not feed nor drink, could not swallow, 2 and lost immediately those milestones already achieved. He lost his potty training skills, lost his vocabulary, and screamed "like a wild person." Thereafter he no longer was able to follow commands and never returned again to his normal behavior. In the words of his maternal aunt, 3 "after that needle, Eric never spoke again." 4 P.Ex. 17.; Transcript of Proceedings (hereinafter Tr.) at 197-198.

1 Dr. Spiro states that this event could possibly be a seizure, but it might be simply a "shaking" due to fever. Dr. Lichtenfeld's opinion is that the event was in fact a seizure and constitutes evidence of brain dysfunction. Mrs. Lassiter testified that she had seen seizures before and recognized it. Based on her description at the emergency room, the treating doctor also concluded that it was a seizure. Transcript at 23.

[*5]

2 Difficulty in swallowing led Mrs. Lassiter to believe that the DPT "caused him to have a sore throat." Her complaint of a sore throat is documented in medical records.

3 Ethyl Floyd, Eric's aunt, and her own small child were living with the family. Eric's father died in 1987.

4 Following the shot all speech stopped apparently. According to the testimony he tried to communicate, but the speech was garbled -- "did not come out normal." Eric is now 25 years old and speaks some words, but no sentences.

At present, Eric is profoundly retarded, cannot care for himself, and is completely dependent on others. He exhibits repetitive stereotyped movements, is incontinent of feces, perseverates, cannot name any objects, rarely smiles, and has a significant lack of verbal communication. Id.

MEDICAL RECORDS

Contemporaneous medical records no longer exist to verify onset of symptoms. The hospital where Eric was taken has been closed and the records have been destroyed. From the very first, however, Mrs. Lassiter's told other treating physicians that the child "got too much DPT," [*6] that his functioning regressed, and that he never regained his former skills. See e.g. P.Ex.15 at 37. Those statements are documented in subsequent medical histories. Voluminous records have been filed in this case relative to Eric's care. Although the records are internally

inconsistent in some details, a thorough review tends to support eyewitness accounts of a sudden change secondary to the DPT booster shot. A few examples of supporting documentation follow:

- * Note of July 18, 1972 from Morningside Clinic: Medical records indicate that Mrs. Lassiter was told to go to the hospital at the time of onset of symptoms which she did, a fact that suggests something serious was occurring at the time.
- * Note of April 21, 1972: After his shot, the patient could not swallow and "lost skill." P.Ex.14 at 7.
- * Office visit note of April 27, 1972: The next DPT shot was to be reduced by half. P.Ex.14 at 1.
- * St. Luke's Hospital patient record of April 24, 1972: After the DPT shot he was irritable and refused to eat. P.Ex.13 at 4.
- * July 18, 1972, Morningside Clinic notes: Mother was concerned that due to the injection of April 14, 1972, "she almost lost him [Eric]" [*7] and he did not respond to treatment. P.Ex.14 at 11.
- * A 1974 medical history:

The mother believes that the patient's functioning regressed after he received his [DPT] inoculation. He became ill hours after the inoculation . . . [symptoms lasting] for about a week thereafter. Allegedly, following the illness, he lost the modest vocabulary he had accumulated and has never regained the level of verbal accomplishments he had prior to becoming sick. (Quoted in part in Tr. at 245-246.

 * St. Luke's Hospital 1978 medical history: Diagnosis of "static encephalopathy . . . FU [follow up] of pertussis encephalopathy" with retardation and hyperactivity. P.Ex.13 at 8.

* St. Luke's Hospital, 1978: "Known case of static encephalopathy after DPT immunization." Id. at 7.

CREDIBILITY ISSUE

The court finds that the symptoms claimed are supported by a preponderance of evidence and may be relied upon as a credible account of events. In reaching its conclusion, the following arguments were considered.

Respondent argues that mother is guilty of exaggeration, and that the court should discredit her entire testimony. The court disagrees. The tendency to [*8] exaggerate was duly noted at hearing and was noted also in the medical records by one treating physician who took a medical history. 5 See Tr. at 243-244. Her exaggerations are noted primarily when she boasts about Eric's achievements. She is proud of her son and very supportive. She can be excused in this regard. The trier of fact has the unique prerogative to assess credibility of fact witnesses as well as weight to be given expert testimony. Throughout these proceedings, and throughout the medical records, Mrs. Lassiter and Mrs. Floyd are consistent about basic events -- those facts that are most relevant to the court's decision. The symptoms described in 1974 are the same described to every medical doctor since 1974, and the same described during case proceedings. Dr. Lichtenfeld came to the same conclusion and considers the eyewitnesses to be reliable as to basic facts. 6

5 The doctor wrote: "In view of the mother's tendency to exaggerate Eric's practical achievements, one is inclined to be skeptical about her reports on his progress in the activities of daily living [after the DPT shot]."

