In the United States Court of Federal Claims
No. 95-451 V
(FILED: July 22, 1998)

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MICHELE Y. TERRAN,
as Legal Representative of
JULIE F. TERRAN, a minor,
Petitioner,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES
Respondent.

National Childhood Vaccine Injury Act; Standard of Review; Retroactivity of Injury Table.

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Andrew W. Dodd, Torrance, California, for petitioner.

Claudia Gangi, United States Department of Justice, Washington, D.C., for respondent, with whom were ***Assistant Attorney General Frank W. Hunger, Director Helen M. Goldberg, Deputy Director John Lodge Euler,*** and ***Assistant Director Gerard W. Fischer***, for respondent.

ORDER

TIDWELL, *Senior Judge*:

This case is before the court on petitioner's motion for review of the January 23, 1998 decision of Special Master Abell denying compensation under the National Child Vaccine Injury Act ("Vaccine Act"), 42 U.S.C § 300aa-1 - 34 (1994). *See Terran v. Secretary of HHS*, No. 95-451V, 1998 WL 55290 (Fed. Cl. Sp. Mstr. Jan. 23, 1998) (dismissal order). For the reasons set forth below, the court denies petitioner's motion for review and affirms the Special Master's decision.[(1)]

FACTS

On behalf of Julie F. Terran ("Julie"), petitioner filed a petition on July 12, 1995 for compensation under the National Childhood Vaccine Injury Act. Julie was born on February 10, 1992, in Phoenix, Arizona. She was in good health and her APGAR[(2)] scores were eight/nine when discharged from the hospital on

February 11, 1992. On March 27, 1992, when Julie was two months old, she received her first DPT vaccination. She received her second DPT vaccination on June 3, 1992, when she was three and one-half months old; her third DPT vaccination on August 10, 1992, when she was 6 months old; and her fourth DPT vaccination, which was an acellular DPT vaccination, on September 22, 1993. Only the third DPT vaccination is at issue in this case.

On August 11, 1992, the day after her third DPT vaccination, Julie suffered a seizure episode lasting approximately seven seconds and causing one of her arms to become stiff. The following day, Julie experienced four afebrile seizures, each roughly one minute in length. Immediately after the four seizures, Julie was rushed via ambulance to Phoenix's Children's Hospital at Good Samaritan Medical Center. On the way to the hospital, Julie played with her oxygen mask and was observed to be active, alert, and non-toxic. Julie was admitted and remained hospitalized for observation from August 12-14, 1992.

On August 13, 1992, Julie suffered another seizure lasting approximately five and one-half minutes. The hospital staff prescribed the anti-convulsant Phenobarbital to Julie. In total, Julie experienced approximately twelve minutes of seizure activity in the seven days following her third DPT vaccination. The seizures continued throughout the next year. On September 12, 1992, Julie suffered a seizure lasting approximately fifty minutes, despite being on Phenobarbital at the time.

Before the third DPT vaccination, Julie's doctor performed several tests to determine if she had permanent brain damage resulting from a meningocele lump removed from her skull before the third DPT vaccination. Tests completed prior to her third DPT vaccination indicated she had no brain abnormalities. On May 18, 1992, an MRI scan reported her brain structure as normal. A biopsy indicated the lump was not cancerous. On May 27, 1992, the lump was surgically removed. Dr. Manwaring, a board certified pediatric neurosurgeon, completed the lump removal follow up and determined Julie's pre-immunization neurological condition to be unremarkable except for moderate strabismus. After the third DPT vaccination, Julie had MRI's on May 21, 1993 and August 13, 1993, which showed no structural pathology in her brain. On September 13, 1993, Dr. Berebitsky, the pediatrician who administered standard well-baby care to Julie, noted that Julie was "well appearing" and "neurologically intact."

Dr. Berebitsky first noted a problem with Julie's neurological condition in November, 1993. At this time, she had a borderline passing score on the Denver Developmental Screening Test. Although genetic test results in June, 1995 and July, 1996 were normal, Julie's seizures continue today and she is currently mentally retarded.

