In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

97-0061V

Filed: July 15, 1999

ZVI RUDAWSKY and STACI RUDAWSKY as the legal representatives of their minor son, DEREK RUDAWSKY,	*	
Petitioners,	*	**UNPUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Curtis R. Webb, Twin Falls, Idaho, for Petitioners.

Andres F. Quintana, United States Department of Justice, Washington, D.C., for Respondent.

DECISION

French, Special Master.

This case concerns the eligibility of Derek Rudawsky (hereinafter Derek) for compensation under the National Childhood Vaccine Injury Compensation Act (hereinafter Vaccine Act, Act, or Program).[1] Petitioners claim that as a result of the diphtheria-pertussis-tetanus (DPT) vaccination administered on August 15, 1995, Derek suffered a residual seizure disorder and chronic encephalopathy. Respondent defends by denying that Derek's injuries are vaccine-related, arguing that the child's injuries are due to a factor unrelated to the DPT, and more likely than not, constitute the first manifestation of an underlying syndrome of unknown origin which is probably genetic in nature.

[1] The statutory provisions governing the Vaccine Act are found at 42 U.S.C.A. § 300aa-1 et seq. (West 1998). Hereinafter, for ease of citation, all § references refer to the amended version of 42 U.S.C.A. § 300aa.

Procedural History

Petitioners filed a petition on behalf of their minor son on January 30, 1997. An evidentiary hearing was held on the issue of causation on May 19, 1998, in San Francisco, California. Petitioners presented the testimony of Staci Rudawsky, Derek's biological mother, Dr. Shanna H. Swan[2], and Dr. Thomas Schweller[3]. Respondent presented the testimony of Dr. Robert Baumann.[4] Petitioners are pursuing their case as an off-table case.

Summary of Facts

The facts presented at the hearing are not in controversy. Derek was born on February 12, 1995, the product of an unremarkable pregnancy, labor and delivery. His newborn examination was normal and he was discharged home on February 13, 1995. During the first six months of life, Derek was healthy and was meeting all of his appropriate developmental milestones--he smiled at one month, and he learned to roll over. Transcript of May 19, 1998 hearing (hereinafter Tr.) at 9. In early August of 1995, Derek was babbling, cooing, smiling, and learning to crawl. Tr. at 10.

On August 15, 1995, Derek received his third DPT vaccination. Despite her infant's crying immediately after the vaccination, Mrs. Rudawsky was able to console her son. Tr. at 10. During the day of the vaccination, Derek was in the care of Joann Sperling, Derek's maternal grandmother. Approximately one-half hour after Derek had arrived at her house, Mrs. Sperling began to notice that Derek was twitching. Mrs. Sperling reported this to her daughter. When Mrs. Rudawsky arrived home in the evening, she observed that Derek was cranky and not as energetic as usual. Tr. at 11.

By about 8:30 p.m. that evening, the twitching had become a fairly consistent

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[2] Dr. Swan received her B.S. from City College of New York in 1958 and her M.S. from Columbia University in 1960. In 1963, Dr. Swan received her doctorate in philosophy from University of California, Berkeley. Currently, Dr. Swan is a lecturer at the University of California, Berkeley and is the Chief of Reproductive Epidemiology Section at the California Department of Health Services.

[3] Dr. Schweller received his B.S. and M.D. from Georgetown University in 1969 and 1973, respectively. Currently, Dr. Schweller has a private practice in San Diego, California and is on the faculty of the University of California at San Diego Medical School. He is Board Certified in Psychiatry and Neurology.

[4] Dr. Baumann received his B.S. from Tufts University in 1961 and his M.D. from Western Reserve University in 1965. He is currently a Professor of Neurology and Pediatrics at the University of Kentucky. He is board certified in pediatrics, psychiatry and neurology, and epidemiology.

rhythmic jerking. Tr. at 11-12. At about 9:00 p.m. the Rudawskys called their pediatrician after becoming concerned that the jerking was continuing. The pediatrician advised the Rudawskys to administer Tylenol since the child had a slight fever of 101 degrees and to call back in one-half hour. Tr. at 12. As directed, the Rudawskys telephoned the pediatrician again and were urged to take Derek directly to the emergency room because the jerking episode was persisting. Tr. at 12. En route to the hospital, the jerking stopped briefly,[5] but five to ten minutes before presenting to the ER, Derek entered into a status epilepticus seizure. Tr. at 12. At the ER, I.V. Valium was administered and Derek's seizure was arrested after a duration of 30 minutes.[6] Tr.. at 13.

Immediately after the seizure, Derek fell asleep until his normal waking time the next morning. Upon waking, Mrs. Rudawsky noticed a difference in the child that continues until this day:

> He--prior to the seizure, as I say, was very normal, he would follow your eyes, certainly that next morning his eyes were glazed, he would certain (sic) recognize me, but he wouldn't follow as closely what I was doing, and that's continued even to this day. Prior to the seizure, he had been sucking his thumb, and completely stopped after the seizure.

Tr. at 15.