[*9]

6 The court was impressed with Dr. Lichtenfeld's objectivity in this regard. He was cross examined about his belief that the witnesses are to be believed about the basic facts on which he bases his opinion. Dr. Lichtenfeld was asked to review many vaccine cases for petitioner's counsel prior to the 1990 statutory deadline for filing and recommended that the vast majority of

those cases be rejected. In his own words, "there were a few cases that seemed to stand out as making sense to me. This was one of them." Tr. at 212-213. At the bottom of his notes he wrote: "This case should be filed." The court agrees with Dr. Lichtenfeld's assessment of the fact witnesses as ingenuous and credible as to critical events.

In short, any inconsistencies or exaggerations found in the testimony or statements documented in the medical records are of minimal import and do not impeach the credibility of the fact witnesses as to their outline of events and the abrupt changes in this little boy following on the heels of his inoculation. In these matters the witnesses are consistent about what happened and they [*10] are supported by the record as a whole.

THE NATURE OF THE INJURY

Having found the facts favorable to petitioner's claim, the larger question concerns their significance. Dr. Lichtenfeld is confident that Eric sustained a vaccine-related encephalopathic event following his vaccination and "he was never okay after that." He bases his opinion on the constellation of symptoms observed, the screaming, seizure, anorexia, the sudden loss of developmental skills, failure to recover those skills, and lack of any evidence of a progressive neurological disease. It is his opinion that Eric's present deficits are related directly to that encephalopathic event.

Respondent's expert believes otherwise, based not only on his opinion that the factual testimony and supporting documentation of onset are inconclusive, but also on what he considers a lack of neurological signs or symptoms:

Q. Then the mother's description of what occurred did not, in your mind, constitute an encephalopathy.

A. That's correct. . . . and no other contemporaneous doctor states that it was a DPT encephalopathy.

Deposition of Dr. Alfred Spiro, at 11.

It is the court's opinion that Dr. [*11] Spiro dismisses too cavalierly the sudden loss of milestones, sudden changes in behavior and personality, and abrupt loss of skills, all of which are recorded throughout Eric's care and treatment and constitute compelling signs of unresolved central nervous system dysfunction. The court finds Dr. Lichtenfeld's opinion to be better reasoned, more persuasive, and more in keeping with the facts.

Based on the court's own findings of fact and the reasons proffered by Dr. Lichtenfeld, the court concludes that Eric, more likely than not, sustained an encephalopathy and that the first manifestation of onset of the injury occurred within the Table time frame. Petitioner is thus entitled to a presumption of causation. Pursuant to the statutory scheme, a petitioner is entitled to receive compensation upon such findings unless respondent successfully establishes that a factor unrelated is more likely the cause of petitioner's injuries. In this case, respondent claims that Eric is autistic and that autism is not caused by DPT. 7

7 In 1974, several months after the onset of encephalopathic symptoms, it was discovered that Eric demonstrated elevated levels of lead. He was treated for lead poisoning, but his overall condition did not change. The experts discussed this issue at length and agree that there is no evidence of a lead-related encephalopathy. They agree that Eric's condition is not due to lead intoxication and that lead poisoning or lead encephalopathy is not considered an alternate cause in this case. See Tr. of September 30, 1994 proceedings at 190. See also Tr. of April 7, 1995 proceedings, Deposition of Alfred Spiro, at 14-15.

[*12] AUTISM AS A FACTOR UNRELATED

MEDICAL TESTIMONY

Respondent argues that Eric's current behavioral manifestations and retardation "fit the pattern of autistic spectrum" disorders with severe mental retardation." Dr. Spiro summarizes:

This child had a [DPT-related febrile] reaction following his DPT booster, but, it is clear that he currently fits into the autistic spectrum disorder with retardation. This group of disorders is totally unrelated to DPT, it usually constitutes a group of genetically determined or idiopathic

disorders (without a clear known etiology). 8

Medical Report of Dr. Alfred J. Spiro, January 5, 1993, Respondent's Exhibit (hereinafter R.Ex.) A at 5; Supplemental Expert Report, May 23, 1996, R.Ex.C.

