

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

E-Filed: June 6, 2012

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MICHAEL A. and SUZANNE M. Lebrun *

Parents and Guardians of *

ALEXANDER J. Lebrun, a minor, *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT OF *

HEALTH AND HUMAN SERVICES *

Respondent. *

* * * * *

No. 08-790V

Autism; Decision on the Record

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

Ryan D. Pyles, United States Department of Justice, for respondent

DECISION¹

On November 4, 2008, Michael and Suzanne Lebrun (“petitioners”) filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation

¹ 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.

Program (“the Program”),² on behalf of their son, Alexander. Petitioners allege that the combination of various vaccinations or the thimerosal content in certain received vaccines, including the flu vaccines, caused Alexander to develop Pervasive Developmental Disorder -- Not Otherwise Specified (“PDD-NOS”), a condition on the spectrum of autism disorders.

On April 15, 2010, petitioners requested a decision on the record. On May 17, 2012, petitioners filed an Amended Motion for a Ruling on the Record.

Because this record does not show entitlement to a Program award, 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 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 these six test cases presenting two different theories on the causation of ASDs. One of theories tested in three of the six test cases was that the mercury content in thimerosal-containing vaccines could affect an infant’s brain, thereby substantially contributing to the causation of ASDs.

Decisions in each of the three “test cases” pertaining to this theory rejected the petitioners’ causation theory. Dwyer v. Sec’y, HHS, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010); King v. Sec’y, HHS, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); and Mead v. Sec’y, HHS, 2010 WL 892248 (Fed. Cl. Mar. 12, 2010). Thus, should petitioners elect to pursue their claim further, petitioners must submit previously unconsidered evidence on the theories of causation evaluated in the OAP or present new theories. Here, petitioners seek a ruling on the record as it presently stands.

II. The Medical Records

Alexander was born October 15, 2003, and appeared to be a healthy newborn. See, e.g., Pet’rs’ Ex. C at 1. He remained generally healthy through October 18, 2005,

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).

but did experience fevers and strabismus of the eyes.³ Id. at 1-5. Alexander's medical records also show that problems with his speech were well documented in April of 2006. Id. at 5. Medical records from June of 2006 indicate a diagnosis of mild autism. Pet'rs' Ex. G at 3. Nothing in the physicians' notes, however, relates either Alexander's speech issues or his autism diagnosis to the vaccines he received.

Alexander received vaccinations at various times between his birth and the emergence of his speech issues -- which were clearly noted in April of 2006 -- when Alexander was 30 months old. Pet'rs' Ex. D. Of note, Alexander received two influenza vaccinations in November of 2004, as he neared 13 months of age. Id. The following year, he received influenza vaccines in October and November, shortly after he reached 24 months of age. Id.

III. Timeliness of Petitioners' Claim on Behalf of Alexander

On February 2, 2009, respondent filed a Rule 4(c) Report providing her initial response to petitioners' vaccine claim. Respondent asserted that the case was untimely based on notes from Alexander's physician in November of 2004, indicating that Alexander "had a few words, but then lost them when he was ten months old." Resp't's Rule 4(c) Report at 3. According to respondent, that particular record suggested that petitioners' case was not timely filed because it was filed in November of 2008, and thus, more than the statutorily afforded 36-month limitations period, running from the date of onset of the earliest noted speech concerns in November of 2004. Id. Respondent acknowledged, however, that "the record is very difficult to decipher," and concluded that, "[a]bsent more medical records," she could not "make a determination as to timeliness." Id.

By written response filed on February 27, 2009, petitioners addressed respondent's expressed concern that their vaccine claim was untimely. Clarifying the November 2004 notes taken by Alexander's pediatrician, petitioners explained that the record correctly reads: "walking at 12 months [,] understands lots [,] words at 10 mo[nths]."⁴ Pet'rs' Resp. to Resp't's Rule 4(C) Report at 2. Urging that the November 2004 record merely documents some of Alexander's early developmental milestones, petitioners contend the record is devoid of direct evidence of Alexander's speech problems until April of 2006. Id. at 3.