Thereafter, Derek suffered from multiple episodes of seizures and was hospitalized for seizures on many occasions.[7] Today, he carries the diagnosis of Severe

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[5] According to Mrs. Rudawsky's testimony, the jerking episode lasted approximately 45 minutes. Tr. at 13.

[6] Mrs. Rudawsky described the jerking that occurred shortly before presenting to the ER as "immediately different [from the previous 45-minute episode of jerking]." Tr. at 13. She went on to testify that the jerking was "much more forceful" and there was "much more stiffening." Tr. at 13.

[7] On cross-examination, Mrs. Rudawsky was questioned concerning a statement in the medical records which reads, "To quote the mother, she is 'not so concerned about his development". Mrs. Rudawsky responded that, at that time, she did not feel like the child was severely delayed, "at least I was hoping, I was very optimistic." Tr. at 28. In addition, Mrs. Rudawsky explained that she was more concerned with stopping the ongoing seizures. "Throughout that time my feeling was if we could stop those seizures he would be fine developmentally. . . What I meant by what's in the medical record is I really do believe if we could stop the seizures I could get his development where it needs to be." She did not focus on the developmental delays as much as controlling and

Myoclonic Epilepsy of Infancy (SMEI). Both Dr. Schweller, for Petitioners, and Dr. Baumann, for Respondent, agree that SMEI (sometimes called SME) is the appropriate diagnosis for Derek Rudawsky.

Statutory Requirements

Petitioners in vaccine cases are entitled to compensation for injuries and for any sequelae causally related to a covered vaccine. DPT is one such vaccine. A Petitioner may establish causation in one of two ways. [8] First, Petitioner may demonstrate what is commonly referred to as a Table case. The Vaccine Table lists vaccines covered by the Act and certain injuries and conditions that may result from the vaccines. § 14. If the special master finds that a person received a vaccine listed on the Table and suffered the onset or significant aggravation of an injury listed on the Table, within the time period prescribed by the Table, then the Petitioner is entitled to a presumption that the vaccine caused the injury. § 13(a)(1)(A). The Petitioner must show that the conditions for which they seek compensation are sequelae of that Table injury. § 14(a)(1)(E).

Second, Petitioner may pursue an off-Table case. In order to demonstrate entitlement to compensation in an off-Table case, a Petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. §§ 11(c)(1)(C)(ii)(I) and (II); Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 369-370 (1990), aff'd without opinion, 950 F.2d 731 (Fed. Cir. 1991). Petitioner does not meet this affirmative obligation by merely showing a proximate temporal association between the vaccination and the injury. Inoculation is not the cause of every event that occurs within a seven to ten day period following it. Without more, a proximate temporal relationship will not support a finding of causation. "[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for Petitioners seeking to prove actual causation. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), *reprinted in* 1986 U.S. Code Cong. and Admin. News 8344, 8356.

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stopping the seizures. Tr. at 30, 34.

[8] Petitioner must prove her case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970)(Harlan, J., concurring), quoting F. James, Civil Procedure 250-51 (1965). Mere existence or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (Cl. Ct. 1984).

Under the Table injury method, after Petitioner has demonstrated the requirements of § 13(a)(1)(A), the burden shifts to the Respondent to prove the injury was caused by factors unrelated to the vaccination in question pursuant to § 13(a)(1)(B). Matthews v. Secretary of HHS, 18 Cl. Ct. 514, 518 (1989); O'Connor v. Secretary of HHS, 24 Cl. Ct. 428, 429-430, fn. 2 (1991), aff'd. 975 F.2d 868. In an actual causation case such as this case, however, the inquiry is "collapsed into a single determination: On the record as a whole, has Petitioner proved, by a preponderance of the evidence, that her injury was in fact caused by the administration of a listed vaccine, rather than by some other superseding intervening cause?" Johnson v. Secretary of HHS, 33 Fed. Cl. 712, 722 (1995) aff'd. 99 F.3d 1160 (Fed. Cir. 1996). *See also,* Bradley v. Secretary of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993); Munn v. Secretary of HHS, 970 F.2d 863, 865 (Fed. Cir. 1992); Wagner v. Secretary of HHS, No. 90-2208V, 1997 WL 617035 (Fed. Cl. 134, 138) (1997) (once Petitioner puts on her prima facie case, the burden shifts to Respondent to prove a factor unrelated to the administration of the vaccine as the more likely cause of the injury); McClendon v. Secretary of HHS, 24 Cl. Ct. 329, 333 (1991), aff'd., 41 F.3d 1621 (1994). Because this is an off-Table claim, Petitioners are following the method commonly referred to as "causation in fact."[9]

The Issues

In order to answer whether Derek's injuries were caused by the DPT vaccination, one must pursue a two-step analysis: (1) *can* the DPT vaccine cause Severe Myoclonic Epilepsy of Infancy (SMEI)? and (2) *did* the DPT vaccination in question cause in-fact Derek's SMEI in this case? *See* Guy v. Secretary of HHS, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); Alberding v. Secretary of HHS, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. Mar. 18, 1994); Housand v. Secretary of HHS, No. 94-441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996).

