

UNITED STATES OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

No. 95-0173V

(Filed: November 16, 2000)

JUSTIN J. GRADY, by his Mother and *
Natural Guardian, CAROL REES GRADY, *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

Ronald C. Homer, Boston, MA, for petitioner.
Linda S. Renzi, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION

Statement of the Case

On March 7, 1995, petitioner filed her petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging Justin J. Grady (hereinafter, “Justin”) sustained a residual seizure disorder (RSD), encephalopathy, and resultant developmental delays due to a DPT vaccination he received on January 19, 1994 when he was two months of age. Petitioners allege that Justin experienced his first observable seizures six days after vaccination, i.e., on January 25, 1994. Pet. at ¶

5. Subsequently, he experienced numerous afebrile seizures. Pet. at ¶ 6. He has been diagnosed with infantile spasms of unknown etiology. Id.

Petitioner filed medical records, an expert report from Dr. Mark R. Geier, an obstetrician and geneticist, and two expert reports from Dr. Ronald S. Gabriel, a pediatric neurologist, plus other material specified below. Respondent filed an expert report from Dr. Joel Herskowitz, a pediatric neurologist.

Because the records are devoid of any support for the allegation of a Table encephalopathy and because the onset of neurologic dysfunction, i.e., infantile spasms, occurred six days post-vaccination, the undersigned did not hold a hearing in this matter. A special master has the discretion to decide a case on written submissions alone, without holding an evidentiary hearing. Vaccine Rule 8(d). Petitioner has failed to show any causal nexus that would justify issuing a decision in favor of compensation.

FACTS

Justin was born on November 18, 1993, and received his first DPT, first OPV, first HiB, and second Hepatitis B vaccinations on January 19, 1994. Med. recs. at Ex. 6, pp. 1, 3. Dr. Susan Cuneo at the Broadway Medical Clinic notes on January 26, 1994 that Justin had a seizure the day before. At 4:30 p.m., he had been staring left and upward for one and one-half minutes on January 25th with limp extremities. At about 5:30 p.m., the same thing happened, and then Justin went to sleep. Overnight, his wakeful periods were shortened. At 6:30 a.m., he was not responsive and his extremities were limp. When he arrived at the hospital, he was more alert. His physical examination was within normal limits. Med. recs. at Ex. 6, p. 23. He responded appropriately for his age. Med. recs. at Ex. 7, p. 4. At the

emergency room on January 26th, Justin was awake, alert, actively exploring the room, smiling, and interacting with his parents. His temperature was normal at 99 degrees Fahrenheit. His deep tendon reflexes were symmetrical and he moved all four extremities. He had no prior fever, chills, congestion, cough, vomiting, diarrhea, or shaking movements. He had playful periods. Med. recs. at Ex. 7, p. 6.

The Gradys returned home. At around 8:00 or 8:30 a.m., Justin's eyes deviated upward to the right. His arms rose and his back stiffened briefly. Then, Justin went into a deep sleep. Since then, he had been less responsive and not himself. He did not have a fever. Justin had otherwise been well. On physical examination, Dr. Cuneo found him to be alert and in no acute distress. His neurological exam showed mild head lag, normal tone, and active and symmetrical reflexes. Med. recs. at Ex. 6, pp. 3-4.

On January 27, 1994, Justin saw Dr. Jeffrey R. Buchhalter, a pediatric neurologist at Oregon Health Sciences University. Justin did well until January 25, 1994 when he had his first seizure. An EEG obtained January 26th was very abnormal due to frequent epileptiform spike wave or sharp wave bursts involving right central, temporal, and at times parietal regions. No clinical concomitants were observed. Dr. Buchhalter felt that Justin's seizures had a right hemispheric focus or they could be infantile spasms. Med. recs. at Ex. 22, pp. 481-82, 526.