DISCUSSION

I. Standard of Review

In reviewing the Special Master's decision, the court may (1) uphold the findings of fact and conclusions of law and sustain the decision, (2) set aside any findings of fact or conclusions of law found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and issue its own findings of fact and conclusions of law," or (3) remand the petition to the Special Master for further action in accordance with the court's direction. 42 U.S.C § 300aa-12(e)(2); *see McCarren v. Secretary of HHS*, 40 Fed. Cl. 142, 145-47 (1997) (clarifying that the standard of review is not de novo, but is the narrow "arbitrary and capricious" standard for both fact and law). The scope of review for this standard is exceedingly narrow; a court "may not substitute its own judgment for that of the Special Master if the Special Master has considered all relevant factors, and has made no clear error of judgment." *Costa v. Secretary of HHS*, 26 Cl . Ct. 866, 868 (1992) (quoting *Loe v. Secretary of HHS*, 22 Cl. Ct. 430, 432

(1991)).

II. Recovery under the Vaccine Act

Under the Vaccine Act, certain prerequisites must be met before petitioner can receive compensation. These prerequisites include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine, 42 U.S.C. § 11(c)(1)(D)(i); (2) that petitioner incurred in excess of $1000 in unreimbursable vaccine related expenses, 42 U.S.C. § 11(c)(1)(D)(i); (3) that the vaccine was administered in the United States, 42 U.S.C. § 11(c)(1)(B)(i)(I); (4) that petitioner did not previously collect a judgment or settlement in a prior civil action, 42 U.S.C. § 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative, 42 U.S.C. § 11(b)(1)(A). These requirements are not at issue in this case.

Recovery under the Act also requires plaintiff to establish causation through one of two methods. First, causation may be presumed if the claimant establishes, through medical records or expert testimony, a claim or an injury listed in the Vaccine Injury Table ("Table"), 42 U.S.C. § 300aa-14(a), and shows by a preponderance of the evidence that the injury occurred within the time period prescribed by the Table. *See id*. § 300aa-13(a)(1)(A). The Table "determines by law that the temporal association of certain injuries with the vaccination suffices to show causation . . . [replacing] traditional tort standards of causation in fact with a causation in law based on temporal association." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

Alternatively, claimants can recover under the Vaccine Act by showing causation in fact if the injury is either not included in the Table, or if a listed table injury has occurred after the corresponding time period has run. *See* 42 U.S.C. § 300aa-11(c)(1)(C). Compensation for non-Table injuries is authorized under 42 U.S.C. § 300aa-11(c)(1), and includes any illness, disability, injury, or condition not listed on the Table or not meeting the Table's requirements. Causation in fact is more difficult to establish because it requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. *See Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Strother v. Secretary of HHS*, 18 Cl. Ct. 816, 820 (1989). In addition, the logical sequence of cause and effect must be supported by medical or scientific evidence. *See* 42 U.S.C. § 300aa-13(a)(1); *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983). Though it is not necessary to show that the vaccination caused the injury with scientific certainty, *see Bunting v. Secretary of HHS*, 931 F.2d 867, 873 (Fed Cir. 1991), a mere temporal association between the injury and the vaccination is not sufficient to establish causation. *See Hasler* 718 F.2d at 205. If a claimant substantiates a claim by either method, the burden of proof shifts to the government to prove that the illness, injury, or death is due to factors unrelated to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B).

III. Revision of the Injury Table

The Secretary of Health and Human Services is authorized to revise the Table by adding or deleting injuries from the table or by altering the required time periods for onset of injury. *See* 42 U.S.C. § 300aa-14(c)(1). When promulgating new regulations, the Secretary "shall provide for notice and opportunity for a public hearing and at least 180 days of public comment." *Id*. Modifications to the table "shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulations." *Id*. § 300aa-14(c)(4).

