IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 08-0122V
Filed: September 13, 2011
Not to be Published

DANIEL KANEFIELD and DENISE KANEFIELD, parents of Adam Jay Kanefield, a minor,	*	
Petitioners,	*	Autism;
v.	*	Petitioners' Motion for a Decision on the Record; Insufficient Proof
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	of Causation; Vaccine Act Entitlement
Respondent.	*	

DECISION[1]

Golkiewicz, Special Master:

On March 3, 2008, Daniel Kanefield and Denise Kanefield filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program ("the Program"),[2] alleging that various vaccinations injured their son, Adam Jay Kanefield ("Adam").

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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 March 14, 2008, petitioners were ordered to file the statutorily required medical records. § 300aa-11(c)(2). In response, petitioners filed medical records on May 23, 2008. On July 2, 2008, respondent filed a Motion to Dismiss, arguing this case was filed after the expiration of the statute of limitations.[3] Petitioners filed a response to the Motion to Dismiss on November 6, 2008.

On September 21, 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. Petitioners failed to respond. On December 3, 2010, petitioners were again ordered to file a statement within 30 days informing the court if they wished to proceed, or otherwise show cause why this case should not be dismissed for failure to prosecute. On December 30, 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.[4]

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

[3] In relevant part, the Vaccine Act provides "in the case of…a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." § 300aa-16(a)(2). This decision does not resolve the issue of whether the instant Petition was filed within the Vaccine Act's statute of limitations. The undersigned notes, however, that the facts discussed, infra, do indicate it is likely that this case was filed after the expiration of 36 months after the occurrence of the first symptom or manifestation of onset of Adam's injury. See Cloer v. Sec'y, HHS, __ F.3d__, 2011 WL 3374302 (Fed. Cir. 2011).

[4] 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).

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, aff'd, 88 Fed. Cl. 706 (2009).[5] 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 Records[6]

Adam was born healthy with no complications on September 1, 2000. Petitioners' Exhibits ("P Ex.") A; C at 2; D at 1. He was generally a healthy baby, except for routine childhood illnesses such as upper respiratory infections. See, e.g., P Ex. E at 27, 28, 34, 36, 38. A peanut allergy was initially suspected but subsequently ruled out. P Exs. E at 26, 29; G at 4.

Adam received routine childhood vaccinations between September 8, 2000, and at least November 8, 2006. P Exs. E at 3; G at 10, 13. After receipt of MMR, varicella, and inactivated polio vaccines, Adam developed a "[b]ump in [his] groin area." P Ex. E at 27. Though the date on this page is September 14, 2001, the same day that he received these vaccinations, the pediatrician recorded that "mom noticed [it] x2 days ago," and that Adam had received "MMR/IPV in that thigh." P Ex. E at 27. It is unclear from this record whether the doctor actually thought the bump was a reaction to vaccination, but in any event the bump had cleared by Adam's December 21, 2001 visit. See P Ex. E at 28. No other adverse reaction to a vaccine or vaccines is reported or observed in the filed medical records, including to his two-month vaccines, discussed in greater detail in Part III.

[5] Petitioners in Snyder did not appeal the decision of the U.S. Court of Federal Claims.

[6] 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.

Initially Adam's speech and language development appeared to be normal. At his six-month well child visit, the pediatrician circled "turns to voice" (P Ex. E at 24), and then at his nine-month well child visit, the pediatrician circled "pre-speech sounds" (P Ex. E at 25). At fifteen months, Adam was saying "mama" and "dada" and waving. P Ex. E at 28. And at two years, Adam had 10 to 15 words and could speak in two word phrases. P Ex. E at 29.

After that, however, Adam's records indicate speech difficulties. At his three-year well child visit in September, 2003, his parents expressed concerns about Adam's "unclear speech." P Ex. E at 37. The pediatrician diagnosed "speech delay" but recommended only monitoring at that point. Id. But in October, 2004, speech delay was still of concern. P Ex. G at 3. Adam was evaluated by a speech and language specialist on February 14, 2005, but the specialist determined that Adam did not qualify for services. P Ex. H at 1-2. By August 23, 2005, a new pediatrician referred Adam for another speech evaluation. P Ex. G at 2, 7. That evaluation, conducted November 1, 2005, determined that Adam had "moderately delayed receptive and expressive language skills." P Ex. G at 27. Adam then began speech therapy. See, e.g., P Ex. G at 31.

Prompted by Adam's behavior at school, petitioners took Adam to pediatric neurologist Debra Balke, M.D., for evaluation on February 22, 2007. She determined that his presentation was "highly suggestive of a diagnosis of an autism spectrum disorder." P Ex. G at 42. Adam received a diagnosis of "Autistic Disorder, high functioning," on September 1, 2007, from Julie Daggett, Ph.D., a clinical psychologist. P Ex. K at 4.

