

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS  
No. 08-496  
Filed: August 30, 2011**

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TAMMY RENEE CONNER and DAVID \*  
LEWIS CONNER, in their own right and \*  
as best friends of Savannah Nicole \*

Petitioners,

v.

SECRETARY OF HEALTH \*  
AND HUMAN SERVICES, \*

Respondent. \*

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

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**DECISION<sup>1</sup>**

**Vowell**, Special Master:

On July 9, 2008, Tammy Renee Conner and David Lewis Conner ["petitioners" or "Mrs. and Mr. Conner"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> [the "Vaccine Act" or "Program"], on behalf of their daughter Savannah Nicole Conner ["Savanah"]. The petition alleged that Savanah suffered "neurological disorders which first manifested themselves after September 1, 2005, when Savanah was 14 months old and at that time the autistic signs began to appear." Petition at 1. Petitioners filed an amended petition on January 21, 2009. The amended petition asserts that Savanah developed

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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.

<sup>2</sup> 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).

normally until she was about 18 months old, other than frequent ear infections and concerns about her hearing. Amended Petition at 2. A hearing to determine the facts surrounding the onset and nature of Savannah's symptoms was held on April 19, 2011. I issued an order setting forth my conclusions on July 26, 2011.

The amended petition is currently the operative claim for compensation pending before this court. On July 9, 2010<sup>3</sup> and again on July 26, 2011, I ordered petitioners to file a second amended petition setting forth their current theory, which now appears to be "an injury due to the effect of a vaccine or vaccines on an underlying mitochondrial disorder." Pet. Post-hearing Br. at 1.

Petitioners failed to respond to my July 26, 2011 Order, and on August 26, 2011, I issued an order to show cause why this case should not be dismissed. In response, petitioners filed a motion for a ruling on the record in this case as it now stands. Because the evidence does not establish entitlement to an award under the Program, this case is dismissed.

### **I. The Omnibus Autism Proceeding.**

This case was 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 disorders" ["ASD"] were caused by one or more vaccinations.<sup>4</sup> A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the Omnibus Autism Program ["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.<sup>5</sup>

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<sup>3</sup> This order was precipitated by a status conference in which petitioners' counsel represented that Savannah did not have an autism spectrum disorder as had been previously alleged, but instead suffered from an as-yet undiagnosed condition. See Order, filed July 9, 2010. Petitioners ignored this order, resulting in a order directing petitioners to show cause why their case should not be dismissed. See Order, filed September 30, 2010. Petitioners responded by filing a statement concerning Savannah's "mitochondrial issues," a letter from a treating physician, and a number of medical journal articles concerning mitochondrial disorders, oxidative stress, and autism.

<sup>4</sup> Petitioners specifically requested that "this matter be included within the Omnibus Autism Claims" in their amended petition. Amended Petition, ¶ 9.

<sup>5</sup> The Theory 1 cases alleged that the measles portion of the measles, mumps, rubella ["MMR"] vaccine could cause ASDs ["Theory 1"]. That theory was presented in three separate test cases during several weeks of trial in 2007. See *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 second theory alleged that the mercury in thimerosal-containing vaccines could directly affect an infant's brain, thereby substantially contributing to the causation of ASD ["Theory 2"]. That theory was presented in three additional test cases during several weeks of trial in 2008. See *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).

Decisions in each of the three Theory 1 test cases 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).<sup>6</sup> Decisions in each of the three Theory 2 test cases 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 the test cases are concluded.

Petitioners in this case appeared to rely on Theory 2, at least initially. The original petition alleged that Savannah was “a member of a subset of individuals who are the subjects of injury from vaccines. . . . due to an adverse reaction to one or more vaccines administered during the first 12 months of her life . . . . These vaccines, either singly or in combination, alone, or in combination with trace mercury based preservatives in some of the vaccines and mercury based preservatives in others, or that preservative alone, resulted in [her] neurological deterioration.” Petition, ¶ 9.