On February 8, 1995, the Secretary of the Department of Health and Human Services released regulations removing residual seizure disorder ("RSD") from the Table and altering the definition of encephalopathy. These regulations went into effect on March 10, 1995, and petitioner filed her claim four months later on July 12, 1995. Petitioner alleges that Julie suffers from RSD and encephalopathy as previously defined, and thus would be entitled to compensation if the Table had not been amended. On review, petitioner raises two arguments involving application of the modified Table to the case.

A. Constitutional Argument

First, petitioner contends that allowing the Secretary to modify the Table is unconstitutional because it is a legislative act not subject to bicameral approval by the House and Senate, and presentment to the President. *See* Pl.'s Mot. for Review at 11-13 (Feb. 12, 1998). The Court of Federal Claims does not have jurisdiction to hear claims that do not obligate the Federal Government to pay money damages. *See Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (no jurisdiction over claims based on due process and equal protection under the Fifth Amendment); *Greider v. Secretary of HHS*, 23 Cl. Ct. 348, 350 (1991); *Adams v. United States*, 20 Cl. Ct. 132, 135 (1990); *Lark v. United States*, 17 Cl. Ct. 567, 569 (1989). Petitioner's constitutional claim is not based on a money mandating provision of the constitution, and as a result, the Court of Federal Claims does not have jurisdiction to decide the constitutional issue.

B. Validity of Table Regulations

Under the Act, challenges to the substance and validity of regulations not involving constitutional issues must be made in a court of appeals of the United States within sixty days of promulgation of the regulation if grounds for the challenge arise before promulgation of the regulation. *See* 42 U.S.C. § 300aa-32. In *O'Connell v. Secretary of Health and Human Services*, 79 F.3d 170 (1st Cir. 1996), plaintiff challenged the propriety of the procedures surrounding the implementation of the March 10, 1995 Table modifications and related definitions, but the plaintiff did not raise constitutional issues. The court held that the Secretary had the authority to issue the regulations and exercised that authority in a procedurally appropriate and substantially permissible manner. *See id*. at 182. Although the Vaccine Act only expressly permits the Secretary to make additions and deletions to the Table, the court held that the Act implicitly grants the Secretary the authority to revise the Qualifications and Aids to Interpretation accompanying the Vaccine Act. *See id.* at 175-76. Therefore, it was permissible for the Secretary to remove RSD from the Table and change the definition of encephalopathy. Petitioner, who first experienced seizures in 1992 and demonstrated a noticeable neurological condition in November, 1993, had the opportunity, not only to comment on the proposed regulations, but also could have challenged the regulations in a United States court of appeals within sixty days of the promulgation of the regulation. The Vaccine Act specifically limits when such challenges can be made and in what court the challenges can be brought. Failure to comply with the statute prevents petitioner from objecting to the substance of the modifications or the way in which they were enacted.

C. Retroactive Application of Table Modifications

Petitioner argues that the modifications to the Injury Table should not apply retroactively because her claim arose before the effective date of the regulations. Petitioner relies on *Landgraf v. USI Film Products*, 511 U.S. 244 (1994), to establish a non-retroactive presumption for federal legislation.

Although there is a deeply rooted presumption against retroactive legislation, "[w]here congressional intent is clear, it governs." *Id.* at 264-65. The Vaccine Act expressly states that revisions to the Table will apply to petitions "filed after the effective date of such regulation." 42 U.S.C. § 14(c)(4). In addition to the statute's express language, the regulations encourage the Special Masters "to apply scientific findings which form the basis of the revised table where appropriate." National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7679. Retroactive provisions often serve legitimate purposes, such as to correct mistakes or to give comprehensive effect to new laws. *See Landgraf*, 511 U.S. at 267-68. The drafters of the Vaccine Act recognized research concerning vaccine related injuries was not complete, and "research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available the Secretary or the Advisory Commission of Childhood Vaccines may propose to revise the table." H.R. Rep No. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Retroactive application of Table revisions allows cases to be decided using the most accurate causation information, regardless of when the injury occurred.

