

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 09-232V
Filed: October 25, 2010**

NICOLE MACMILLAN and DARRIN
MACMILLAN, in their own right and as
best friends of their son, Caiden
MacMillan,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Decision on the Record;
Pervasive Developmental
Disorder; Various Vaccines;
Failure to Produce an Expert
Report

DECISION¹

Vowell, Special Master:

On April 15, 2009, petitioners filed a petition in the National Vaccine Injury Compensation Program [“the Program”],² on behalf of their son, Caiden MacMillan [“Caiden”]. The petition alleges that Caiden’s pervasive developmental disorder [“PDD”] was the “result of vaccinations he received during his two years of life.” Petition [“Pet.”] at 1. On October 1, 2010, after unsuccessfully attempting to obtain an opinion on causation from a medical expert, petitioners requested that I decide this case on the record as it stands. I find that the information in the record does not show entitlement to an award under the Program.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims’ website, in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, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

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).

I. The Procedural History.

The petition indicates that Caiden's PDD "first manifested itself in early to mid 2007 and was diagnosed as Autism on August 3, 2007." *Id.* The remainder of the 11-page petition for compensation discusses a number of theories, noting that Caiden had a "febrile reaction to each vaccination," that his mother received a thimerosal containing influenza vaccination during the fourth month of her pregnancy, and that the pertussis toxin, to which Caiden "had a reaction every time" was known to cause "neurological malfunction." Pet. ¶¶ 5, 6, 8. The petition discusses a number of scientific studies of pertussis, calcium, blood flow, "G proteins," and "L channels." See *generally* Pet. ¶¶ 8-14. In ¶ 15 of the petition, petitioners allege:

[I]t is more likely than not that his deterioration from a normal child to an autistic child is the result of being exposed to pertussis toxin on numerous occasions concluding with the July 2007 vaccination by which time the change in his personality and developmental progress was sufficient to note. However he also could have been injured by the Thimerosal containing vaccines he received at four months gestation and at eight and a half months of age. Therefore there are two ways Caiden could have been injured by the vaccinations he received.

The petition was accompanied by an affidavit of Caiden's mother, and Exhibits 1-15, which consisted of medical records filed in a manner that did not comport with the Guidelines for Practice in the Vaccine Program. Exhibits 16-25 include the scientific journal articles referenced in the petition, none of which link pertussis or mercury to autism spectrum disorders. No report of any medical expert causally linking Caiden's PDD to his vaccinations accompanied the petition.

In the initial status conference on June 22, 2009, the special master then assigned to this case gave petitioners until September 3, 2009, to determine whether to join their petition to others pending in the Omnibus Autism Proceeding ["OAP"]. Order filed June 22, 2009. That special master subsequently enlarged that time to December 8, 2009. Order filed Sept. 19, 2009. In an order filed on December 10, 2009, the special master noted that petitioners elected not to join the OAP. Accordingly, he ordered petitioners to file an expert report in support of their case, or a status report detailing progress in obtaining an expert report, by February 19, 2010. Petitioners ignored this deadline.

No further action took place in this case until the case was reassigned to me on March 31, 2010. Of note, the three test case decisions on the theory that thimerosal-containing vaccines could cause autism spectrum disorders were publically released on March 12, 2010. All three decisions concluded that there was insufficient evidence to demonstrate that thimerosal-containing vaccines played any role in the development of

autism spectrum disorders. *E.g., Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). Those decisions were not appealed.

I held a status conference on April 6, 2010. Counsel for petitioners indicated that they were having difficulty obtaining an expert to support their case. See Order filed April 7, 2010. In the same filing, I ordered petitioners to file by June 8, 2010, (i) an expert report; (ii) a status report identifying evidence they wish to incorporate from the OAP; and (iii) a replacement set of medical records properly organized in accordance with the Guidelines for Practice under the National Vaccine Injury Compensation Program.

I subsequently granted petitioners an enlargement of time until August 3, 2010, to file their expert report. Order filed June 4, 2010. I also granted petitioners an enlargement of time until July 16, 2010 to reorganize and refile the medical records and to identify evidence from the OAP that they wished to incorporate into this case. Order filed June 16, 2010. Petitioners failed to file the medical records, or otherwise respond, on July 16, 2010. Although petitioners refiled the medical records on July 30, 2010, they failed to notify the court whether they will incorporate any OAP evidence. They also failed to file an expert report linking Caiden's condition to a vaccine and failed to request an enlargement of time in order to do so.

On August 10, 2010, I ordered petitioners to comply with my order to produce an expert report and to identify what, if any, OAP evidence they wish to incorporate into this case, or otherwise show cause by Monday, August 30, 2010, why this case should not be dismissed for failure to prosecute. Petitioners responded to the show cause order and requested an additional 45 days to file an expert report. I granted that extension, and order petitioners to file an expert report, as well a status report identifying what, if any, evidence from the OAP they wished to incorporate into this case, by October 18, 2010. On September 20, 2010, petitioners filed a status report noting that they would not incorporate any of the OAP evidence. On October 1, 2010, Petitioners filed a motion for a decision on the record, noting they were unable to obtain an expert report.

