

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

E-Filed: July 11, 2012

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PETE SARULLO and MELINDA SARULLO, as legal representatives for their minor daughter, SOPHIA ISABELLA SARULLO,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Respondent.

\* \* \* \* \*

UNPUBLISHED

**No. 01-0604V**

Autism; Decision on the Record; Thimerosal-Containing Vaccines; Prader-Willi Chromosomal Marker Discovered during Genetic Testing

Peter H. Meyers, Washington, D.C., for petitioners.

Lynn E. Ricciardella, United States Department of Justice, for respondent.

## DECISION<sup>1</sup>

On October 18, 2001, Pete and Melinda Sarullo (petitioners) filed a petition pursuant to the National Vaccine Injury Compensation Program (the Program),<sup>2</sup> on

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<sup>1</sup> Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this ruling 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.

behalf of their daughter, Sophia Isabella (Isabella). The Sarullos filed an amended petition on February 25, 2011, alleging that the mercury component of the vaccine preservative thimerosal in certain vaccines administered to Isabella acted in concert with Isabella's underlying genetic condition to cause "neurological injuries, developmental delay, autism and behavioral regression." Amend. Pet. at 1, ¶ 24. Isabella received the vaccines at issue on July, 20 1998, October 20, 1998, February 22, 1999, August 19, 1999, and March 16, 2005.<sup>3</sup> Petitioners allege that certain other vaccines received in 1998 and 1999 significantly aggravated Isabella's injuries. Amend. Pet. at 1-2.

## **I. Development of the Record**

Petitioners filed Exhibits 1-20 with the petition in 2001, and filed additional medical records on April 18, 2002, specifically Exhibits 21-23. Approximately two months later, on June 19, 2002, petitioners filed a status report indicating that all medical records had been filed.

Petitioners were afforded a generous opportunity to identify an expert. Between July 18, 2002 and April 1, 2004, petitioners were granted seven enlargements of time within which to file an expert report. Periodic status conferences were conducted with the parties to learn more about petitioners' efforts to obtain an expert report.

On May 17, 2004, petitioners asked to stay their case during the course of the Omnibus Autism Proceedings (OAP).<sup>4</sup> Petitioners anticipated that the merits of their claim would be informed by the outcome of the OAP inquiry into whether a causal relationship existed between thimerosal-containing vaccinations and autism spectrum disorders. See Notice Regarding "Omnibus Autism Proceeding," May 24, 2004.

The last of the OAP "test cases" became final in 2010. By order dated January 31, 2011, petitioners were advised of the OAP test case decisions; petitioners also were advised to file an amended petition if they desired to proceed with their vaccine claim.

On February 25, 2011, petitioners filed an amended petition reiterating their request for compensation, arguing that their claim was distinguishable from the OAP test cases. Amend. Pet. ¶ 25. Petitioners reasoned that they were not alleging, as had been

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<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).

<sup>3</sup> Petitioners have not filed any additional medical records since April 18, 2002, and thus, have not filed the March 16, 2005 record of vaccination.

<sup>4</sup> The OAP is described more fully in Section II of this decision.

claimed in the test cases, that “thimerosal directly caused [Isabella’s] autism.” Id. Instead, they sought Program compensation on the ground that Isabella’s underlying genetic condition prevented her from properly disposing of the mercury-containing thimerosal introduced by her vaccines. Id.

Petitioners again undertook efforts to retain an expert after the case stay was lifted. Petitioners filed a status report on April 16, 2012 requesting more time to identify an expert witness. Petitioners moved for another extension of time to file their expert report on May 3, 2012. Nearly 45 days later, on June 17, 2012, petitioners moved for a ruling on the record, without filing an expert report.

## **II. 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 more than 5,000 petitions filed in this court, was set forth in six entitlement decisions issued by three special masters as test cases for two theories of causation litigated in the OAP.

Ultimately, the Petitioners’ Steering Committee (PSC), an organization formed by attorneys representing petitioners in the OAP, litigated the six test cases involving two different theories on the causation of ASDs. Relevant to this ruling on the record are two of the issues that were evaluated during the OAP. The second theory considered during the OAP was whether the mercury content in thimerosal-containing vaccines could adversely affect an infant’s brain, and thereby cause the development of an ASD. Dwyer v. Sec’y of Health and Human Servs., 2010 WL 892250 (Fed. Cl. Mar. 12, 2010); King v. Sec’y of Health and Human Servs., 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); and Mead v. Sec’y of Health and Human Servs., 2010 WL 892248 (Fed. Cl. Mar. 12, 2010). Also considered as an aspect of the first theory petitioners presented during the OAP was whether certain individuals have a genetic hypersusceptibility to the effect of mercury. Hazlehurst v. Sec’y of Health and Human Servs., 2009 WL 332306 (Fed.Cl. Feb. 12, 2009); Cedillo v. Sec’y of Health and Human Servs., 2009 WL 331968 (Fed. Cl. Feb. 12, 2009); and Snyder v. Sec’y of Health and Human Servs., 2009 WL 332044 (Fed. Cl. Feb. 12, 2009). Neither of these postulates was found to be supported by reliable evidence.