In addition, the rationale behind the presumption against retroactivity is not applicable in this case. In *Landgraf*, the court states that absent clear congressional intent for retroactivity, there is a presumption against retroactivity because persons "should have an opportunity to know what the law is and to conform their conduct accordingly." *Landgraf*, 511 U.S. at 265. With the Vaccine Act, however, it is impossible for a child to conform his or her injury to the old Table, so the reasoning behind the non-retroactivity presumption is not applicable in this case.

Petitioner also argues that there should be a presumption against retroactive application of the Table because Julie had a "vested right in a cause of action for asserted vaccine-related injury on or about August 10, 1992." *See* Pl.'s Mot. for Review at 11. First, "the Vaccine Act does not implicate any 'fundamental right' . . . [because] a 'noncontractual claim to receive money from the public treasury enjoys no constitutionally protected status.'" *Black v. Secretary of HHS*, 93 F.3d 781, 787 (Fed. Cir. 1996) (citing *Weinberger v. Salfi*, 422 U.S. 749, 772 (1975)). The mere fact that the "statute is retroactive does not make it unconstitutional [because] a legal claim affords no definite enforceable property right until reduced to a final judgment." *Arbour v. Jenkins*, 903 F.2d 416, 420 (6th Cir. 1990) (citing *Sowell v. American Cyanamid Co.*, 888 F.2d 802, 805 (9th Cir. 1989)) (application to Federal Employees Liability Reform and Tort Compensation Act). Julie does not have an automatic right to compensation until the Special Master or an appellate court rules that she does. Therefore, her rights cannot be abridged until there is a final judgment. Second, the Table is revised to reflect advances in modern medical science. Application of the new Table to petitioner's case is neither unfair nor does it deprive her of any rights because current medical research does not establish a presumption of causation between the pertussis vaccine and RSD or encephalopathy as defined by the old Table. Although Julie may have been able to prove causation under the old Table using prior medical evidence, modern medical research prevents Julie from proceeding under a Table causation theory.

IV. Causation in Fact

Petitioner concedes that there is no Table Injury under the present Table, and in the alternative, argues that the Special Master's conclusion concerning causation in fact is erroneous because the Special Master inappropriately discounted petitioner's expert Dr. Menkes and never ruled on petitioner's straightforward clinical explanation of causation. The arbitrary and capricious standard applied in the review of Vaccine Act cases is highly deferential. *See Hines*, 940 F.2d at 1528. The court cannot merely substitute its

judgment for the judgement of the decision maker. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Reversible error is extremely difficult to demonstrate "[i]f the Special Master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision . . . ." *Hines*, 940 F.2d at 1528. The central consideration is whether the Special Master acted rationally. *See id.* (citing *Midtec Paper Corp. v. United States*, 857 F.2d 1487 (D.C. Cir. 1988)*; United States v. Garner*, 767 F.2d 104, 116 (5th Cir. 1985); *Summar v. Secretary of HHS*, 24 Cl. Ct. 440, 443 (1991).

Petitioner seeks to prove causation in fact with the testimony of Dr. Menkes, who is board certified in pediatrics and neurology and is a consultant for the Committee on Adverse Vaccine Reactions for the Institute of Medicine. Dr. Menkes theorized that the pertussis toxin can cause a seizure disorder with potential evolution to retardation by entering the brains of young children (under six months) when the blood brain barrier is not yet operative. The pertussis toxin can also enter the brain of a young child with a developed blood-brain barrier because the anti-toxins in the vaccine lower the blood-brain barrier through a process called pinocytosis and allow the pertussis toxin to enter the brain. In addition, Dr. Menkes opined that Julie suffered a complicated seizure within the parameters of National Childhood Encephalopathy Study (NCES), which establishes an association between the pertussis vaccine and encephalopathy.