II. The Medical Records.

Caiden was born on February 22, 2006, with Apgar³ scores of nine at one minute and nine at five minutes. He received a hepatitis B vaccination the next day; his two month vaccinations on April 20, 2006; his four month vaccinations on June 28, 2006; his

³ The Apgar score is a numerical assessment of a newborn's condition, usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1670 (30th ed. 2003).

six month vaccinations on August 29, 2006; an influenza vaccination on November 9, 2006; and subsequent vaccinations through July, 2007.⁴ See Pet. Ex. 3, p. 2. In her affidavit, Caiden's mother notes that "Caiden had a 101 [degree] fever for 3 days after his two month vaccinations, along with extreme fatigue and listlessness and a 104 [degree] fever for 3 days after his four month and six month vaccinations, along with extreme irritability and excessive crying and a rash all over his body for one week after vaccinations he received at 13 months and 16 months of age."⁵ Affidavit of Nicole MacMillan, filed with the Petition on Apr. 15, 2009 ["N. MacMillan Aff."], ¶ 8. The only report of a high fever in Caiden's medical records was made at a December 13, 2006, pediatrician visit. Pet. Ex. 3, p. 27. The MacMillans reported that Caiden had a fever that had lasted three days that had reached as high as 104 degrees. Pet. Ex. 3, p.27. This fever occurred almost one month after his last vaccination on November 9, 2006. See Pet. Ex. 3, p. 2. No report of fever, or any other vaccine reaction, was made after his two month vaccinations, his four month vaccinations, or his six month vaccinations. See Pet. Ex. 3. The MacMillans reported that Caiden had a rash at his January 25, 2007, pediatric visit, which the pediatrician diagnosed as eczema. Pet. Ex. 3, p. 24. This report was made two months after Caiden's last vaccination on November 9, 2006. See Pet. Ex. 3, p.2. The MacMillans reported a rash again on April 24, 2007, as a "rash on both arms for [a] couple days." Pet. Ex. 3, p. 14. This was one month after Caiden's 13 month vaccinations. See Pet. Ex. 3, p. 2. The medical records contain no report of a rash closer in time to his 13 month vaccinations, and no report of a rash after his 16 month vaccinations. See Pet. Ex. 3.

In her affidavit, Caiden's mother notes that "Caiden hit all his developmental milestones for the first nine months ... until about a month after his flu vaccination [on November 9, 2006]." N. MacMillan Aff. ¶ 3. On both November 29, 2006, and March 28, 2007, Caiden's pediatrician noted that he was "developmentally appropriate for [his] age." Pet. Ex. 3, pp. 17, 30. On July 11, 2007, Caiden's pediatrician noted "some developmental delays" during his well-child visit. Pet. Ex. 3, p. 8-9. Caiden was evaluated by neurodevelopmental pediatrician Beth Parrish, M.D., on August 3, 2007. Pet. Ex. 3, p. 93. Doctor Parrish's report notes that the MacMillans had "a long history of concerns about various aspects of [Caiden's] development and behavior." Pet. Ex. 3, p. 97. Doctor Parrish concluded that "a diagnosis of autism spectrum disorder would be applicable" in Caiden's case, and that "[e]tiology is likely genetic." Pet. Ex. 3, p. 97.

⁴ Caiden's two month vaccinations included a combination injection containing diphtheria, tetanus, acellular pertussis ["DTaP"], hepatitis B ["hep B"], and inactivated polio virus ["IPV"] [collectively, "Pediarix"]; a haemophilus influenzae type b ["Hib"]; and pneumococcal conjugate. Caiden's four month vaccinations included Pediarix, Hib, and pneumococcal conjugate. Caiden's six month vaccinations included Pediarix and pneumococcal conjugate. Caiden also received hepatitis A, pneumococcal conjugate, rubella, and varicella on March 28, 2007; mumps on May 2, 2007; and DTaP, Hib, and measles vaccinations on July 11, 2007. Petitioners' Exhibit ["Pet. Ex."] 3, p. 2.

⁵ Mrs. MacMillan was likely referring to the vaccinations Caiden received on March 28, 2007, as his 13 month vaccinations. She was likely referring to the vaccinations he received on July 11, 2007, as his 16 month vaccinations.

III. Causation in Fact.

To receive compensation under the Program, petitioner must prove either 1) that Caiden suffered a “Table Injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or 2) that Caiden 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 Caiden suffered a “Table Injury.” Further, the medical records do not contain evidence or a medical opinion indicating that Caiden’s PDD was vaccine-caused.

A petitioner may not receive a Program award based solely on the petitioner’s claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). 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.

Accordingly, it is clear from the record in this case that petitioners have failed to demonstrate either that Caiden 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.

Denise K. Vowell
Special Master