

On April 16, 2008, petitioner was ordered to file the statutorily required medical records. § 300aa-11(c)(2). In response, petitioner filed medical records on July 22, 2008. On August 27, 2008, also pursuant to the undersigned's April 16, 2008 Order, respondent filed a Statement Regarding Whether the Claim Should Proceed in the Omnibus Autism Proceeding ("OAP") wherein respondent concluded that the record supports a finding that the case was timely filed and involved an autism spectrum disorder. Petitioner then filed additional records on October 31, 2008.

On September 23, 2010, petitioner was informed that the OAP test cases had been decided and was ordered to file a statement within 30 days informing the court if petitioner wished to proceed with this claim. On October 20, 2010, petitioner filed a request that this case be decided on the record as it now stands. 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 5,400 cases filed under the Program in which it has been alleged that disorders known as "autism" or "autism spectrum disorders" ("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 OAP, 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 ASD. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine could cause ASD. 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,

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).

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 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 Records⁵

Brandon was born healthy on April 5, 2004, with Apgar scores of 8 and 9. P Ex. 3 at 4; see also P Ex. 1. Early on he experienced discharge from both eyes, slight jaundice, and poor weight gain. P Ex. 3 at 6-8, 12-13, 15. Nonetheless, Brandon's pediatrician assessed him as a "well baby" with normal development on August 12, 2004. P Ex. 3 at 16. He received routine childhood vaccinations between April 5, 2004, and October 23, 2006. P Ex. 5 at 1-2.

On January 20, 2005, Brandon's mother reported he was not feeding well, though the pediatrician assessed Brandon's appetite and growth as normal. See P Ex. 3 at 18. On April 14, 2005, Brandon's parents were concerned that he was not yet walking. P Ex. 3 at 19. The pediatrician did note that Brandon would pull to stand, cruise, and babble; he assessed Brandon's development as normal. Id.

On April 26, 2005, Brandon presented to the pediatric clinic with a rash on his face and legs. P Ex. 10 at 1. The nurse noted it was a "Possible Reaction to Vaccine," and listed vaccinations Brandon had received on April 14, 2005: varicella, MMR, pneumococcal conjugate, hemophilus influenzae type B, and diphtheria-tetanus-acellular pertussis ("DTaP"). Id.; see also P Ex. 5. The examining physician noted that Brandon may have had a reaction to the varicella vaccine or the MMR vaccine. P Ex. 10 at 1. There is no subsequent note indicating when this rash resolved, or whether a treating physician attributed it more definitively to vaccination. On August 3, 2005, Brandon again presented with a rash in the form of "bumps," diagnosed by the pediatrician as impetigo. P Ex. 11; see also P Exs. 12-13 (indicating Brandon continued to experience impetigo and viral rash throughout that month).

At a well infant visit on April 20, 2006, the history notes parental concern with "speech delay, mild dev[elopment] delay," and suggests a diagnosis of autism. P Ex. 15. The pediatrician's assessment clarifies that autism was suspected at that time, and the pediatrician referred Brandon for further evaluation to rule out autism. Id.

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

⁵ The undersigned will not discuss the medical records in detail in this decision, but has reviewed and considered all of the medical records and evidence filed by petitioner, except Petitioner's Exhibit ("P Ex.") 33, filed in Spanish. The record contained in P Ex. 33 is dated November 20, 2006, months after Brandon's diagnosis, and appears to be related to speech therapy. Thus, this record is not pertinent to the involved causation claims.

On June 26, 2006, Brandon underwent a developmental evaluation at the John Richards Learning Center. Stephanie Eischen-Lee, Ph.D., a clinical psychologist, concluded that “Brandon’s developmental presentation and history is consistent with a diagnosis of Autism.” P Ex. 6 at 4. This diagnosis was clarified to be “provisional” in a subsequent evaluation on July 13, 2006, by Maria Frailey, Ph.D., a clinical psychologist, and was largely based on Brandon’s speech delay and repetitive behaviors. P Ex. 7 at 6. In a dysmorphology consultation with Keith Vaux, M.D., Brandon was diagnosed with “unknown multiple malformation syndrome” characterized by “several minor malformations.” P Ex. 20 at 1, 3. The physician could not “rule out that this may in fact have a genetic etiology.” P Ex. 20 at 3. Subsequent genetic testing was unable to detect or rule out a genetic cause. See P Exs. 23; 25; 26. In the filed medical records, no treating physician attributed Brandon’s autism to a vaccine or vaccines.

III. Causation in Fact

To receive compensation under the Program, petitioner must prove either 1) that Brandon suffered a “Table Injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Brandon 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 Brandon suffered a “Table Injury.” Further, the record does not contain a medical opinion or any other persuasive evidence indicating that Brandon’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. In addition, a recent report from the Institute of Medicine has rejected a causal link between the MMR vaccine and autism, and it has found inadequate evidence to accept or reject a causal link between the DTaP vaccine and autism. Institute of Medicine, Adverse Effects of Vaccines, Evidence and Causality (2011) at 112-15 (discussing MMR), 468-69 (discussing DTaP).

The Act at § 300aa-13(a) provides that the special master may not make “a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” 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. Thus, this Petition remains unsupported by either medical records or medical opinion. In accordance with section 13(a), the undersigned has no option but to **deny** petitioner’s claim for want of proof. See Fesanco v. Sec’y, HHS, ___ Fed. Cl. ___, 2011 WL 1891701 (2011) (affirming another special master’s ruling in similar circumstances).

A review of the Record shows that petitioner has failed to demonstrate either that Brandon 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.**

IT IS SO ORDERED.

Gary J. Golkiewicz
Special Master