Dr. Kristan C. Collins noted on February 1, 1994, that Justin was diagnosed with infantile spasms. Med. recs. at Ex. 6, p. 4. Mr. and Mrs. Grady spoke with Dr. Thomas E. Olsen on March 7, 1994 about their concern that pertussis vaccine caused Justin's infantile spasms. Med. recs. at Ex. 6, p. 8. Dr. Olsen felt this was certainly not the cause but Mr. Grady thought that because Justin was well before the vaccination and then developed infantile spasms after the vaccination, "there must be an association." Id. Justin's grandmother mentioned that once when Mr. Grady had a vaccination, he

developed a rash on his hands for which no one knew the cause but the grandmother thought it was the vaccination. Id. The Gradys had not yet accepted Justin's seizure disorder and had been contacting patients and physicians all around the country for advice and help. Id.

Dr. Tallie Z. Baram, a pediatric neurologist at Children's Hospital in Los Angeles, saw Justin on February 14, 1994, and opined that he has infantile spasms probably secondary to a yet unclear brain abnormality. Med. recs. at Ex. 13, p. 2.

On June 7, 1994, Dr. Buchhalter noted that in children with infantile spasms, seizure outcome and development do not always go together but usually both are the result of an underlying process. Med. recs. at Ex. 22, p. 509.

Other Submitted Material

Mrs. Carol Rees Grady, Justin's mother, submitted an affidavit, dated March 1, 1995. P. Ex. 5. She states that Justin received his DPT, OPV, HiB and Hepatitis B vaccinations on January 19, 1994. Six days later, on January 25, 1994, his eyes went up as if he were looking out of the left corner of his eyes. P. Ex. 5, at ¶ 6. The same thing occurred an hour later. Afterward, his body went limp. He cried out twice during the night. Id. at ¶ 7. At about 6:30 a.m. on January 26, 1994, he was not responsive and Mrs. Grady took him to the emergency room. The doctors examined Justin and found nothing abnormal. Mrs. Grady returned home with Justin and his eyes floated upward, and he had subtle flexion of his trunk and partial raising of his arms for 30 minutes. Then he went to sleep. Id. at ¶ 7.

Mrs. Grady took Justin to the medical clinic on January 26, 1994 and the doctor thought that he might be having seizures. Id. at ¶ 8.

Mrs. Grady filled out a Vaccine Adverse Event Reporting System (VAERS) form on October 17, 1994, on which she states that Justin received his first DPT on January 19, 1994 at 10:45 a.m. and had the onset of his adverse event on January 25, 1994 between 4:00 and 5:00 p.m. The first event was a seizure, with another occurring an hour later. P. Ex. 9.

Petitioner filed an affidavit from Dr. Mark R. Geier, dated August 31, 1995.¹ P. Ex. 14. Dr. Geier is an obstetrician and geneticist. P. Ex. 14, at ¶ 1. He opines that Justin would fit within the National Childhood Encephalopathy Study (NCES)² and that Justin has an off-Table RSD and encephalopathy occurring six days post-DPT vaccination. He opines Justin is entitled to compensation. *Id.* at ¶ 27.

Attached to Dr. Geier's affidavit are a number of exhibits, including exhibit D, which has an article entitled, "Pertussis Immunization and Serious Acute Neurological Illnesses in Children," by D. Miller, N. Madge, J. Diamond, J. Wadsworth, and E. Ross, *Brit. Med. J.* 307:1171-76 (1993). This is a follow-up study to the NCES and two of its authors were also authors of the NCES (Miller and Ross). On page 1173 of this study, the authors state, "[p]reviously reported analyses showed that cases of infantile spasms were not specifically associated with recent diphtheria, tetanus, and pertussis immunization, and they are therefore excluded from all the analyses in this paper."

¹ During a telephonic status conference on October 26, 1999, petitioner's counsel stated that he would use Dr. Geier for the purpose of statistics only.

² R. Alderslade, M.H. Bellman, N.S.B. Rawson, E.M. Ross, and D.L. Miller are the authors of "The National Childhood Encephalopathy Study: A report on 1000 cases of serious neurological disorders in infants and young children from the NCES research team," Department of Health and Social Security. Whooping Cough: Reports from the Committee on the Safety of Medicines and the Joint Committee on Vaccination and Immunisation (London: Her Majesty's Stationery Office, 1981). P. Ex. F.