Because the decisions in the test cases rejected the causation theories proposed here by petitioners, petitioners must now present previously unconsidered evidence in support of their offered theories of causation or pursue new theories. Without filing any more evidence, petitioners have chosen to seek a ruling on the record.

### III. The Medical Records

Isabella was born on May 11, 1998, weighing six pounds and twelve ounces. Pet'rs' Ex. 1. She was discharged home on May 13, 1998, with a diagnosis of jaundice. Pet'rs' Ex. 3 at 2.

Isabella received routine childhood vaccinations. On the day of her birth, Isabella received her first vaccine of Hepatitis B (Hep B). Pet'rs' Ex. 7. When she was just over two months old, on July 20, 1998, she received vaccinations for Diphtheria-Tetanus-acellular Pertussis (DTaP), Hemophilus Influenza Type B (HIB), Polio (IPV), and a second administration of the Hep B vaccine. Id. At five months of age on October 20, 1998, Isabella received a second administration of the DTaP, HIB, and IPV vaccines. Id. Petitioners contend that the administered Hep B, HIB, and DTaP vaccines were responsible for causing Isabella's "neurological injury and seizure disorder" which, in turn, led to her "development of autism." Amend. Pet. ¶ 24.

On December 3, 1998, petitioners took Isabella to a pediatric neurologist to evaluate her infantile spasms. Pet'rs' Ex. 9 at 1. The neurologist advised petitioners to avoid any further pertussis vaccines due to Isabella's "evolving neurological process." Id. at 3.

On May 22, 1999 and August 19, 1999, Isabella received administrations of the DT vaccine, a formulation that does not have a pertussis component. Pet'rs' Ex. 7. Isabella also received administrations of the HIB vaccine and Hep B vaccine on February 22, 1999, as well as administrations of the IPV, HIB, and Measles-Mumps-Rubella (MMR) vaccines on August 19, 1999. Id. Petitioners allege that the administered IPV and MMR vaccines significantly aggravated Isabella's injuries. Amend. Pet. ¶ 23.

As recorded in a November 28, 1998 medical history, Isabella contracted an upper respiratory infection around the beginning of November. Pet'rs' Ex. 22 at 50. An earlier dated record seems to address the same infection, indicating that on October 30, 1998, Isabella had a temperature of 101 and was prescribed the antibiotic amoxicillin.<sup>5</sup> Pet'rs' Ex. 20 at 3. Shortly after her infection cleared, Isabella began to have regular episodes involving the widening of her eyes, the extension of her arms and legs, and the stiffening of her entire body. Pet'rs' Ex. 22 at 50. An increase in the frequency of these episodes prompted petitioners to take Isabella to the hospital for an evaluation in November of

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<sup>5</sup> "Amoxicillin is used to treat certain infections caused by bacteria, such as pneumonia; bronchitis; gonorrhea; and infections of the ears, nose, throat, urinary tract, and skin." U.S. National Library of Medicine, PubMed Health, Amoxicillin, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000837/> (last reviewed Sept. 1, 2010).

1998. Id. Isabella spent several days there. Id. She was discharged with a diagnosis of infantile spasm syndrome. Id.

Following her hospital discharge, Isabella was treated with the anticonvulsant ACTH<sup>6</sup> to manage her spasms; Isabella's spasms significantly decreased after she began receiving injections, but she became less alert mentally. Pet'rs' Ex. 22 at 50, Pet'rs' Ex. 5 at 1, Pet'rs' Ex. 9 at 2. During an evaluation on December 3, 1998, the examining neurologist noted developmental regression. Pet'rs' Ex. 9 at 4.

As documented in the interview records dated December 1998 of another pediatric neurologist, petitioners reported that Isabella was developing more slowly than their other children. Pet'rs' Ex. 5 at 1. But Isabella's treating pediatrician found her development at that time still within the normal range. Pet'rs' Ex. 4.

In meetings with other doctors, petitioners noted that Isabella had shown visual attention problems since birth. Pet'rs' Ex. 21 at 18, Pet'rs' Ex. 10 at 1. Petitioners reported that Isabella was never able to make eye contact and focused elsewhere instead. Pet'rs' Ex. 10 at 1. In September of 1998, petitioners began to notice that Isabella's eyes occasionally wandered outward. Pet'rs' Ex. 5 at 1. On October 26, 1998, petitioners took Isabella to see an ophthalmologist who diagnosed her with the eye conditions of amblyopia<sup>7</sup> and exotropia.<sup>8</sup> Pet'rs' Ex. 8 at 2.