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[9] In 1995, the Department of Health and Human Services (the Respondent in all vaccine cases), exercised its statutory authority to amend the Vaccine Injury Table set forth in §14 of the Act. Two changes are relevant to this case. Residual Seizure Disorder was removed from the Table, and the definition of "encephalopathy" was changed. All cases filed after March 10, 1995 are subject to the revisions (Petitioners here filed their case on January 30, 1997). The Rudawskys, therefore, cannot pursue an on-Table case, unless they can prove that the seizure disorder was accompanied by an encephalopathy that meets the new guidelines for that injury. Proof of an encephalopathy is now far more onerous than formerly, and Petitioners cannot meet the new guidelines. In this court's experience, few Petitioners have been able to meet the new criteria for a "Table" encephalopathy.

EXPERT TESTIMONY

Dr. Thomas Schweller, for Petitioners:

Both neurologists, Dr. Schweller, for Petitioners, and Dr. Baumann, for Respondent, agree that Derek's condition is correctly diagnosed as SMEI, Severe Myoclonic Epilepsy of Infancy. Derek has frequent mixed seizures, mainly myoclonic, and psycho-motor retardation. Tr. at 72. His present condition is "chronic encephalopathy", that is, "an ongoing disturbance of the nervous system." Tr. at 73. Approximately 20 years ago, this particular type of seizure disorder was separated out from a broad group of five or six, or more, different myoclonic seizure disorders. The broader group, Dr. Schweller explains, includes a broad spectrum of myoclonic seizures. At one end, one observes a benign type that seems to resolve itself within about three years, while others, including SMEI, continue on a disastrous downhill course. A range of disorders exists in between the two extremes. Tr. at 89-90. Somewhere under 200 children have been identified as demonstrating this particular type of seizure disorder, now called SMEI. Tr. at 77. Dr. Schweller is of the opinion that at the time of the DPT vaccination, Derek's chronic disorder was "activated," which, he testified, equates to "causation." Id.

Based on his own experience, and relying also upon epidemiological studies of the incidence of neurological damage following the pertussis vaccine, Dr. Schweller is of the opinion that the DPT, in general, is capable of causing chronic injury to the central nervous system. He holds that opinion in spite of a controversy that exists whether such causal relationship has been actually proved. The opposing view, he argues, is held by various experts who apply differing definitions or terminology to the issues involved. Unless they [the opposition] can point to a "marker," something one can actually see, they are reluctant to accept a causal relationship and will go so far as to state only that a causal relationship may be "possible." Tr. at 75. He argues further, that in so doing, they do not "go along with what has been the clinical experience over a period of time . . . where we see things happen." It is agreed that a biological or biochemical marker for a DPT vaccine injury has yet to be identified, although, he states, "the science [eventually] comes back to explain them at a later time." Id. As a clinician, he believes, on the basis of experience and observation, "that often we have to deal with clinical information first and that the scientific information follows later." Tr. at 76.

Dr. Schweller finds relevant the now famous National Childhood Encephalopathy Study (hereinafter NCES) considered the most important and by far the largest published case-control study of the relationship between the pertussis vaccine and encephalopathy. The NCES is a study of two million doses of vaccine administered in England, Scotland, and Wales between 1976 and 1979. The study found a statistically significant elevated rate of risk of neurological illness in association with the administration of DPT vaccine within a seven day period. A ten-year follow up study of case children included in the NCES led the Institute of Medicine (IOM), to conclude that in rare instances the pertussis

vaccine can cause chronic (permanent) neurological injury in children who first demonstrate "a serious neurological injury," as that term is defined by the NCES. This court ascribes considerable weight to the IOM conclusions.[10]

Dr. Schweller believes that Derek's initial injury is sufficiently severe to have qualified him for inclusion in the NCES study. In other words, had Derek been alive and in England at the time of the original National Childhood Encephalopathy Study (NCES), his type of seizure disorder would have qualified him for inclusion in that particular epidemiological study. Tr. at 77. Dr. Schweller's criteria for Derek's inclusion include the following facts: His seizure was obviously more than a simple febrile seizure; the initial jerking persisted for approximately 45 minutes; he then had a follow-on episode of status epilepticus that persisted for at least an additional 30 minutes; he required hospitalization; an intravenous administration of medications was required to stop the seizing; and the onset of seizure activity occurred in very close temporal association with the vaccine, that is, within 12 hours of vaccination, well within the NCES parameters. Dr. Schweller believes these criteria put his injury into the category of the NCES study. Tr. at 77.