8 The term "etiology" is a synonym for cause or origin.

Dr. Spiro cites the following symptoms on which he bases his autism diagnosis: stereotypical movements, lack of eye contact, perseveration, speech/language disorder and lack of verbal communication, hands in [*13] constant motion, and the fact that onset was unnoticed during the first year or so -- a not uncommon occurrence in autism. Tr. of April 7, 1995, Deposition of Alfred Spiro, at 17-20. In his opinion, all Eric's difficulties can be explained by a diagnosis of autism.

Dr. Spiro argues that he has never seen any individual autistic children where there was a causal link between the autism and the administration of DPT vaccine. He cites the 1991 Institute of Medicine (IOM) Report, "Adverse Effects of Pertussis and Rubella Vaccines," page 152 which concludes that "there is no evidence to indicate a causal relation between DPT vaccine or the pertussis component of DPT vaccine and autism."

Petitioner, on the other hand, argues that autism cannot be considered a cause of Eric's condition because autism is not a disease but a syndrome (group of symptoms) with multiple causes. "An encephalopathy, whatever its cause or etiology, can produce brain damage which results in autistic-like symptoms or behaviors." P. Memorandum filed April 23, 1996 at 2.

Petitioner relies upon recent medical literature to support his theory. Five articles were submitted as petitioner's Exhibits 19 through 23 and [*14] will be discussed briefly. These articles do not challenge the possibility that in any individual case autism may be caused by a genetic factor, but they support the claim that other causes have been implicated as well. According to Merritt's Textbook of Neurology, 9th ed., 1995, --

Autism is one of the developmental disorders of brain function; as in the others, there

are several causes. In most cases, the cause is unknown.... There may be an inherited susceptibility to some environmentally determined stress. In few cases, there is evidence of tuberous sclerosis, hypomelanosis of Ito, fragile X, phenylketonuria, congenital rubella, neonatal herpes simplex, hydrocephalus, malformation, or other static encephalopathy. Perinatal brain injury does not cause autism as an isolated deficit. (Emphasis supplied.)

P.Ex. 23 at 513.

Doctors Steffenburg and Gillberg list many disorders, 22 in all, which have been associated with autism. They conclude that autism is not a disease but "represents a behavioral syndrome with multiple etiologies. . . . Autism can be the final common expression of various contributory/etiological factors." They explain further that genetic [*15] factors are in operation in some cases. "Disease entities or pre-and perinatal damage leading to destruction/dysfunction in certain brain areas can cause autism in others." "The Etiology of Autism," P. Ex. 21 at 65, 73-75, Gillberg, ed. Diagnosis and Treatment of Autism, Gillberg, ed., Proceedings of the State-of-the-Art-Conference on Autism: held May 8-10, 1989, in Goteborg, Sweden. (Emphasis supplied.)

Dr. Gerhard Bosch states in his treatise on "Infantile Autism" that various factors or noxae working together can cause autistic symptoms, either triggering the autistic behavior or intensifying the effect. P.Ex.20, at 130. He explains further that as a result of "cerebral affections suffered in early childhood a clinical picture could develop that would be indistinguishable from that of infantile autism." He cites case reports in which insults to the brain were followed by onset of infantile autism. "Autism can occur or be closely simulated in children with known organic brain damage." Other etiologic factors include complications at birth, prenatal damage, infectious diseases, encephalitis. "In one case an indeterminate post-natal feverish illness occurred, after which [*16] the development of the child is said to have changed. . . . Symptomatologically equivalent cases of autism [can be caused] by cerebral-organic damage." Id. at 132-134.

In his treatise entitled "Recent Neurobiological Findings in Autism," Luke Y. Tsai also lists a similar variety of established neurologic disorders reported in autism including viral infections and other toxic or environmental causes of brain damage. He explains that it is now well accepted that autism results from dysfunction in certain parts of the central nervous system (CNS) that affect language, cognitive and intellectual development, and the ability to relate. He believes autism may be "the common pathway of a diverse range of organic brain conditions" including both prenatal and post-natal

infections or injuries, the latter accounting for those whose autism is manifested "after a period of apparently normal development." Id. at 83-84. P. Ex. 21.