III. Causation in Fact

In their motion for a decision on the record, as well as in prior filings, petitioners argue that Adam received a vaccine at two months of age that was not recommended by the Food and Drug Administration ("FDA"), and this vaccination caused or contributed to Adam's autism. Specifically, they allege that he received a combination of the diphtheria-tetanus-acellular pertussis vaccine and the hemophilus influenzae type B vaccine, that such a combination was not recommended for administration to children younger than 15 months of age, and that this vaccination contained more thimerosal than Adam would have received if he had received the appropriate vaccines. See, e.g., Petitioners' Response to Respondent's Motion to Dismiss, filed Nov. 6, 2008, at 2.

The medical records provide some support for their allegation that Adam received a combined DTaP and Hib vaccine—the lot numbers for those vaccines indicate the same Aventis vaccine was administered for his two-month vaccinations. P Ex. E at 3. Petitioners allege that this vaccine was TriHIBit, the brand name for a combination of DTaP and Hib manufactured by Aventis, which is now part of Sanofi. See Petitioners' Narrative of Case, filed May 23, 2008, with P Exs. A-L. Petitioners report conversations they had with the staff at their pediatrician's office as well as phone

calls they placed to the Centers for Disease Control, a "National Immunization Program," and "UCSF." P Ex. F at 1. According to petitioners, they were advised that as a consequence of this administration, Adam possibly developed insufficient immunity to Hib, and he should receive a fifth Hib vaccine instead of the typical four to ensure immunity. See P Ex. F at 1-2. The records indicate Adam received a fifth Hib vaccine, supporting this allegation. See P Ex. E at 3, 28.

If the vaccine that Adam received was TriHIBit, petitioners are correct that it is only recommended for administration of the fourth doses of DTaP and Hib, given at approximately 15 months of age. See Haemphilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) ActHIB Package Insert and Patient Information, Sanofi Pasteur, May 6, 2009, at pp. 6-7, 12, 21, available at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM109841.pdf.[7] The manufacturer advises that "clinical trials in infants younger than 15 months of age have indicated that [TriHIBit] may induce a lower immune response to the Hib vaccine component than [Hib] given separately," and that TriHIBit "should NOT be used in infants for the first three doses" for this reason. Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine [Absorbed] Tripedia Package Insert and Patient Information, Sanofi Pasteur, December 2005, at 6, available at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM101580.pdf (emphasis original).

While it is not a certainty that Adam received TriHIBit, it is not necessary to make that determination. The critical point is that even if petitioners did establish this factual predicate, their allegations that they were advised that Adam may have developed insufficient immunity due to receipt of TriHIBit **does not support** their claim that TriHIBit caused or contributed to Adam's autism.

Petitioners appear to attempt this linkage by contending that it was the additional thimerosal that Adam received that caused his injury, seeking to distinguish his case from the test cases that rejected a causal link between thimerosal and autism. In so alleging, petitioners presumably rely on the amount of thimerosal Adam received from TriHIBit that would have been in excess to the amount of thimerosal he would have received from separate DTaP and Hib vaccines, as well as the amount of thimerosal he received in his fifth dose of Hib.

However, there is no evidence in the record documenting how much thimerosal TriHIBit contained in 2000. The Physicians' Desk Reference entry for TriHIBit notes that both Tripedia and ActHIB contained thimerosal prior to the 2001 removal, but does not specify in what amounts. See Physicians' Desk Reference 2340-45 (53rd ed. 1999). The Institute of Medicine report on thimerosal in vaccines reports that separately, the DTaP and Hib vaccines each contained 25 micrograms of thimerosal at this time. Institute of Medicine, Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders, 27, 29 (2001).[8] If Adam had been

[7] This product information sheet explains that TriHIBit is formulated when ActHIB, a Hib vaccine, is reconstituted with Tripedia, a DTaP vaccine.

[8] Respondent filed this report into the OAP record.

vaccinated according to the recommended schedule, he would have received both DTaP and Hib, as separate vaccines, during this two month well-child visit. And although Adam then received a fifth dose of Hib, which could have contributed an additional 25 micrograms of thimerosal to Adam's system at the age of 15.5 months, petitioners have submitted no evidence indicating that such an amount would lead to results different than those in the second theory test cases. See, e.g., Dwyer, 2010 WL 892250, at *167 (concluding that there was no reliable evidence that thimerosal-containing vaccines contribute "more than miniscule levels" of mercury in the brain).[9]

To receive compensation under the Program, petitioners must prove either 1) that Adam suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Adam 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 Adam suffered a "Table Injury." Further, the record does not contain a medical opinion or any other persuasive evidence indicating that Adam'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. Petitioners' assertions that Adam was improperly vaccinated and injected with excessive thimerosal are mere allegations unsupported by the record. Critically, even if supported by the record, there is no medical opinion opining to the cause and effect. 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 diphtheria, tetanus, accellular 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 Fescano v. Sec'y,HHS, __ Fed. Cl. __, 2011 WL 1891701 (2011) (affirming another special master's ruling in similar circumstances).

[9] In the slip version of this decision provided on the U.S. Court of Federal Claims website, this discussion may be found at page 260. See http://www.uscfc.uscourts.gov/node/5026.

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