Dr. Schweller describes the clinical course of Derek's injury:

> He was developing normally, he had a sudden change [first manifested by] onset of seizures, they didn't start out as myoclonic seizures but they started out as what we would, I guess, call clonic seizures, something switched on and that switch occurred within one day of the DPT immunization. Once that switch was turned on for Derek, he has continued his course, really unabated[.] . . . This is typical [of SMEI.]. . . [F]rom what I can read of the particular syndrome, the onset or the turning on the switch in several cases has been associated with a febrile event, which certainly the DPT would be a type of febrile event which would be able to turn the switch on. . . . There is a debate about how exactly to even classify [his] seizures . . . . there are features that look local , there are features that look generalized . . . . [No particular EEG pattern, such as hypsarrhythmia exists (hypsarrhythmia is a pattern associated with infantile spasms)] So you have this particular disorder where you have no real

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[10] Stratton, Howe, & Johnson, Eds., Division of Health Promotion and Disease prevention: Institute of Medicine: DPT Vaccine & Chronic Nervous System Dysfunction: A New Analysis, National Academy Press, Washington, D.C. 1994 at 15. The IOM is an independent non-governmental body associated with the National Academy of Sciences. The mission of the IOM is to advance and disseminate scientific knowledge to improve human health. "The Institute provides objective, timely, authoritative information and advice concerning health and science policy to the government, the corporate sector, the professions, and the public."

> understanding of exactly the pathophysiology of the syndrome. Tr. at 77-79. . . . But one doesn't as yet, know exactly why and how the disease happens, other than it appears to be associated with a triggering or an onset . . . in an otherwise perfectly normal appearing or acting and developing child.

Tr. at 80.

The following interchange was initiated by the Court:

> THE COURT: The implication of what you have said about a triggering event was very interesting . . . If some event triggers this condition, do you equate that with causing that condition?
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> THE WITNESS: I do, in this respect . . . This particular disease is exceedingly rare . . . and the question that I don't know anyone can answer one way or another is, if you didn't happen to have a triggering event, would this disorder ever occur . . . if those circumstances hadn't come together at one time, would he still have had the disorder? . . . We may some time in the future know . . . whether there is something else that is different about Derek that explains why he responded to the DPT immunization in this way. . . . This particular syndrome is one of the few that I know that specifically addresses the fact that febrile events can be the onset of seizures and can be the onset of the clinical manifestation of the disease.

Tr. at 82-83.

According to Dr. Schwellers' description, one cannot tell at first, if the onset of a seizure disorder is going to be benign or have a more ominous prognosis. Dr. Schweller applies his own criterion that if the DPT is the trigger, he believes "a very tight time frame" between the onset and the vaccination or trigger is significant. The closer the time frame between onset and trigger, the higher the odds are of a causal relationship. In Derek's case, the close temporal relationship, within 12 hours, was a telling consideration in forming his opinion. Tr. at 85-87.

Dr. Shanna Swan, for Petitioners:

This court has learned, over the years of hearing vaccine cases, that DPT injuries cannot be determined by empirical evidence, that is, no "markers" have been identified to clarify the role DPT plays in any individual case. This means means that a DPT injury cannot be distinguished from central nervous system injuries caused by other factors. For this reason, Petitioners support their claim by epidemiological evidence provided by the National Childhood Encephalopathy Study (NCES).

Epidemiologist, Dr. Shanna Swan focused on the value of epidemiology in determining causation in individual cases. She is of the opinion that the NCES provides valid epidemiological support for Petitioners' claim in this case. As stated earlier, the NCES is the most important and by far the largest published case-control study of the relationship between the pertussis vaccine and encephalopathy. The NCES addressed cases of serious acute neurologic illnesses in children ranging from ages 2 to 35 months. Dr. Swan considers the NCES to be a valuable scientific tool to determine causation under the "preponderance" standard of proof applicable in vaccine cases. Tr. at 65. The NCES and its conclusions, according to Dr. Swan supports a conclusion that the DPT, in fact, caused Derek's SMEI.

Dr. Swan explains that epidemiologists make associations that pertain to groups. Epidemiologists assess the probabilities of risk of causation in such groups and insofar as an individual belongs to that group, any association made would necessarily apply to the individual unless special circumstances would require the individual to be excluded.[11] "Probabilities" are not speculative, she argues; they guide clinical and practical judgment in individual cases. Tr. at 61.[12] This premise underlies Petitioners' reliance upon the NCES.

Not only do epidemiologists make causal associations between specific agents and disease outcomes but epidemiologists must measure the strength of association between an exposure and a disease. This is the concept of relative risk. Tr. at 45. In terms of the NCES, the relative risk of serious acute neurological illness in relation to recent DPT vaccination was 3.3.[13] Id. In other words, the initial neurological event was found by the first NCES study to have a 3.3 relative risk which indicates that in about 66

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[11] Dr. Swan elucidated this controversial issue with an example regarding smoking. "So. . . . when we say that . . . people who smoke ten years or more have a ten fold increased risk of lung cancer, we're [making] a general statement for the entire group. Insofar as an individual belongs to that group, that increased risk applies to that individual" unless some special circumstance makes the individual ineligible for membership in that group. Tr. at 40.