Dr. Suzanne Steffenburg states in her article entitled "Neuropsychiatric Assessment of Children with Autism: A Population-Based Study," that the majority of children with autism and autistic-like conditions have overt signs of brain dysfunction." P. Ex. 22 [*17] at 495. The implication is "that brain damage or dysfunction causes autism . . . that autism and autistic-like conditions are neurobiologically very similar . . . and that autism is likely to be a biological disorder with multiple aetiologies [sic]." Id. at 507-509. She concludes that "gene disorders, chromosomal abnormalities, certain hereditary traits and structural brain anomalies caused by environmental hazards, singly or in combination, clearly coincide with the autistic symptomatology. Rather than deciding that autism is 'the cause,'" it should be understood that it is a symptom of an underlying disorder. Id. at 509.

DISCUSSION

Before compensation may be awarded to a petitioner, § 13(a)1(B) requires the court to find that there is not a preponderance of the evidence that the petitioner's condition is due to a factor unrelated to the vaccine. Respondent must assume the burden of proving a factor unrelated once petitioner has established a Table injury. Section § 13(a)(2)(A) of the Act provides, however, that petitioner's presumption of causation cannot be defeated by a factor unrelated that is "idiopathic, unexplained, unknown, hypothetical, or undocumentable." [*18] An exception to this general rule has been carved out by § 13(a)(2)(B) relative to infection, toxins, trauma, or metabolic disorders. Section 14(b)(3)(B) of the Act provides that --

If in a proceeding on a petition it is shown by a preponderance of the evidence than an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table.

As applied to this case, these sections require no more than a showing that there was a metabolic disturbance and that more likely than not it caused the encephalopathy. See e.g. Dieudonne v. Secretary of H.H.S, 1996 U.S. Claims LEXIS 202, No. 90-1695V, slip op. at 17 (Ct. Fed. Cl. Spec. Mstr. Nov. 27, 1996). See also Bastian v. Secretary of HHS, 1996 U.S. Claims LEXIS 202, No. 90-1161V (Ct. Fed. Cl. Spec. Mstr. Sept. 22, 1994). The fact that respondent has not identified a specific metabolic disorder by name, therefore, in and of itself,

is irrelevant. But even so, respondent is required to establish that a metabolic disorder exists. That requirement has not been met in this case.

A careful interpretation of the literature indicates that autism can be mirrored by a condition that [*19] includes "autistic-like" signs or symptoms. Eric's condition has never been diagnosed conclusively as autism according to the medical records. The predominating diagnosis refers instead to "static encephalopathy" with autistic tendencies in addition to delayed development." Deposition of Alfred Spiro at 21. The diagnosis of autism proposed by Dr. Spiro is explained only briefly and is without adequate foundation. Based on a review of the medical literature, it appears that some term other than autism is probably more accurate. Petitioner quotes, for example, the following from Merritt's Textbook of Neurology, 9th ed., 1995:

The term "pervasive developmental disorder (PDD) is preferred to 'autism' because it stresses variability in symptoms and severity and denies that autism is a disease with a single cause." PDD is used in the Revised Diagnostic and Statistical Manual of the American Psychiatric Association as an umbrella term for frankly autistic children and for other children with similar but fewer, less severe symptoms.

P.Ex. 23 at 513.

Dr. Spiro has not explained clearly why he believes, first, that Eric meets the criteria for autism, 9 or second, why [*20] he believes that Eric suffers a metabolic disturbance -- other than for the reason that many autistic conditions are so related. Respondent did not attempt to address the articles submitted by petitioner to support petitioner's theory nor has respondent explained why the articles are not relevant to this case. Respondent's theory in defense, therefore, is not only undocumentable, unknown and inadequately supported, it is also speculative.

9 Dr. Spiro acknowledges that the onset of autism is usually insidious rather than, as in this case, an acute event, and that the description of onset in this case is not completely typical of autism. He speculates that perhaps Mrs. Lassiter merely attributed a longstanding event [autism] to something that happened suddenly [the DPT shot] which, he states, is not uncommon among parents who are in denial. Deposition of Dr. Spiro at 33-34. The court finds this an unlikely explanation.

CONCLUSIONS

In summary, respondent's evidence and proffered explanations are weak, [*21] unconvincing, and insufficient to support a finding of an underlying metabolic or genetic disorder as the cause of Eric's affliction. Petitioner has presented a better case in support of a Table injury.

The court concludes that a preponderance of the evidence requires a finding for petitioner. The parties are directed to pursue discussions and negotiations for determining the appropriate amount of compensation to which petitioner is entitled.

IT IS SO ORDERED.

E. LaVon French, Special Master