Also attached to Dr. Geier's affidavit is exhibit E, which includes the Institute of Medicine (IOM) article, "DPT Vaccine and Chronic Nervous System Dysfunction. A New Analysis" (National Academy Press, 1994). On page 8 of 17 pages, the IOM, referring to the NCES, states, "The authors did not include cases with infantile spasms in the calculations regarding DPT on the basis of post-hoc analyses showing no association between infantile spasms and earlier DPT immunizations."

Petitioner filed a report from Dr. Ronald S. Gabriel, a pediatric neurologist, dated July 2, 1999. P. Ex. 26. Petitioner termed this report "supplemental," although she apparently did not file a prior report from him. (In his report, however, Dr. Gabriel refers to a report dated January 23, 1999.) Dr. Gabriel opines that Justin's condition is a consequence of pertussis vaccine. He rules out possible causes other than the vaccine. In support of his opinion, Dr. Gabriel states that epidemiological analysis firmly supports a cause and effect relationship, citing the IOM review of the NCES that there is an 80 percent chance that the relationship between DPT and Justin's condition is causal. P. Ex. 26, p. 2.

Attached to Dr. Gabriel's report are exhibits A through I. Exhibit A is the same as Dr. Geier's exhibit E, i.e., the IOM report, except it is a pre-publication copy so that the statement in the published version on page 8 that the NCES did not include cases with infantile spasms occurs here on page 6.

Exhibit B attached to Dr. Gabriel's report is the Report of the Ad Hoc Subcommittee on Childhood Vaccines, June 9, 1994, by the National Vaccine Advisory Committee, which concludes that for a vaccine to have caused RSD, the RSD must follow an acute encephalopathy. P. Ex. 26, Ex. B, p. 9.

Exhibit C attached to Dr. Gabriel's report is "Risk of Serious Acute Neurological Illness After Immunization With Diphtheria-Tetanus-Pertussis Vaccine," by J.L. Gale, et al., *JAMA* 271:37-41

(1994). The authors attempt to evaluate the association between serious acute neurological illness and whole-cell pertussis vaccination by setting up estimated odds ratios (OR) for onset of serious acute neurological illnesses within seven days of vaccination. The study does not find any statistically significant increased risk of onset of serious acute neurological illness in the seven days post-DPT vaccination in young children. The authors could not do an OR for infantile spasms because of an insufficient number of discordant pairs between vaccinees and non-vaccinees (at least two potential control children were selected for each case child). *Id.* at 38. They discuss the phenomenon in the NCES that shortly after DPT vaccination, there was an increased relative risk (RR) of infantile spasms above one but this fell to below one afterward so that the overall estimate of RR for the first 28 days after DPT was nearly one. The NCES authors interpreted this as possible evidence of a triggering, but noncausal, effect of DPT, i.e., unmasking an acute illness otherwise destined to occur. *Id.* at 41.

Exhibit D attached to Dr. Gabriel's report is the follow-up study to the NCES in the *British Medical Journal* that is Dr. Geier's exhibit D.

Exhibit E attached to Dr. Gabriel's report is the consensus statement from the Ad Hoc Committee for the Child Neurology Society on "Pertussis Immunization and the Central Nervous System" (1991). The paper does not deal with infantile spasms.

Exhibit F attached to Dr. Gabriel's report is the NCES. In Table V23, the authors show three cases of infantile spasms occurring within seven days of DPT vaccination within category IA (normal-normal), and three cases of infantile spasms occurring within seven days of DPT within category IB

(normal-abnormal), for a total of six cases of infantile spasms occurring within seven days of DPT.³ In Table V24, the authors show four cases of infantile spasms occurring within seven days of Dt (diphtheria-tetanus, but not pertussis) vaccination within category IA (normal-normal), one case of infantile spasms occurring within seven days of Dt within category IB (normal-abnormal), and three cases of infantile spasms (including one with Down's syndrome) occurring within seven days of Dt in category II (abnormal-abnormal), for a total of eight cases of infantile spasms occurring within seven days of Dt (or seven cases of infantile spasms following Dt if the Down's syndrome child is omitted). Thus, within seven days of vaccination, there were more cases of infantile spasms occurring after Dt than after DPT. Ex. F, p. 133-36.