The Special Master analyzed whether petitioner advanced a reputable and reliable medical or scientific explanation supporting the theory that the pertussis vaccine caused Julie's injuries. The Special Master applied *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to analyze whether there was an objective, independent validation of the expert's theory, and thus whether the theory was reliable. In *Daubert*, the court generated four factors to determine whether scientific evidence was relevant and reliable, and therefore, admissible under the Federal Rules of Evidence. These factors are (1) general acceptance in the scientific community, (2) whether the theory has been subjected to peer review and publication, (3) whether it can and has been tested, and (4) whether the known potential rate of error is acceptable. *See Daubert*, 509 U.S. at 593-94. The Special Master recognized the relevance of the *Daubert* analysis, but also states that the reliability determination is not limited to the *Daubert* factors. The Special Master concluded the causation theory presented by petitioner's expert did not meet the standards of scientific reliability enunciated in *Daubert*.

In *Estep v. Secretary of HHS*, 28 Fed. Cl. 664 (1993), the court objected to the use of *Daubert* in a vaccine case because the Supreme Court applied the *Daubert* analysis to determine admissibility of evidence under the Federal Rules of Evidence, which do not apply in Vaccine cases. *See id.* at 668 n.1. Although the Federal Rules of Evidence do not apply in vaccine cases, the court believes *Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence. *See Leary v. Secretary of HHS*, No. 90-1456 V, 1994 WL 43395, at *9 (Fed. Cl. Sp. Mstr. Jan. 31, 1994). While the Supreme Court designed the test to determine whether evidence is relevant and reliable in the context of the Federal Rules of Evidence, it is equally capable of being used to determine whether information is relevant and reliable in the context of the Vaccine Act. It was not arbitrary and capricious for the Special Master to apply *Daubert* in this case to determine that Dr. Menkes' theory was not reliable scientific evidence. His theory has never been published, it has not been tested on humans, the rate of error is completely unknown, and Dr. Menkes admits that only 20% of professionals in his field would support his theory.

Petitioner objects to the Special Master's application of the *Daubert* guidelines, arguing that *Daubert* requires a flexible analysis designed to eliminate "junk science." Petitioner contends that correct application of the guidelines establishes that Dr. Menkes' theory is not "junk science" and should be admissible. In support of this argument, petitioner asserts that the theory has been sufficiently tested on animals, the animal testing results have been published, the rate of error prong does not apply because

there is no scientific technique at issue, 80% of pediatric neurologists view the theory as valid, and 20% agree with the theory. The Special Master held that Dr. Menkes' theory did not by a preponderance of the evidence meet the standards of scientific reliability enunciated in *Daubert*. The Special Master did not conclude that the Dr. Menkes' theory was junk science nor that the theory was inadmissible. The Special Master applied *Daubert* to measure the reliability and credibility of Dr. Menkes' theory compared to the theories offered by the respondent. It was not irrational for the Special Master to conclude that the theory was unreliable. The theory has never been tested on humans. Dr. Menkes admitted that he did not write a paper on the theory because "he know[s] it would never have been published." Dr. Menkes also noted that the theory is "not in the main stream of thought," and he admitted that while 80% of pediatric neurologists may view the theory as valid, only 20% would concur with his findings of causation. Therefore, it was not arbitrary and capricious for the Special Master to conclude that the theory was not sufficiently reliable to prove by a preponderance of the evidence that the DPT vaccine caused Julie's injuries.

The Special Master had the opportunity to observe the testimony, consider the comportment of the witnesses, and ask questions of each witness. The Special Master was uniquely able to make witness credibility determinations. The Special Master is not bound by the opinions of the expert witnesses and can reject the testimony for reasonable basis. 42 U.S.C. § 300aa-13(b)(1); *Aea v. United States*, 26 Cl. Ct. 878, 881 (1992), *aff'd* 6 F.3d 787 (Fed. Cir. 1993). Based on the *Daubert* analysis and the Special Master's observance and questioning of the witness, the Special Master's conclusion that the expert evidence was not sufficiently reliable was not irrational nor arbitrary and capricious.

