

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 2-1831V

Filed: March 21, 2011

SANDRA A. DANERI, parent of Erik Daneri,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

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Petitioner’s Motion for a Decision on the Record; Insufficient Proof of Causation; Vaccine Act Entitlement

DECISION¹

Vowell, Special Master:

On December 12, 2002, Sandra A. Daneri [“petitioner”] filed a Short-Form Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program [“the Program”],² on behalf of her son, Erik Daneri [“Erik”]. In effect, by use of the special “Short-Form” developed for use in the context of the Omnibus Autism Proceeding [“OAP”], the petition alleges that various vaccinations injured Erik. On March 15, 2011, petitioner informed the court of a change of address. **The clerk of court shall update court records to reflect petitioner’s current address and telephone number:**

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information, that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

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Also on March 15, 2011, petitioner made an oral motion for a ruling on the record as it now stands. Voris Johnson, counsel for respondent, indicated he had no objection to the motion. Because the information in the record does not show entitlement to an award under the Program, this case is dismissed.

I. The Omnibus Autism Proceeding

This case is one of more than 5,000 cases filed under the Program in which it has been alleged that disorders known as “autism” or “autism spectrum disorder” [“ASD”] were caused by one or more vaccinations. A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the more than 5,000 petitions filed in this court, was set forth in the six entitlement decisions issued by three special masters as “test cases” for two theories of causation litigated in the OAP and will not be repeated here.³

Ultimately, the Petitioners’ Steering Committee [“PSC”], an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of ASDs. The first theory alleged that the measles portion of the measles, mumps, rubella vaccine could cause ASDs [“Theory 1”]. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in thimerosal-containing vaccines could directly affect an infant’s brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC’s first theory rejected the petitioners’ causation theories. *Cedillo*, 2009 WL 331968, *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst*, 2009 WL 332306, *aff’d*, 88 Fed. Cl. 473 (2009), *aff’d*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder*, 2009 WL 332044, *aff’d*, 88 Fed. Cl. 706 (2009).⁴ Decisions in each of the three “test cases” pertaining to the PSC’s second theory also rejected the petitioners’ causation theories, and

³ The Theory 1 cases are *Cedillo v. Sec’y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); *Hazlehurst v. Sec’y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); *Snyder v. Sec’y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). The Theory 2 cases are *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec’y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec’y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁴ Petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

petitioners in each of the three cases chose not to appeal. *Dwyer*, 2010 WL 892250; *King*, 2010 WL 892296; *Mead*, 2010 WL 892248. Thus, the proceedings in these six test cases are concluded. Petitioners remaining in the OAP must now decide to pursue their case, and submit new evidence on causation, or take other action to exit the Program. The petitioner in this case has requested a ruling on the record as it now stands.

II. The Medical Records

Erik was born on January 23, 1998. Petitioner's Exhibit ["Pet. Ex."] 1, p. 2. His admission exam was significant for "slight caput,"⁵ and at discharge he was diagnosed with slight jaundice. Pet. Ex. 1, p. 2. He received routine childhood vaccinations between February 28, 1998, and January 28, 2002, as well as a two-dose seasonal influenza vaccination in the fall of 2002. See Pet. Ex. 2, p. 1. He experienced normal childhood illnesses such as vomiting, rashes, diarrhea, ear infections, fevers, upper respiratory infections, and rotavirus. See Pet. Ex. 2. His pediatrician noted no problems at his three-year well check-up. Pet. Ex. 2, p. 25. There are no reports of a vaccine reaction in any of the evidence filed.

On September 18, 2001, the pediatrician's records indicate petitioner called to report concerns from Erik's teachers regarding his behavior. Pet. Ex. 2, p. 30. This prompted a visit on September 27, 2001, and the records of this visit explain that the teachers had observed echolalia and abnormal and stereotypical behavior patterns. Pet. Ex. 2, p. 30. The pediatrician recommended testing for autism, including hearing and speech evaluations, and psychological testing. The doctor also ordered a blood screen to rule out Fragile X syndrome, a known genetic cause of autism, and that was negative. Pet. Ex. 2, p. 30.

On October 22, 2001, psychologist Ana Byrne diagnosed Erik with Pervasive Developmental Disorder, Not Otherwise Specified, which is an autism spectrum disorder. Pet. Ex. 3, p. 4. A speech language pathologist evaluated Erik on October 25, 2001, and again on November 8, 2001, concluding that he exhibited moderate to severely delayed receptive and expressive language. Pet. Ex. 4, p. 3.

III. Causation in Fact

To receive compensation under the Program, petitioner must prove either 1) that Erik suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Erik suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). An examination of the record did not uncover any evidence that Erik suffered a "Table Injury." Further, the record does not contain a medical opinion or any other persuasive

⁵ This reference indicates diffuse edematous swelling of the soft tissues of the scalp related to delivery. It typically disappears within the first few days of life. NELSON TEXTBOOK OF PEDIATRICS 714 (18th ed. 2007).

evidence indicating that Erik's autism spectrum disorder was vaccine-caused. The evidence produced in the OAP test cases does not support petitioner's allegation of vaccine causation; rather it indicates that vaccines are unlikely to cause autism spectrum disorders. Petitioner has presented no additional evidence demonstrating that vaccines can cause autism spectrum disorders or that they did cause Erik's disorder.

A petitioner may not receive a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). In this case, because there are insufficient medical records supporting petitioner's claim, a reliable medical opinion must be offered in support. Petitioner, however, has offered no such opinion.

Accordingly, it is clear from the record in this case that petitioner has failed to demonstrate either that Erik suffered a "Table Injury" or that his injuries were "actually caused" by a vaccination. **Thus, this case is dismissed for insufficient proof. The clerk shall enter judgment accordingly.**⁶

IT IS SO ORDERED.

Denise K. Vowell
Special Master

⁶ This document constitutes my final "Decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). If petitioner wishes to have this case reviewed by a Judge of the United States Court of Federal Claims, a motion for review of this decision must be filed within 30 days. After 30 days the Clerk of this Court shall enter judgment in accord with this decision. If petitioner wishes to preserve whatever right petitioner may have to file a civil suit (that is a law suit in another court) petitioner must file an "election to reject judgment in this case and file a civil action" within 90 days of the filing of the judgment. 42 U.S.C. § 300aa-21(a).