[12] Respondent questioned Dr. Swan about whether attribution of causation in individual cases would not amount to mere speculation. Dr. Swan responded that attributing causation cannot ever be proved absolutely in a single case by using epidemiology, but it is certainly not whimsical. "Given the body of evidence that we have and the probabilities that we have, we have much more than whimsy here-- we have strong evidence of causation, which gives you information about all the children in this study." Tr. at 62.

[13] A relative risk of one would indicate no association between the causative agent and the outcome. The risk in the unexposed and the exposed would be the same. Tr. at 48, 56.

percent of the group, the outcome can be attributed to the prior event, the DPT vaccination.[14] Dr. Swan identified the relative risk as even higher, 4.0, for children who experienced the acute neurological illness within 12 hours. Tr. at 46.

In addition, Dr. Swan testified that a confidence interval of 95% is accepted in the scientific community as the standard for indicating "statistical significance."[15] The NCES found the association between recent DPT vaccination and serious acute neurological illness to have reached ninety-five percent certainty, a factor that gives validity to the findings of this particular epidemiological study. Tr. at 68.

In short, according to Dr. Swan, if Derek's injury would have qualified him for inclusion in NCES, then the conclusions reached by that study apply to Derek and, more likely than not, in his case, a causal connection is probable between the DPT shot and Derek's subsequent reaction. Dr. Swan believes that Derek's injury fits into NCES definition of encephalopathy[16], and she believes also that he would have been eligible for inclusion in the original NCES. Tr. at 43, 50.[17] All of the information and statistics therefore would apply to Derek as it would apply to all children who met the criteria. Tr. at 49.

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[14] Dr. Swan further testified that in the follow-up study to the original NCES the relative risk rose to 5.5 and for children who on follow-up were found to have more serious dysfunctions, the relative risk increased to 7.3. Tr. at 46. Thus, the follow-up study strengthens the likelihood of DPT as the causative factor to 7.3, which makes it 86.3 percent more likely that the outcome was caused by the prior event, DPT, than by chance or some other cause.

[15] According to Dr. Swan, the term statistically significant is a term of art used frequently by epidemiologists. Tr. at 68-69.

[16] The NCES definition of encephalopathy is as follows, "In NCES the terms acute or subacute encephalitis, encephalomyelitis and encephalopathy were used to denote a spectrum of clinical characteristics, including altered levels of consciousness, confusion, irritability, changes in behavior, screaming attacks, neck stiffness, convulsions, visual auditory and speech disturbances, motor and sensory deficit. The term encephalopathy was used when the cause of the cerebral disorder is not immediately obvious. Stephenson recognized that encephalopathy represents a vague term, difficult to define, used to denote any neurological abnormality of the brain." (Emphasis supplied). Tr. at 43-44.

[17] In several other cases, the court has dealt with the question of inclusion of children in the original NCES. The court notes that the NCES applied a very high standard for inclusion. The factors utilized in determining eligibility for inclusion are total time spent in seizure state in the first 72 hours(not less than 30 minutes), complicated seizures, and hospitalization of the child following the acute neurologic event.

Dr. Robert Baumann, for Respondent:

Respondent's defense is basically three-fold. First, it is Dr. Baumann's opinion that Derek's initial injury does not reach the requisite severity for an encephalopathy as that term is defined in the revised guidelines established pursuant to the recent amendments to the Vaccine Injury Table. Second, Dr. Baumann does not agree that the NCES can be used as valid evidence of a neurological injury in an individual case, but only as it relates to the group. Third, he considers SMEI to be a factor unrelated to the vaccine. His reasoning follows:

Dr. Baumann believes that Derek's injury cannot be related to the vaccine because he did not display the requisite signs of a neurological injury:

> If you get a neurologic injury . . . presumably from the pertussis component, what you have is an acute injury and with an acute neurologic injury you get encephalopathic. Tr. at 120. This child never had an encephalopathy, --

He had no evidence of intracranial pressure, no bulging fontanel, no evidence of damage apparent on the EEG, "and we would have seen a dramatic loss of developmental ability . . . within, you know, the next day when he woke up from this stuff[.] Tr. at 120-121.

Moreover Dr. Baumann believes one cannot rely on the NCES or relate NCES conclusions to children in the U.S. He adds that one cannot equate a study of children in the U.K. in the 1970's and the genetic make-up of children born in the United States in 1995: "I mean that's easy, as is the environment, as are whatever ambient viruses are, the diet is very different. Tr. at 133. So to believe that this group of kids born here in 1995 have identical risk for this sort of exposure to the kids born in the entire U.K. . . . I do not think is an appropriate parallel." Id. He disagrees with the way Dr. Swan applies group data, epidemiologic data, to individual patients. He argues that clinicians would not agree with the way Dr. Swan applies epidemiologic data or statistical data to individuals: "I can tell you that that is untrue. . . . These are group data, they are used for groups." Tr. at 127.

