

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS  
No. 08-220V  
Filed: September 12, 2011  
Not to be Published**

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Matthew Anthony Clark Starita, a minor, \*  
by his parents and natural guardians, \*  
PAUL LAWRENCE STARITA and \*  
MARY ELIZABETH STARITA, \*

Petitioners, \*

v. \*

SECRETARY OF HEALTH \*  
AND HUMAN SERVICES, \*

Respondent. \*

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

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

**Golkiewicz**, Special Master:

On March 28, 2008, petitioners Paul Lawrence Starita and Mary Elizabeth Starita filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation

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 Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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

Program (“the Program”),<sup>2</sup> alleging that various vaccinations injured their son, Matthew Anthony Clark Starita (“Matthew”).<sup>3</sup>

On April 4, 2008, petitioners were ordered to file the statutorily required medical records. § 300aa-11(c)(2). In response, petitioners filed medical records on July 24, 2008. On September 8, 2008, also pursuant to the undersigned’s April 4, 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 involves an autism spectrum disorder.

On September 22, 2010, petitioners were informed that the OAP test cases had been decided, and they 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 of Continuation to Supplement Record, indicating their intent to file documentation of recent testing and reports of a metabolic disease diagnosis. Petitioners further indicated that after supplementing the record, they would request a ruling on the record.

On March 11, 2011, petitioners were ordered to file the supplemental records. On May 9, 2011, petitioners filed an additional exhibit containing medical records. Petitioners’ Exhibit (“P Ex.”) 48. They also filed a motion requesting that this case be decided on the record as it now stands (“P Mot.”). In their motion, petitioners contend that Matthew had a preexisting condition that made him more vulnerable to vaccine injury, and they further contend that receipt of the MMR vaccine on September 1, 2004 caused brain injury, ultimately diagnosed as autism. On May 19, 2011, respondent filed a response to this motion, arguing that petitioners had failed to demonstrate that the MMR vaccine caused Matthew’s condition. Because the information in the record does not show entitlement to an award under the Program, this case is dismissed.

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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 filed a “Short-Form Autism Petition for Vaccine Compensation,” a form developed for the filing of claims alleging that vaccines caused autism spectrum disorders. The Short-Form Petition adopts the allegations made in the Master Autism Petition for Vaccine Compensation, authorized by Autism General Order 1, issued by the undersigned on July 3, 2002. The Master Petition alleges that as a result of either the measles, mumps, rubella vaccine (“MMR”), thimerosal-containing vaccines, or both, a vaccinee developed autism. In a more recent filing, petitioners in this case narrowed their causation theory to focus solely on Matthew’s receipt of the MMR vaccine on September 1, 2004. See Petitioner[s] Motion for Ruling on the Record, filed May 9, 2011.

## 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.<sup>4</sup>

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 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).<sup>5</sup> 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.

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<sup>4</sup> 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).

<sup>5</sup> Petitioners in Snyder did not appeal the decision of the U.S. Court of Federal Claims.

## II. The Medical Records<sup>6</sup>

Matthew was born healthy on August 6, 2002, with Apgar scores of 8 and 9. P Ex. 1; P Ex. 3. Matthew received recommended childhood vaccines between October 11, 2002, and at least September 13, 2005. P Ex. 2. In his first two years, Matthew was relatively healthy, but experienced typical childhood illnesses such as upper respiratory infections (see, e.g., P Exs. 10; 11; 19), and he also fractured his right arm (P Ex. 16).

Matthew received the MMR vaccine, on which petitioners base their causation theory, on Sept 1, 2004. P Exs. 2; 23. At that visit, Matthew's pediatrician noted that Matthew was "doing great." P Ex. 23. There is no subsequent report or observation of any adverse reaction to this vaccine.<sup>7</sup>

Matthew's next pediatric visit appearing in the record occurred on April 11, 2005, seven months following his immunization. P Ex. 24 at 1. This was a sick visit; Matthew presented with a chief complaint of vomiting since the night before. The pediatrician noted that Matthew was "awake [and] alert" as well as "well hydrated." Id. Later that day, petitioners took Matthew to the Emergency Department of Children's Hospital and Health Center in San Diego, California ("Children's Hospital"). The history noted that Matthew continued to vomit throughout the day and had developed a fever. P Ex. 24 at 2. Matthew's treating physicians were concerned that his presentation, as well as his sister's diagnosis of maple syrup urine disease ("MSUD"), a metabolic disorder, indicated Matthew might also have MSUD. Id. The physician observed a change in Matthew's mood and alertness, and also noted that Matthew had been given a drug at his pediatrician's office that would have made him sleepy. P Ex. 24 at 2. Matthew was lethargic even after the drug wore off. Id. at 33. After two days, Matthew was discharged with a diagnosis of "viral gastroenteritis" (P Ex. 24 at 37); he had tested positive for rotavirus (P Ex. 24 at 14, 38).