The amended petition did not specify a theory, contending only that her autism spectrum disorder was “caused by vaccines administered in her first years of life.” Amended Petition at 1. However, by opting into the Omnibus Autism Program [“OAP”] (see Amended Petition, ¶ 9), petitioners were, in effect, alleging that either Theory 1 or Theory 2, or both, applied to Savannah's case. (Autism General Order 1, 2002 WL 31696785 at \*4, 2002 U.S. Claims LEXIS 365 at \*11 (Fed.Cl. Spec. Mstr. July 3, 2002)).

Although not set forth in an amended petition, petitioners now contend that Savannah suffers from an undiagnosed condition, probably mitochondrial in nature, and that the vaccines she received aggravated this disorder, producing symptoms similar to an ASD.

## **II. The Relevant Medical History.**

I have previously set forth factual findings pertaining to the onset and nature of Savannah's symptoms. See Order, filed July 26, 2011. The findings and discussion of the medical records and petitioners' testimony contained in that Ruling are hereby incorporated into this decision.

In summary, I found that, contrary to petitioners' allegations and testimony, that there was no reliable evidence that Savannah experienced any adverse reactions to any vaccinations received during her first year of life. She received a formal diagnosis of Pervasive Developmental Disorder—Not Otherwise Specified [“PDD-NOS”] from a clinic at the University of Iowa on January 12, 2007, when she was two and one half years of

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<sup>6</sup> Petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

age, but had been receiving early intervention services for speech delay for about six months at the time of her diagnosis.

Although petitioners now assert that Savannah suffers from a mitochondrial disorder, the medical records do not reflect such a diagnosis. At best, they establish that treating physicians are exploring the likelihood of such a diagnosis.

### III. Failure to Establish Vaccine Causation

Under the Vaccine Act, the petitioner bears the burden of proving a vaccine-caused injury. There are two ways causation may be demonstrated. First, a petitioner may establish a “Table”<sup>7</sup> injury. Alternatively, a petition may prove that a vaccine listed on the Table actually caused or significantly aggravated an injury (an “off-Table” injury).

Petitioners have not alleged a Table injury, and are proceeding on a cause-in-fact claim. To establish causation in an off-Table injury case, a petitioner must show preponderant evidence of “(1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). See §§ 300aa-11(c)(1)(C)(ii); 300aa-13(a).

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. Petitioners did not file any additional evidence on whether vaccines can cause ASDs nor did they provide any persuasive evidence addressing the effect of vaccines on an underlying mitochondrial disorder.<sup>8</sup>

Under the Vaccine Act, a special master cannot find a petitioner has proven his case by a preponderance of the evidence based upon “the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a)(1). Petitioner is “required to substantiate [this claim] with independent evidence.” *Lett v. Sec’y, HHS*, 39 Fed. Cl. 259, 262 (1997). Failure to substantiate a claim will result in dismissal. See *Tsekouras v. Sec’y, HHS*, 26 Cl. Ct. 439 (1992), *aff’d per curiam*, 991 F.2d 810 (Fed. Cir. 1993); *Sapharas v. Sec’y, HHS*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b).

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<sup>7</sup> See § 300aa-11(c)1(C); 42 C.F.R. § 100.3 (2010).

<sup>8</sup> Petitioners did file some medical articles pertaining to a possible connection between mitochondrial disorders and vaccinations producing symptoms resembling ASD. This evidence is unpersuasive for several reasons. First, there is no reliable evidence that Savannah actually has a mitochondrial disorder. Testing to date has been negative. Second, although some of the filed articles suggest that children with mitochondrial disorders react poorly to vaccines, there is no reliable evidence that Savannah experienced any vaccine reactions. Finally, no qualified physician has opined that Savannah’s condition, whatever its nature, was caused by any vaccine.

Accordingly, it is clear from the record in this case that petitioners have failed to demonstrate that Savannah's condition, whether it is an ASD or aggravation of an underlying mitochondrial disorder, was caused-in-fact by a vaccination. **Thus, this case is dismissed for insufficient proof. The clerk shall enter judgment accordingly.**

**IT IS SO ORDERED.**

**s/Denise K. Vowell**  
**Denise K. Vowell**  
Special Master