

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS  
No. 08-0448V  
Filed: September 12, 2011  
Not to be Published**

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STEVEN P. PYRDECK and TANYA  
L. PYRDECK, parents of Connor J.  
Pyrdeck, a minor,

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

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

**Golkiewicz**, Special Master:

On June 17, 2008, Steven P. Pyrdeck and Tanya L. Pyrdeck filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program (“the Program”),<sup>2</sup> alleging that various vaccinations injured their son, Connor J. Pyrdeck (“Connor”). Specifically, petitioners allege that on June 16, 2005, Connor received a

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 Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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

<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).

pneumococcal conjugate vaccine, a measles-mumps-rubella (“MMR”) vaccine, and a varicella vaccine, and that these vaccines caused Connor’s autism. Petition at 1.

On June 24, 2008, petitioners were ordered to file the statutorily required medical records. § 300aa-11(c)(2). In response, petitioners filed medical records on July 10, 2008.<sup>3</sup> Petitioners then filed a statement regarding onset on August 28, 2008 (“P Statement”), and additional records on February 23, 2009. On April 8, 2009, also pursuant to the undersigned’s June 24, 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 involved an autism spectrum disorder.

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 29, 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.<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

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<sup>3</sup> It appears petitioners filed these medical records with the Petition in June 2008. Nevertheless, they were formally filed into the record on July 10, 2008.

<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).

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.

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

Connor was born prematurely at 34-5/7th weeks on March 29, 2004. Petitioners' Exhibit ("P Ex.") 1; P Ex. 2 at 1. He was delivered via cesarean section because of complications due to a maternal history of neonatal death,<sup>7</sup> methylenetetrahydrofolate reductase ("MTHFR") deficiency,<sup>8</sup> and oligohydramnios.<sup>9</sup> P Ex. 6 at 23, 34. Connor's Apgar scores were 8 and 9, but his prematurity, along with respiratory and feeding problems, kept him hospitalized for eleven days. P Ex. 2 at 1-2.

Early on, Connor experienced normal childhood illnesses such as upper respiratory infections (see P Ex. 2 at 33, 35, 38) and he also developed food allergies (id. at 31, 32, 33, 37), eczema (id. at 31, 38), and a staph infection (id. at 36). Connor continued to have feeding problems. At fourteen months, he would not feed himself or

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

<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> The Pyrdecks' first child was born prematurely at 34 weeks and died at 1 day of age, etiology unknown. P Ex. 2 at 1; P Ex. 6 at 23.

<sup>8</sup> After the death of her first child, Mrs. Pyrdeck underwent genetic testing that revealed a MTHFR mutation. P Ex. 2 at 1. MTHFR deficiency is a defect in folate metabolism that can damage the central nervous system. Dorland's Illustrated Medical Dictionary 1171 (31st ed. 2007). Mrs. Pyrdeck took folic acid and baby aspirin during her pregnancy with Connor to counteract the effects of this deficiency. P Ex. 2 at 1.

<sup>9</sup> Oligohydramnios is the presence of less than the normal amount of amniotic fluid. Dorland's Illustrated Medical Dictionary 1338 (31st ed. 2007).

drink from a cup, and his pediatrician noted that Connor was a “poor eater.” P Ex. 2 at 25. His food allergies may have exacerbated this problem, as they appeared to cause numerous bouts of vomiting and diarrhea. See P Ex. 2 at 33, 37.

Connor received routine childhood immunizations from March 30, 2004, through at least September 28, 2005. P Ex. 3 at 60-61.<sup>10</sup> The records contain no report or observation of an adverse reaction to a vaccine or vaccines, though Connor’s pediatrician withheld an influenza vaccination due to Connor’s egg allergy.<sup>11</sup> P Ex. 2 at 19.

On June 16, 2005, Connor received pneumococcal conjugate, MMR, and varicella vaccinations at his pediatrician’s office. P Ex. 2 at 25; P Ex. 3 at 60. At that time, Connor’s language, motor skills, and social skills were found to be age appropriate. P Ex. 2 at 25. The pediatrician noted that Connor was “irritable” and that he had “3-5 word[s].” Id. Connor was either then seen by his pediatrician, or his pediatrician consulted with the petitioners telephonically, on June 20, July 12, July 25, and July 28, 2005. P Ex. 2 at 27. He was then seen by his pediatrician on August 15, August 20, August 31, and September 3, 2005. P Ex. 2 at 21, 26. The records of these consultations contain no notes regarding a reaction to the June 16th vaccinations or any changes in Connor’s behavior and development. P Ex. 2 at 21, 26-27. However, petitioners allege that on July 1, 2005, “we began to notice changes in Connor’s actions. Over the next few weeks, Connor began to avoid eye contact, and would walk in continuous circles without deviation. He would fixate on his hands and fingers, additionally he lost his developing speech.” P Statement at ¶3; see also Petition at ¶7. There is no corroboration in the filed medical records of petitioners’ account of changes in Connor beginning on July 1, 2005.