Dr. Baumann agrees that Derek's condition is consistent with severe myoclonic epilepsy in infancy and that this syndrome has a bad prognosis.[18] Tr. at 117, 118. He is of the opinion that SMEI constitutes an underlying epileptic syndrome of unknown

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[18] A syndrome is not a discrete disease, but is "a set of symptoms which occur together; the sum of signs of any morbid state." Dorland's Illustrated Medical Dictionary, 27th Ed. at 1629.

origin, probably a genetic disorder-- and adds that these epileptic syndromes are capable of damaging the brain over time (Tr. at 140) --

> [n]ot in the sense that a lot of people think of genetic disorders that your mom and dad have it, but as a genetic disorder in that you get a series of chromosomes from your mom and a series of chromosomes from your dad that make the underlying mechanism in certain cells of the central nervous system dysfunction when you reach a certain age, and then continue to dysfunction. . . . This, I think, is a genetic disorder. . . . I think you are born with this disorder.

Tr. at 141-142.

Dr. Baumann did not offer any medical literature that confirms his hypothesis or suggests that a majority of the medical community would agree, but he intimated that some of his colleagues have similar theories about SMEI.

DISCUSSION

Dr. Baumann concurs with Dr. Schweller's opinion in two significant matters. First, Dr. Baumann agrees that Derek would have met the criteria for having sustained a "serious neurological injury" as defined in the NCES, and had Derek been living in the U.K. at the time, he would have been included with the other children studied by the NCES. Tr. at 149. He believes simply that the NCES conclusions cannot be used to indicate causation in an individual case. Second, Dr. Baumann suspects, also, that "the fever probably helped him have the seizure," although he believes the basic underlying causes and mechanisms of his unfortunate seizure disorder were already in place before the adverse event. Tr. at 150. The similarities between the two experts end there. Each of these matters will be discussed separately.

Epidemiological Evidence

The role of epidemiological studies in establishing evidence of causation, in particular, the role of the NCES as it applies to Derek Rudawsky, is important to Petitioners' claim. Petitioners claim that the NCES is of value for the purpose of establishing a nexis between the vaccine and Derek's seizure disorder. Respondent, of course, disagrees. Epidemiology is defined as --

> [T]he science of studying factors determining and influencing the frequency and distribution of disease, and other health-related events and their causes in a defined human population for the purpose of establishing programs to prevent and control their development and spread. Also, the sum of knowledge gained in such a study. (Emphasis supplied.)

Dorland's Illustrated Medical Dictionary, 27th Ed. at 566.

Precedence

The Courts have held that reliance upon epidemiological studies as evidence of causation in individual cases is not misplaced. Epidemiological evidence has been considered valuable as scientific evidence in many cases where there is no direct evidence of causation: Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 311 (5th Cir. 1989). (Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it[.] An odds ratio or relative risk greater than two can demonstrate a causal relationship); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 959 (3rd Cir. 1990). ([A] relative risk greater than "2" means that the disease more likely than not was caused by the event.); In re Joint Eastern and Southern District Asbestos Litigation, 52 F.3d 1124, 1138 (2nd Cir. 1995) (without "direct proof of causation," the preponderance of epidemiological evidence standard can be met where the relative risk exceeds two); See also, Manko v. U.S., 636 F. Supp. 1419, 1434 (W.D. Mo. 1986); Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1092 (D. Md. 1986) aff'd 814 F.2d 655 (4th Cir. 1987). ([I]n epidemiological terms, a two-fold increased risk is an important showing for plaintiffs to make because it is the equivalent of the required legal burden of proof--a showing of causation by the preponderance of evidence or in other words, a probability greater than 50%).

In Knudsen v. Secretary of HHS, 35 F.3d 543 (Fed. Cir. 1994), the U. S. Court of Appeals for the Federal Circuit held that although bare statistical facts alone are insufficient to establish causation in a particular case, causation may be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child. [19]

Against this background, then, following the Knudsen and Grant courts, and other cases cited above, the court gives credence to the position taken by the IOM that the NCES is a valid epidemiological study which found risk ratios at and above those required to establish the likelihood of causation by the relative preponderance standard. Although criticisms have been raised about the reliability of the NCES, the critics have been unable to invalidate its conclusions. Relying on the testimony of both experts, in this case, the court finds that Derek indeed fits the profile for children included in the epidemiology study and that NCES conclusions, therefore, can be attributed legally to him. Further, Derek's initial injury and his clinical course, the SMEI, would have been included in the NCES definition of a "serious acute neurological injury," leading the court to conclude that the NCES provides strong support for a vaccine-related cause of Derek's condition. In addition, based on the opinions of the experts, the court finds that,

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[19] Knudsen, at 549-550. See also, Grant v. Secretary of HHS, 956 F.2d. 1144, at 1148.

more likely than not, Derek's present condition constitutes the sequela of his initial vaccine-related injury. (Dr. Baumann acknowledges that this particular disorder "has a bad prognosis") Tr. at 117.

