

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 08-0507V
Filed: September 12, 2011
Not to be Published**

Geoffrey Luke Fabre, a minor, by his
parents and natural guardians,
GEORGE FABRE and PATRICIA
FABRE,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Autism;
Petitioners' Motion for a Decision
on the Record; Insufficient Proof
of Causation; Vaccine Act
Entitlement

DECISION¹

Golkiewicz, Special Master:

On July 14, 2008, George Fabre and Patricia Fabre filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program (“the Program”),² alleging that various vaccinations injured their son, Geoffrey Luke Fabre (“Geoffrey”).

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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)). **As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing.** Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.

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).

On July 23, 2008, petitioners were ordered to file the statutorily required medical records. § 300aa-11(c)(2). In response, petitioners filed medical records, an affidavit, and a statement regarding onset on September 22, 2008. Petitioners then filed additional records on March 19, 2009. On April 24, 2009, also pursuant to the undersigned's July 23, 2008 Order, respondent filed a Statement Regarding Whether the Claim Should Proceed in the Omnibus Autism Proceeding ("OAP") wherein respondent concluded that she could not determine whether this case was filed before the expiration of the statute of limitations.

On September 27, 2010, petitioners were informed that the OAP test cases had been decided and were ordered to file a statement within 30 days informing the court if petitioners wished to proceed with this claim. On October 18, 2010, petitioners filed a motion for a decision 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,

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).

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 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 petitioners in this case have requested a ruling on the record as it now stands.

II. The Medical Records⁵

Geoffrey was born healthy on October 1, 2001, with Apgar scores of 9 and 9. Petitioners' Exhibits ("P Ex.") 1; 55.⁶ He received routine childhood vaccinations between October 27, 2001, and at least November 10, 2005. P Ex. 2. Geoffrey experienced normal childhood illnesses such as upper respiratory infections. See, e.g., P Exs. 8; 10; 12; 13; 17; 19; 21; 32; 33. At two months, Geoffrey's pediatrician detected a heart murmur and referred him for further evaluation. P Ex. 4. The cardiologist confirmed the presence of a murmur but determined that it was of "no hemodynamic significance." P Exs. 5; 6 at 2. The murmur had spontaneously closed by April, 2003. P Ex. 20. Geoffrey was also noted to have poor eating habits. P Ex. 22.

At his two-year well child visit, Geoffrey's pediatrician noted a concern about his language development. While Geoffrey had "100 words," he could not speak in two word sentences. This may have been attributable to the family's bilingual household. P Ex. 22. This problem appeared to be of less concern at Geoffrey's three-year well child visit. P Ex. 29.

At some point in spring or summer, 2005, Geoffrey became less communicative. On August 31, 2005, Geoffrey underwent a behavioral evaluation at the pediatrician's office. The history notes from this exam include parental concerns that Geoffrey was not following directions, was ignoring or selectively listening, and was selectively choosing to respond to questions or to speak. He also was demonstrating a preference for playing by himself. P Ex. 34. At a November 30, 2005 gastrointestinal exam, the Fabres told the physician that "[a]bout six months ago, [or around early June, 2005,] he became withdrawn and less communicative." P Ex. 37 at 1. At Geoffrey's four-year well child visit in October, 2005, the pediatrician recorded that Geoffrey's speech was

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 petitioners.

⁶ Petitioners numbered and paginated their initial filing of exhibits, concluding with P Ex. 54. Their supplemental filing was not numbered or paginated, but is referred to here as P Ex. 55.

“100%” understandable, and that Geoffrey was bilingual and speaking in full sentences. P Ex. 36. Nonetheless, the pediatrician referred Geoffrey for a developmental pediatric evaluation for his “selective mutism.” P Ex. 36.

On January 3, 2006, neurodevelopmental pediatrician Elliot S. Gersh evaluated Geoffrey, and concluded Geoffrey had a disorder on the autism spectrum. P Ex. 38.⁷ A January 13, 2006 neurological exam with Bennett Lavenstein, M.D., included a history of “normal development until 45 months [or 3 years, 9 months] of age when he stopped playing with toys, had regressive behavior, a decline in speech, evidence of repetitive movements, some stereotype, some evidence of staring spells but not overt seizures and then subsequently, some emotional outbursts, the latter of which have settled down.” P Ex. 40 at 1. Doctor James Rubenstein of the Kennedy Krieger Institute Autism Clinic diagnosed Geoffrey with a static encephalopathy of unknown etiology; Childhood Disintegrative Disorder (“CDD”),⁸ an ASD; severe receptive-expressive communication disorder; and a history of language and behavioral regression. P Ex. 44 at 1. Testing was unable to identify a cause for Geoffrey’s problems. See P Exs. 39; 41; 42; 47.

In the filed medical records, no treating physician attributed Geoffrey’s CDD to a vaccine or vaccines. The records also contain no report or observation of an adverse reaction to vaccination. Geoffrey had last received vaccines in January, 2003 (see P Ex. 2), more than a year before he began to exhibit signs of regression in spring or summer, 2005. He then received vaccines in October and November, 2005 (id.), several months after his regression began.

III. Causation in Fact

To receive compensation under the Program, petitioners must prove either 1) that Geoffrey suffered a “Table Injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Geoffrey 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 Geoffrey suffered a “Table Injury.” Further, the record does not contain a medical opinion or any other persuasive evidence indicating that Geoffrey’s autism spectrum disorder was vaccine-caused. Petitioners are not bound by the results of the test cases, but the evidence produced in the test cases does not support petitioners’ 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

⁷ Only one page of Doctor Gersh’s January 3, 2006, three-page report was filed. See P Ex. 38.

⁸ CDD is a diagnosis on the autism spectrum presenting as “children with apparently normal development by age two [who] experience a profound loss of skills and disintegration of functioning after age three and before age 10. In later years, these children present similarly to children with severe autistic disorder.” Dwyer, 2010 WL 892250, at *31.

or reject a causal link between the diphtheria, tetanus, acellular pertussis (“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 petitioners’ claim, a reliable medical opinion must be offered in support. Petitioners, however, have 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** petitioners’ 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).

Accordingly, it is clear from a review of the record in this case that petitioners have failed to demonstrate either that Geoffrey 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