The NCES's decision not to include infantile spasms in its epidemiological analysis of RR is made explicit in subsequent articles and literature (see Geier exhibits D and E). However, one can see from the above tables that although the NCES included infantile spasms in its study initially, the authors found that the same (or actually higher) incidence of onset of infantile spasms occurring after Dt as after DPT within seven days of vaccination could not support a conclusion that there was a statistically significant RR of infantile spasms post-DPT. See generally, Barnes v. Secretary of Dept. of Health & Human Servs., 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997) (finding DPT does not cause infantile spasms in children with tuberous sclerosis).

Exhibit G attached to Dr. Gabriel's report is an article entitled "Diphtheria-Tetanus-Pertussis Vaccine and Serious Neurologic Illness: An Updated Review of the Epidemiologic Evidence," by K.R.

³ There were no infantile spasms occurring in category II (abnormal-abnormal) within 7 days of DPT.

Wentz, et al., *Ped* 87:287-96 (1991). It also states the point in exhibit C attached to Dr. Gabriel's report that the NCES found neither the excess within seven days nor the deficit between seven and 28 days post-vaccination of infantile spasms following DPT and Dt to be statistically significant and, thus, excluded infantile spasms from their subsequent analyses. Ex. G, p. 292.

Exhibit H attached to Dr. Gabriel's report is the IOM's *Adverse Effects of Pertussis and Rubella Vaccines*, chapter 4, pp. 65-124 (National Academy Press, 1991). After reviewing the medical literature, the authors conclude that the NCES's showing of nearly identical rates of onset of infantile spasms following Dt and DPT vaccinations means that DPT does not increase the risk of infantile spasms. Also, because the NCES reported that 41 percent of previously normal children who had infantile spasms were reported to be neurologically normal 15 days postadmission or on discharge, the IOM authors thought the accuracy of the diagnosis was doubtful since one would not expect recovery from infantile spasms within two weeks. Ex. H, p. 74. Most controlled studies did not observe an increased risk of infantile spasms post-DPT vaccination. The IOM authors conclude that the "evidence does not indicate a causal relation between DPT vaccine or the pertussis component of DPT and infantile spasms." *Id.* at 76-77.

Exhibit I attached to Dr. Gabriel's report is "The National Childhood Encephalopathy Study: A 10-Year Follow-Up," by N. Madge, J. Diamond, D. Miller, E. Ross, C. McManus, J. Wadsworth, and W. Yule (Cambridge University Press, 1993). It is obviously more expansive (117 pages long) than exhibit D, the *British Medical Journal* article (six pages long). The *British Medical Journal* article focused on whether pertussis vaccine can lead to permanent brain damage. The 10-year follow-up focused on the sequelae of the neurological illnesses described in the NCES. *Id.* at 2. These

various neurological illnesses were divided into categories (encephalopathies, severe febrile convulsions, “other” severe convulsions, infantile spasms) without conclusions as to vaccine relatedness because the authors’ sole focus was on the sequelae of these conditions after ten years.

After a telephonic status conference with counsel on December 13, 1999, the undersigned ordered petitioner to file a supplemental report from Dr. Gabriel addressing the following issues: (1) how he could refer to the NCES as supportive of his opinion of causation when the NCES specifically excluded infantile spasms from its analysis and found no higher incidence of infantile spasms post-DPT; (2) whether Dr. Gabriel opined Justin had encephalopathy at the time of the onset of his infantile spasms; and (3) whether Dr. Gabriel agreed with the diagnosis of infantile spasms.

Petitioner filed a supplemental report from Dr. Gabriel, dated February 25, 2000. P. Ex. 27. Dr. Gabriel states that the NCES was not likely “to bear fruit with respect to a single seizure type” because it extracted out a small number. He also stated that infantile spasms represent an encephalopathy whose onset was probably due to DPT and which evolved over a matter of days until it became clinically manifest. Dr. Gabriel states that an EEG done earlier than Justin’s onset of seizures would have likely been abnormal post-DPT. Id.