There is corroboration of changes by September 7, 2005; Connor’s pediatrician noted during a sick visit that Connor “talks to his hand” and that Connor’s mother was “concerned re: development.” P Ex. 2 at 20. This record does not indicate when such changes began. At Connor’s 18 month well visit on September 28, 2005, the pediatrician observed that Connor had no words and no receptive language. P Ex. 2 at 20. The pediatrician also noted Connor was still not feeding himself. Id. The pediatrician assessed Connor with possible Pervasive Developmental Disorder and possible autism. Id. Connor was formally diagnosed with autistic spectrum disorder and static encephalopathy by pediatric neurologist David J. Callahan, M.D., on

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<sup>10</sup> Petitioners paginated their exhibits 2-5 continuously, such that the two-page P Ex. 3 is pages 60 and 61.

<sup>11</sup> Children with an egg allergy may experience anaphylaxis after receipt of a vaccine developed in hens’ eggs, as the influenza vaccine often is. See, e.g., Stanley Plotkin et al., Vaccines, 266,380 (5th ed. 2008).

September 29, 2005. P Ex. 4 at 62-63. Subsequent genetic testing was negative for possible causes. P Ex. 4 at 64; see also P Ex. 2 at 49-54.<sup>12</sup>

In the filed medical records, no treating physician attributed Connor's autism to a vaccine or vaccines. Notably, Connor's pediatrician administered inactivated polio, diphtheria-tetanus-acellular pertussis ("DTaP"), and hemophilus influenzae type B vaccines on September 28, 2005. P Ex. 2 at 20; P Ex. 3 at 60. This was the same visit where she determined that Connor was possibly exhibiting signs of autism. P Ex. 2 at 20. Petitioners also acknowledge that their pediatrician advised them that vaccines do not cause autism. P Statement at ¶4.

### III. Causation in Fact

To receive compensation under the Program, petitioners must prove either 1) that Connor suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Connor 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 Connor suffered a "Table Injury." Further, the record does not contain a medical opinion or any other persuasive evidence indicating that Connor's autism spectrum disorder was vaccine-caused.

Petitioners appear to allege the second theory from the test cases, that mercury in thimerosal, a preservative used in vaccines, could affect an infant's brain and substantially contribute to autism. That theory was carefully considered and rejected in the OAP test cases. See Part I, supra. In their Petition and in their Statement Regarding Onset, petitioners indicate that they had questioned their pediatrician regarding the mercury content of Connor's vaccines. See Petition at ¶7; P Statement at ¶4. In their motion for a decision on the record, petitioners argue that two studies of mercury toxicity<sup>13</sup> support their theory that Connor's vaccines, received June 16, 2005, caused his autism.

These studies cannot support petitioners' claim for two reasons. First, petitioners base their theory on Connor's receipt of pneumococcal conjugate, MMR, and varicella

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<sup>12</sup> This testing was filed along with mercury testing conducted in summer 2007, nearly two years after Connor's diagnosis. Testing done at Children's Hospital in St. Louis, Missouri, indicated Connor's mercury level was normal in July 2007. P Ex. 2 at 55. Testing conducted in June 2007 at a private French laboratory indicated that a "Urinary Porphyrin Profile" was "suggestive" of "a remarkable mercury toxic effect on bodily physiology." P Ex. 2 at 56. Without a qualified physician's opinion interpreting these results, the undersigned cannot draw conclusions from them regarding causation. But as both tests were conducted long after Connor's diagnosis, and thus provide no information regarding Connor's mercury level at the time he began to exhibit autistic symptoms, their bearing on causation in any event is negligible.

<sup>13</sup> Petitioners cite T. Burbacher et al., Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal, Envtl. Health Persp. 113(8): 1015–21 (2005) and L. Magos et al., The comparative toxicology of ethyl- and methylmercury, Arch. Toxicol. 57: 260–67 (1985). The PSC filed both studies into the OAP record.

vaccines. While some vaccines were routinely manufactured prior to 2001 using thimerosal as a preservative, these three vaccines have never contained thimerosal. Institute of Medicine, Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders, 27, 29 (2001).<sup>14</sup> Accordingly, administration of them did not introduce mercury into Connor's system, and they cannot be causative of his autism under a causation theory based on thimerosal. Second, both of the studies cited by petitioners were specifically addressed in the test cases. After careful consideration, the special masters who decided those cases determined the studies did not support causation. See, e.g., Dwyer, 2010 WL 892250, at \*82, 94 (discussing the Magos study) and \*90-94 (discussing the Burbacher study).<sup>15</sup> Petitioners produced no new evidence that questions the analysis performed in the test cases.

Even if petitioners are not relying on a thimerosal-based claim, 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 or reject a causal link between the 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 Fesanaco 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 Connor 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

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<sup>14</sup> Respondent filed this report into the OAP record.

<sup>15</sup> In the slip version of this decision provided on the U.S. Court of Federal Claims website, these discussions may be found at pages 141-48 (discussing the Burbacher study) and 129-30, 149 (discussing the Magos study). See <http://www.uscfc.uscourts.gov/node/5026>.