SMEI as a Factor Unrelated

The court is of the opinion that SMEI cannot qualify as a factor unrelated in this case. Respondent argues to the contrary that Derek's condition can be attributed to SMEI and that SMEI constitutes an unidentified, preexisting, underlying neurological condition that became apparent only because the time was ripe. Dr. Baumann believes that SMEI is probably a genetic or metabolic disorder. Two medical articles submitted as Respondent's exhibits, however, discuss SMEI, the first of which identifies the condition as "cryptogenic (of unascertainable origin) epilepsy;" Respondent's Exhibit (R. Ex.) I at 2386; the second medical article states that SMEI involves "an unknown mechanism." R. Ex. K at 626. In fact, a history of epilepsy, of any nature was found in only 25% to 30% of SMEI patients, not enough to ascribe, conclusively, a genetic origin. Little is known, apparently, about this disorder. No evidence of an underlying genetic or metabolic disorder has been identified in Derek's case, and its presence is alleged only as a hypothesis. Because SMEI has admittedly an unknown etiology, a finding in favor of Respondent's theory is prohibited by §13(a)(2)(A) of the Vaccine Act. A hypothetical or unidentified etiology cannot support legally a finding of a factor unrelated.[20]

"A Trigger" as Cause

The concept of DPT as a "trigger" has been addressed in several vaccine cases and a brief discussion of the significance of "triggering" or "unmasking" may be relevant. As discussed earlier, Dr. Schweller testified that the onset of this particular seizure disorder is frequently triggered by fever. Dr. Schweller considers such trigger to be consistent with "cause." Dr. Baumann's position on the other hand rejects such theory, although his reasoning is somewhat equivocal. In questioning Dr. Baumann stated:

I think what you have is this underlying cellular mechanism that makes

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[20] The term "factors unrelated to the administration of the vaccine"--(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." §13(a)(2)(A). Respondent has failed also to establish that Derek's SMEI meets any of the statutory exceptions to that prohibition set forth in §13(a)(2)(B--) [The term factors unrelated to the administration of the vaccine] "(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death."

> these cells electrically unstable and thus liable to have seizures. And it's well known in young children that if your cells are electrically unstable, liable to having seizures, there's certain phenomenon that makes seizures more likely. Fever in young children is high among those phenomenon. . . . [A]nd you start having the seizures. It doesn't mean the fever causes the seizures or the sequela. . . . some of the kids also trigger without fever. Tr. at 143-144.

Later during cross examination, Dr. Baumann testified:

> [W]hen they reach a certain stage in this illness if they get a fever they're more likely to have a seizure, I think that's correct, and I think in that regard then that having the fever helped him have the seizure. But, I really think the basic underlying causes and mechanisms were there before he received his DPT. Tr. at 150.

The Institute of Medicine (IOM) addressed the issue of triggering in its 1994 Report. The IOM found no supportable distinction between scenarios in which the DPT caused an acute neurological illness and subsequent chronic nervous system dysfunction, or one in which the DPT merely "triggered" such illness and subsequent dysfunctions. Specifically, the IOM analysis states that the DPT might trigger such injury and thereby be an immediate proximate cause, but nevertheless [is] still a cause. (Emphasis supplied.)[21] Following the IOM analysis, the following cases found a causal link between DPT and seizures on the basis that the DPT caused a fever that triggered seizures. McMurry v. Secretary of HHS, No. 95-682V, 1997 WL 402407, (Fed. Cl. Spec. Mstr. June 27, 1997); (Court granted no significance to the difference between "trigger" and "cause." Respondent could not impeach Petitioners' evidence when its own witness testified that DPT triggered the seizure even though the expert denied that "trigger"meant the same as cause.)[22] Gall v. Secretary of HHS, 1998 WL * * * (Fed. Cl. Spec. Mstr.

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[21] Stratton, Howe, & Johnson, Eds., Division of Health Promotion and Disease Prevention: Institute of Medicine: DPT Vaccine & Chronic Nervous System Dysfunction: A New Analysis, National Academy Press, Washington, D.C. 1994 at 13-15.

[22] The Special Master in McMurry, rejected Respondent's argument that we know the injured would have had his unfortunate outcome or condition because he developed it, and once you have it you know he would have had it. Special Master Millman considered that argument to be circular and a play on words. The Special Master held that one cannot say three years down the road that because he developed this, that it would have developed anyway--not without some evidence that such scenario would in fact have developed. In other words, the McMurry court held that Respondent must provide some evidence that the injured's underlying condition was in fact present before the onset of seizures. (Emphasis supplied.) No such evidence has been presented in

October 30, 1998); (Petitioners prevailed on the basis that DPT induced, provoked, or "triggered" the vaccinee's underlying condition which, in fact caused her death.)

The issues discussed in McMurry, are similar to those in the present case. Respondent's expert, Dr. Fenichel, a pediatric neurologist, testified in McMurry , that the DPT can cause fever that causes seizures, however, the fever caused seizures, in that particular case (McMurry), only because the individual was "susceptible" and would eventually have seized anyway. He was of the opinion that because the injured did not have an encephalopathy (as that condition is defined by Respondent and as Dr. Baumann, in like manner, also theorizes in the present case) the DPT did not have an injurious effect. McMurry, at 6:

> In essence, Dr. Fenichel testified [in McMurry] that [the injured child] seized because she would have had a seizure anyway, and he knows that she would have had a seizure anyway because she seized. Id.