The Special Master found the conclusions of the Institute of Medicine ("IOM") of the National Academy of Sciences to be credible.[(3)] The Vaccine Act charges the IOM to review the medical and scientific literature on possible adverse consequences of pertussis and rubella vaccines and to prepare a report on the results of its review. The Special Master concluded that the charge given to the IOM and the scope of its review made its conclusions authoritative. *See Terran*, 1998 WL 55290, at *10. Under the IOM report, there is a causal relationship between the DPT vaccination and febrile seizures. Since Julie experienced afebrile seizures, the IOM report does not establish causation by a preponderance of the evidence. Second, the IOM report concludes that there is a causal relationship between the DPT vaccination and chronic nervous functions that meet NCES criteria. To comply with the NCES study, the child must either suffer an acute encephalopathy, thirty minutes of seizure activity within seven days of the vaccination, or a complicated seizure which is characterized by a coma lasting two hours or more, seizures followed by paralysis, or other neurological signs not previously present lasting 24 hours or more. Julie did not experience an altered level of consciousness, as required for an acute encephalopathy. She only experienced twelve minutes of seizure activity within seven days of the vaccination. Finally, Julie did not experience a complicated seizure because she did not lapse into a coma, experience paralysis, or demonstrate other neurological signs. The Special Master carefully considered the merits of the IOM study and rationally decided it was reliable. He also considered Julie's medical history, compared it to the IOM requirements, and concluded that her injuries did not comply with the IOM study and thus, petitioner failed to establish causation under the IOM report.

Petitioner also argues that the Special Master failed to rule on her straightforward clinical explanation of causation and that petitioner established a prima facie case. First, petitioner argues that Julie suffered an encephalopathy in close proximity to the DPT vaccination. Although the Special Master concluded that Julie suffers from encephalopathy now, it is not proven that she had encephalopathy immediately after the DPT vaccination because she was alert, responsive and non-toxic in the ambulance. In addition, temporal association is not sufficient proof of causation. *See Hasler*, 718 F.2d at 205. Second, petitioner argues that there is no other viable explanation for Julie's disorder. The Federal Circuit has held that "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual and legal causation." *See Grant*, 956 F.2d at 1149. Third, petitioner states that Julie was normal prior to

the vaccination, but this cannot prove causation alone because children can develop seizure disorders or encephalopathy for numerous reasons unrelated to the DPT vaccination. Finally, petitioner argues simply that Julie exhibited a unique seizure disorder triggered by the pertussis vaccine and that her medical history matches Dr. Menkes' theory. Simply stating that causation is proven without supporting evidence, or using evidence that has already been discredited by the Special Master is not sufficient to establish a claim by a preponderance of the evidence.

CONCLUSION

Upon review of Special Master Abell's decision and applicable case law, the court finds that the petitioner has failed to demonstrate that denial of their claim was arbitrary, capricious, or otherwise not in accordance with the law. As a result, petitioner's motion for review is denied. The court pursuant to 42 U.S.C. § 300aa-12(e)(2)(A), hereby sustains the Special Master's January 23, 1998 decision. The Clerk of the court is directed to enter judgment accordingly.

IT IS SO ORDERED.

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MOODY R. TIDWELL
Senior Judge

1. Consequently, petitioner's May 6, 1998 request for oral argument is denied.

2. Numerical value assigned to the evaluation of the physical status of a newborn infant based on heartbeat rate, respiratory (breathing) effort, muscle tone (firmness of muscles), response to stimulation, and skin color. The best score is ten. *See* J.E. Schmidt, M.D., *Attorney's Dictionary of Medicine and Word Finder* at A-327 (1995).

3. The IOM's conclusions were published in two reports: Institute of Medicine, *Adverse Affects of Pertussis and Rubella Vaccines* (Nat'l Academy Press 1991) and Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (Nat'l Academy Press 1994).