Testing to detect MSUD during Matthew's April, 2005, hospitalization found no signs of the disorder. See P Exs. 24 at 38; 33 at 28. When Matthew experienced similar symptoms and hospitalization in December, 2005, he was again tested for MSUD. P Ex. 33 at 28.<sup>8</sup> The results of that testing were not filed into the record, but genetic testing results from 2010 indicate Matthew does not have the genetic mutations characteristic of MSUD. See P Ex. 48 at 2, 6. Matthew's metabolic specialist, William

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<sup>6</sup> 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.

<sup>7</sup> In addition, medical records contain no report of adverse reactions to any vaccines. On August 8, 2003, it appears the pediatrician withheld one vaccine, but administered two others, noting "caused extreme irritable" next to the withheld vaccine, Prevnar, a pneumococcal conjugate. P Ex. 14. Matthew had received this vaccine before, on February 7, 2003. See P Ex. 2. This notation suggests that the pediatrician may have attributed prior irritability to receipt of Prevnar. This falls short of supporting petitioners' allegations here, however, as petitioners' do not base their theory on receipt of Prevnar or on injury in the form of irritability. Matthew later received a second pneumococcal vaccination on February 11, 2004. P Ex. 2.

<sup>8</sup> This record also indicates Matthew was tested for MSUD on December 31, 2004, and the results were negative. See P Ex. 33 at 28. Those results were not filed into the record.

Nyhan, M.D., nonetheless “believe[s] this is MSUD of attenuated form” and advised the Staritas to continue a treatment regiment for the disorder. P Ex. 48 at 6.

The records first indicate the Staritas were concerned with Matthew’s development at a pediatric visit on July 15, 2005. His parents expressed concern about Matthew’s speech, and the pediatrician referred him for further evaluation. P Ex. 25. Matthew was then evaluated on September 7, 2005, at Children’s Hospital’s Developmental Evaluation Clinic. The evaluator, Renee Barbieri-Welge, Ph.D., confirmed Matthew’s speech delay, but concluded that although “Matthew is showing some features of Pervasive Developmental Disorder, [he] is not meeting full criteria for a formal diagnosis of Pervasive Developmental Disorder Not Otherwise Specified.” P Ex. 28 at 6. A speech and language evaluation on October 18, 2005, confirmed Matthew had a “severe receptive language disorder” and a “moderate expressive language disorder.” P Ex. 31 at 4. Matthew began services responsive to his possible ASD soon after these evaluations, and he received a confirmed ASD diagnosis in 2008. P Ex. 45 at 14.

No treating physician has opined in the filed records that the MMR vaccine, or any other vaccine, caused or contributed to Matthew’s current condition. No treating physician has opined in the filed records that MSUD, or any other underlying condition, made Matthew more susceptible to a vaccine injury.

### III. Causation in Fact

To receive compensation under the Program, petitioners must prove either 1) that Matthew suffered a “Table Injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Matthew suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); see also *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (setting forth a three-prong test for causation in fact). An examination of the record did not uncover any evidence that Matthew suffered a “Table Injury.”

The record also does not contain a medical opinion or any other persuasive evidence indicating that Matthew’s autism spectrum disorder was vaccine-caused. The evidence produced in the OAP test cases does not support petitioners’ allegation that the MMR vaccine can cause ASD; rather it indicates that the MMR vaccine is unlikely to cause ASD. See also Institute of Medicine, *Adverse Effects of Vaccines, Evidence and Causality* 112-15 (2011) (rejecting a casual relationship between MMR vaccine and autism). Petitioners allege that “Matthew had a preexisting condition, a metabolic disease, which made him more vulnerable to vaccine injury.” P Mot. at 3. While one of Matthew’s treating physicians believes that Matthew has MSUD, repeated testing has failed to confirm this diagnosis. Without more information from this treating physician, or another doctor qualified to opine, the undersigned cannot conclude that petitioners have established by a preponderance of the evidence that Matthew had a preexisting metabolic disease. Even if petitioners did establish Matthew had a preexisting metabolic disease, they have submitted no evidence demonstrating that it can make a vaccinee more vulnerable to vaccine injury. They have also submitted no evidence demonstrating it did so in Matthew’s case. Finally, they have submitted no evidence that the seven to ten months between Matthew’s receipt of MMR in September, 2004,

and the symptoms observed in April, 2005, and July, 2005, is a medically-accepted time frame for the MMR vaccine to cause these problems.

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 the review of the record in this case that petitioners have failed to demonstrate either that Matthew 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.**

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**Gary J. Golkiewicz**  
Special Master