

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 0001-93V
Filed: June 21, 2011**

DAVID KRAUSE, as parent *
and next friend of KELSEY KRAUSE, *
a minor, *

Petitioner, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

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

DECISION

Campbell-Smith, Chief Special Master:

On February 22, 2001, David Krause filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program [the Program],¹ on behalf of his daughter, Kelsey Krause [Kelsey].² The Petition alleges that a Measles, Mumps, and Rubella [MMR] vaccination, received on February 23, 1998, caused Kelsey's "mild" autistic disorder.³ Petition; Petitioner's Exhibit [Pet. Ex.] at 4.

¹ 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).

² As of June 02, 2011, Kelsey is fifteen years of age and thus, still a minor.

³ Because autism is not an injury listed on the Vaccine Injury Table (see 42 C.F.R. § 100.3(a) (2010)), this decision analyses petitioner's claim as a causation-in-fact injury (see § 300aa—11(c)(1)(C)(ii)(1)).

On August 22, 2002, petitioner filed a status report indicating his intent to opt into the Omnibus Autism Proceeding [OAP]. This case was transferred into OAP on August 30, 2002. Thereafter, petitioner filed part, but not all, of the medical records pertinent to causation. See Order dated April 19, 2011 granting an extension until May 23, 2011 for the filing of outstanding medical records. The petitioner has not yet filed a Statement of Completion indicating that all medical records in support of this claim have been filed.

Instead, Petitioner filed a motion for a ruling on the record on March 30, 2011 and an amended motion for a ruling on the record on May 20, 2011, seeking a ruling in this case 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 5,000 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 the more than 5,000 petitions filed in this court, 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.⁴

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 ASDs. The first theory alleged that the measles portion of the MMR vaccine could cause ASDs [Theory 1]. 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,

⁴ 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).

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).⁵ 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.

Each Petitioner remaining in the OAP must now decide to pursue his or her case, and submit new evidence on causation, or take other action to exit the Program. Petitioner in this case has requested a ruling on the record as it now stands.

II. The Medical Records

Kelsey was born November 19, 1996. (Pet. Ex.11). Approximately six weeks before Kelsey's birth, her mother was treated for a vaginal culture positive Group B Streptococcus infection (Pet. Ex. 45).

Kelsey was born weighing eight pounds and one ounce (Pet. Ex. 45). Within the first twenty-four hours of life, she was admitted into special care due to her leukocytosis,⁶ intermittent interruption of breathing (hypoxia), and heart murmur (Pet. Ex. 6 at 38). She was weaned from the oxygen without difficulty, and her murmur resolved within two days (Pet. Ex. 45).

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

⁶ Leukocytosis is "a transient increase in the number of keukocytes (white blood cell) in the blood" resulting from various causes such as "hemorrhage, fever, infection, or inflammation." Dorland's Illustrated Medical Dictionary 1043 (31st ed. 2007).

Petitioner contends that prior to Kelsey receiving her MMR vaccination, (Pet. Ex. 1) she had well-baby exams at Northpoint Pediatrics in Indianapolis at ages 13 days, 1, 2, 3, 4, 6, and 9 months (Pet. Ex. 31). On February 23, 1998, Kelsey received a MMR vaccine (Pet. Ex. 1). On May 27, 1998, three months later, Kelsey's mother reported a gradual downward trend in Kelsey's cognitive development (Pet. Ex. 2). After receiving the vaccine in question, Kelsey stopped speaking (she was previously reported to use approximately seven words), was fussy, and pulled at her ears (Pet. Ex. 2). Kelsey's mother noticed behavior changes in her daughter that concerned her because it appeared that "Kelsey [was] in another world and [was] not acting like she would [have] expect[ed] her to" act (Pet. Ex. 3). Ultimately, Kelsey was diagnosed with "mild" autistic disorder on November 19, 1998. See Pet. Ex. 4, 6, at 6, 10.

Kelsey's parents sought treatment for her autistic condition. Dr. Dale Guyer treated Kelsey at the Center for Innovative Medicine, with secretion and nutritional supplements (Pet. Ex. 10 p.3). He noted Kelsey made "progressive improvements" under his care in both her motor and social skills (Pet. Ex. 10 p. 8, 9). Kelsey's parents also sought out both occupational and speech language therapy at Drexler and Associates Inc. where the health care professionals noted that Kelsey responded well to the care provided (See Pet Ex. at 18, 20-24).

III. Vaccine Causation

To receive compensation under the Program, petitioner must either prove that his child "sustained an injury or condition set forth in the Vaccine Injury Table" within the requisite time frames, or he must carry his burden to "demonstrate by preponderant evidence that the vaccine was a "substantial factor" in, and a "but for" cause of, the vaccine's current condition by adducing evidence supporting each of Althen's three factors." Hennessey, 2009 WL 1709053, at *40 (referencing Althen v. Sec'y, HHS, 418 F.3d 1274 (Fed. Cir. 2005), which sets forth a three-prong test for determining causation in fact in Vaccine Act cases). Strother v. Secretary of HHS, 18 Cl. Ct. 816, 818(1989), aff'd, 950 F.2d 731 (Fed. Cir. 1991). 42 USC 300aa-13(a)(1)(A).

Autism is not a Table injury for the MMR vaccine, nor is it a Table injury for any of the vaccines included in the Vaccine Act. Petitioner must, therefore, meet the more strenuous burden that Kelsey's mild autistic disorder was in fact caused by her February 23, 1998 vaccination. 300aa-11(c)(1)(C)(ii)(I) and 13(a). To meet the burden, the petitioner must present more than evidence of a temporal association. See Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992); see also Strother, 21 Cl. Ct. 465, 370 (1990), aff'd, 950 F.2d 731 (1991);

accord Hasler v. U.S., 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

The evidence produced in the OAP test cases does not support petitioner's allegation of vaccine causation; rather it indicates that the MMR vaccine is unlikely to cause ASDs. Petitioner did not file any additional evidence on whether vaccines can cause ASDs to propose an alternative theory and, therefore, has failed to prove that vaccines can cause ASDs. At best, the medical records show a temporal link between receipt of the MMR vaccine and a decrease in Kelsey's cognitive skills. See Pet. Ex. 2, 3. Although the medical records indicate that Dr. Guyer cited to Dr. Wakefield's "efforts and research" as support for a casual association, Dr. Wakefield's efforts and research were rejected as scientifically unreliable in the test cases and therefore, this statement alone in Kelsey's medical records does not provide adequate reasoning or medical support for Dr. Guyer's expressed belief that Kelsey's MMR vaccine was causally related to her cognitive decline (Pet Ex. 4). The record does not contain a medical opinion or any other persuasive evidence indicating that Kelsey's autism spectrum disorder was caused by the MMR vaccine.

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 petitioner's claim, a reliable medical opinion must be offered in support. Petitioner, however, has offered no such opinion.

Because it is clear from the record in this case that petitioner has failed to demonstrate that Kelsey's autism was caused by the MMR vaccination, **thus, this case is dismissed for insufficient proof. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

Patricia E. Campbell-Smith
Chief Special Master