The Special Master in McMurry, rejected the expert's circular argument, stating that "[f]ollowing this logic, the cause of any post-vaccinal non-Table injury would have to be other than the vaccine from its mere occurrence." The Special Master in McMurry gave no significance to the difference between trigger and cause and held that Congress intended to compensate those persons injured by the vaccine and was not concerned about whether the child was susceptible to the injury unless the Respondent proved a known factor unrelated to the vaccine was, in fact, the cause of the child's condition.

In similar fashion, Dr. Baumann has been unable to support his argument that an underlying cellular mechanism made Derek susceptible to seizures. He suggests that the DPT might possibly have caused the fever and that the fever might have helped Derek to have seizures (Tr. at 150) by triggering the onset of Derek's disorder, but he does not waver in his opinion that a previously unknown underlying condition was its ultimate cause under the assumption that the trigger seems to "click in at a certain age." [23] Tr. at 141. The court here raises the issue of triggering only because it offers an alternative basis for the court's decision favoring Petitioners' claim. Following the reasoning in McMurry, the undersigned finds no evidence in this case of an underlying disorder to trigger or unmask. Dr. Baumann does not challenge the fact that the first manifestation of the child's syndrome was the onset of clonic seizures within hours of the administration of the DPT. Id.

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the case of Derek Rudawsky.

[23] Dr. Baumann admits that very little is known about the underlying instability about which he hypothesizes, and acknowledges that in a child born with "instability in his brain," that instability, over time, could possibly resolve. Tr. at 158-159. Derek's deficits are not expected to resolve.

The court concedes that Dr. Baumann's theory is altogether possible. In future years, science may prove his theory correct. Failure of any empirical evidence in Derek's case, however, and failure of evidence in medical literature to support Dr. Baumann's hypothesis of an underlying cellular instability, genetic or metabolic, as the acknowledgeable cause of SMEI, require the court to find that Respondent has failed to establish a factor unrelated by the legal standards that obtain under the Vaccine Act.

One last issue must be addressed. Respondent argues that Derek's initial injury was simply not severe enough to have caused permanent damage to the brain. Dr. Baumann holds the opinion that unless the onset of seizures is accompanied by an encephalopathy that meets the new, highly restrictive definition of that injury, Petitioners cannot meet the criteria for establishing a "serious acute neurological injury" nor prevail in their claim. Respondent urges the court to adopt the new criteria for both on-Table and off-Table cases. The court declines to do so and disagrees with that theory. The revised criteria for an encephalopathy is not intended to restrict offers of proof in causation in fact cases although those criteria may be considered in all claims. If the court were to require the restrictive definition urged in this case, it would be tantamount to eliminating all causation in fact cases. Moreover, it would negate the findings and conclusions of the NCES and render the NCES ineffective as evidence. Most of the children in the NCES did not fit Respondent's definition of encephalopathy but causation was found nonetheless. The revised on-Table definition is aimed at relaxing the standard of proof only when the injury is of such devastating proportions that it meets the more stringent guidelines. It is not intended to foreclose causation in fact cases.[24]

As Petitioners' counsel argued in his closing statement, the IOM did not adopt such restrictive definitions of the kind of illnesses and injuries that the DPT vaccine can cause. The IOM, in 1994, supported the proposition that the vaccine can cause all serious acute neurological illness as defined by the NCES. Tr. at 166-167. This court gives considerable weight to the IOM as an unbiased source of information. Derek's initial injury meets the NCES guidelines for a serious acute neurological event. In fact, Derek's injury (prolonged seizure activity), was the largest category of serious neurological injuries included in the NCES. Almost two-thirds of children studied were in Derek's category. The court found Dr. Schweller's testimony to be better reasoned, more in keeping with the facts and more persuasive than that of his opponent. Inasmuch

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[24] The undersigned special master notes that in the majority of cases before me, those clinicians who are treating physicians testifying on behalf of Petitioners, tend to disagree with the revised definition as inconsistent with the state of medical science as practiced by such clinicians and represents only the most severe and catastrophic of encephalopathic events. Respondent's experts, disagree, of course. The undersigned gives considerable weight to the opinions of these treating physicians who note that not all encephalopathies are identical in severity, but which can, nonetheless, result in permanent damage.

as the court finds that a preponderance of evidence supports the validity of the NCES and its conclusions, the court concludes that Petitioners have succeeded in establishing their claim.

CONCLUSIONS

Petitioners have met all qualifications for establishing that Derek Rudawsky sustained an injury caused by the DPT vaccine, and that his present condition is causally related to that injury. Respondent has failed to demonstrate a factor unrelated as the cause of Derek's injury. All other statutory requirements have also been satisfied. Petitioners are entitled to compensation for the future care and rehabilitation of their injured child. The parties are directed to implement discussions as to the appropriate amount required to care for Derek's vaccine-related needs.

IT IS SO ORDERED.

E. LaVon French
Special Master