On March 13, 2000, the undersigned held another telephonic status conference with counsel wherein the undersigned requested a second supplemental report from Dr. Gabriel to explain the basis for his statements that vaccines cause infantile spasms, that DPT causes infantile spasms, and that encephalopathy begins subclinically. The undersigned issued an Order to this effect on March 13, 2000. On May 18, 2000, during another telephonic status conference, petitioner’s counsel informed

the undersigned that Dr. Gabriel would not give a third report to answer the questions described in the Order of March 13, 2000.

Respondent filed the expert medical report of Dr. Joel Herskowitz, a pediatric neurologist, dated July 24, 2000. R. Ex. A. Dr. Herskowitz notes that petitioner's claim is for an off-Table injury. Use of the NCES to buttress an opinion of causation is unjustified because it excluded infantile spasms from its analysis. Id. at 3. Dr. Herskowitz felt that if Justin had an encephalopathy soon after his DPT, he would have manifested profound changes in behavior and mental state sooner than six days. Descriptions of Justin's behavior in the Emergency Room on January 26, 1994 fall far short of an encephalopathic state of unarousable unresponsiveness. Id. at 4. Being a little poky and sleeping longer than usual do not rise to the level of encephalopathy particularly when Justin was awake, alert, actively exploring the examining room, smiling, and interacting with his parents. Id. Dr. Herskowitz concludes that DPT did not cause Justin to suffer encephalopathy or a seizure disorder.

DISCUSSION

Because the onset of Justin's seizures occurred off-Table, petitioner cannot benefit from a statutory presumption of causation. 42 U.S.C. § 300aa-14. Dr. Gabriel's statement that if an EEG had been performed earlier than Justin's onset of infantile spasms, it would have been abnormal does not suffice to place the onset of his seizures within three days of DPT vaccination. Dr. Gabriel is engaging in pure speculation when he posits that Justin's onset of infantile spasms predated his clinical symptoms but occurred after vaccination. Assuming, arguendo, that they did predate clinical manifestation, there is no proof of when they started. Justin might also have had an abnormal EEG

before he received his DPT vaccination on January 19, 1994 if one had been performed. Therefore, the undersigned holds that the onset of infantile spasms was January 25, 1994.

Petitioner alleges encephalopathy as well as seizures. However, Dr. Gabriel's statement that infantile spasms are a type of encephalopathy is not helpful in evaluating whether Justin had an acute encephalopathy, with its concomitant loss of consciousness, as Dr. Herskowitz described. A child who is awake, alert, interacting with his environment and parents, and smiling does not have an acute encephalopathy. That Justin developed a chronic encephalopathy due to the effect either of his infantile spasms or some unknown cause for both the spasms and the developmental delay is undeniable, but does not serve to implicate the vaccination as its cause. So we are left with the question of whether Justin's DPT vaccination caused the onset of his infantile spasms six days later.

For petitioner to satisfy her burden of proving a prima facie case of causation in fact of infantile spasms, she must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993); Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the vaccine, Justin would not have had his injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Petitioner has presented no credible evidence to support either Dr. Geier's or Dr. Gabriel's opinion that DPT caused Justin's infantile spasms. Their reliance on the NCES is misplaced because, as amply discussed above, the NCES did not conclude that DPT causes infantile spasms. It expressly found no statistical significance between the onset of infantile spasms after DPT and after Dt vaccines. Other material that petitioner provided does not deal with infantile spasms post-DPT.

Dr. Geier's affidavit gives no basis other than the NCES and the IOM for his opinion on causation. All the IOM does is summarize the NCES. Dr. Gabriel's two reports discuss his opinion of causation based on apparently two points: the NCES supports his view, and Justin's infantile spasms/encephalopathy probably began before six days after the DPT vaccination. The first point is erroneous. The NCES does not support his view. The second point is speculative.

Lastly, Dr. Gabriel bases his opinion on the fact that no one has found a cause for Justin's infantile spasms. Simply because no cause other than the DPT has been found does not mean that DPT must be the cause. See Grant, supra. Petitioner has provided no credible evidence to link DPT vaccine and Justin's infantile spasms.

The case is tragic, but not compensable. Petitioner has failed to prove a prima facie case of causation in fact.

CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master