As part of the evaluation and treatment of Isabella's infantile spasms, she underwent genetic testing and chromosomal analysis in December of 1998. Pet'rs' Ex. 9 at 4, Pet'rs' Ex. 11. Genetic testing revealed that Isabella has an additional chromosome formed from "two copies of the pter->q13 segment of chromosome 15." Pet'rs' Ex. 11. This type of chromosomal abnormality is associated with Prader-Willi/Angelman syndrome, a condition marked by particular developmental abnormalities. See Pet'rs' Ex. 11; Robert M. Kliegman et. al., Nelson Textbook of Pediatrics 412-13 (19th ed. 2011).

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<sup>6</sup> ACTH, also known as a "repository corticotropin injection," is a "gel form" of a manufactured hormone administered subcutaneously or intramuscularly for the treatment of infantile spasms. Dorland's Illustrated Medical Dictionary, 941 (32nd ed. 2012). It has prolonged effects. Id.

<sup>7</sup> Amblyopia is an "impairment of vision due to abnormal development, [that occurs] without [a] detectable organic lesion of the eye." Dorland's at 58.

<sup>8</sup> Exotropia is a condition where "there is permanent deviation of the visual axis of one eye away from that of the other eye." Dorland's at 661.

After petitioners received the results of Isabella’s genetic testing, they were referred to Dr. Hans-Georg Bock for further evaluation and counseling. Pet’rs’ Ex. 10 at 1. Dr. Hans-Georg Bock explained to the Sarulloos that Isabella’s chromosomal abnormality presented a “very high risk of . . . moderate to severe mental retardation, seizures, autistic features, [impaired] growth, and other [characteristic] abnormalities.” Id.

In March of 2001, Isabella received a diagnosis of autism. Pet’rs’ Ex. 17 at 2. Petitioners claim that the genetic abnormality in Isabella’s “15th chromosome prevented her from eliminating the mercury containing thimerosal” she received from certain vaccinations and thereby, resulted in a seizure disorder and neurological injury that led to “the development of autism.” Amend. Pet. ¶ 24. Petitioners further claim that the “administration of Polio and MMR vaccines in 1998 and 1999” significantly aggravated Isabella’s neurological injuries. Id. at ¶ 23.

#### **IV. Causation in Fact**

To receive compensation under the Program, petitioners must prove either: (1) that Isabella suffered a “Table Injury”—that is, an injury falling within the Vaccine Injury Table—corresponding to one of her vaccinations; or (2) that Isabella suffered an injury that was caused in fact by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Because autism is not listed on the Vaccine Table, petitioners must show that the vaccinations Isabella received caused her condition. Fesanco v. Sec’y of Health and Human Servs., 99 Fed. Cl. 28, 33 (2011); see also Hazelhurst v. Sec’y of Health and Human Servs., 604 F.3d 1343, 1349 (Fed. Cir. 2010).

Petitioners may not receive a Program award based solely on their claims alone. Rather, the petition must be supported by either the medical records or the opinion of a competent physician. § 300aa-13(a)(1). In this case, the medical records supporting petitioners’ claim are insufficient, and petitioners have offered no medical opinion in support of their causation theory.

Moreover, the evidence adduced in the OAP test cases does not support petitioners’ theory of vaccine-related causation. To the contrary, the OAP evidence indicates that a genetic inability to eliminate mercury derived from administered vaccines is an unlikely cause of autism. See Mead v. Sec’y of Health and Human Servs., 2010 WL 892248 at \*56-63 (examining the theory that certain people have an inborn inability to remove mercury from their body and finding the postulate not to be a scientifically reliable one).

Here, petitioners have not filed an expert report or other evidence to support their theory. Nor have petitioners filed any evidence regarding how the IPV and MMR vaccines might have significantly aggravated Isabella’s injuries. Lacking either a

medical opinion or persuasive evidence indicating that Isabella’s autism was caused by or significantly aggravated by the vaccines she received, the record in this case fails to establish that Isabella suffered a “Table Injury” or that her injuries were caused in fact by her vaccinations. **This case must be dismissed for insufficient proof. The Clerk of the Court is directed to enter judgment accordingly. Entry of judgment may be expedited by the filing of a joint notice not to seek review.**

**IT IS SO ORDERED.**

s/ Patricia E. Campbell-Smith  
Patricia E. Campbell-Smith  
Chief Special Master