³ Strabismus is a visual problem that occurs when the eyes are not aligned and point in different directions. What is Strabismus, Am. Acad. of Ophthalmology (June 4, 2012), <http://www.geteyesmart.org/eyesmart/diseases/strabismus.cfm>.

⁴ Petitioners state that they gleaned this meaning from the physician's notes after contacting the physician, but petitioners have not provided any independent corroboration from the physician.

Respondent replied on December 22, 2009, arguing that the medical records support a finding that the first signs of Alexander's autism disorder appeared more than a year before April of 2006. See Resp't's Supplemental Report at 2-3. Respondent pointed specifically to notes from a pediatric visit in September of 2006, indicating: "First words were noted by 11-months, though Mrs. Le Brun noted concerns with [Alexander's] limited use of words and phrases to communicate." Id. at 3 (emphasis added). Respondent asserted that this record would appear to suggest that Mrs. Lebrun was concerned about Alexander's speech when he was 11-months old (in September of 2004). But again, respondent conceded her inability to determine whether the claim was timely filed due to the incompleteness of the medical records. Id.

In their Final Submission of Evidence, dated April 15, 2010, petitioners again addressed respondent's allegations of untimeliness. Petitioners contended that respondent has taken Mrs. Lebrun's statements, as documented during the September 2006 visit, out of context. Pet'rs' Final Submission of Evidence at 2. Petitioners asserted that the phrase "First words were noted by 11-months" reflected a past recollection, while the reported concern about Alexander's "limited use of words and phrases to communicate" reflected a then-current impression in 2006. Id. at 3.

The Vaccine Act provides:

no petition may be filed for compensation under the Program for [injury from a vaccine] after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury. . .

§ 300aa-16(a)(2). In Cloer v. Sec'y of Health and Human Servs., the Court of Appeals for the Federal Circuit stated that the "statute of limitations begins to run on . . . the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical community at large." 654 F.3d 1322, 1340 (Fed. Cir. 2011).

As respondent admits, Alexander's medical records are, at best, inconclusive as to whether Alexander exhibited any symptoms associated with his autism prior to April of 2006. See Resp't's Supplemental Report at 3. The medical records certainly suggest that Alexander exhibited speech issues, perhaps as early as August or September of 2004, before his receipt of the 2004 flu vaccines, and more than 36 months before the vaccine claim was filed. On this evidence of Alexander's limited speech -- an early indication of autism -- petitioners' claim was not timely filed and must be dismissed. Assuming, however, the factual record was not sufficiently clear to place the onset of Alexander's speech issues before April of 2006, when concerns about Alexander's speech were documented unambiguously, then petitioners' claim would be deemed timely filed. If

such were the circumstances, and out of an abundance of caution on this record, the undersigned turns now to consider the merits of petitioners' claim.

IV. Causation in Fact

Petitioners alleged that Alexander's autism was "caused-in-fact by the (a) thimerosal present in the flu shot and other vaccinations, or, in the alternative (b) . . . [the] sum total of vaccinations administered to Alex . . . whose body was inherently unable to process the antigenic materials present[.]" Petition, ¶ 11.

To receive compensation under the Program, petitioners must prove either 1) that Alexander suffered a "Table Injury" -- that is, an injury falling within the Vaccine Injury Table -- corresponding to one of his vaccinations, or 2) that Alexander suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Because autistic conditions are not listed on the Vaccine Table, petitioners must show that vaccinations Alexander received actually caused his 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).

Here, petitioners describe the onset of Alexander's symptoms as occurring shortly after his receipt of the 2005 influenza immunizations. Pet'rs' Final Submission of Evidence at 5. Petitioners blame the thimerosal in the 2005 influenza immunizations for Alexander's injury. But, petitioners do not explain how the same vaccines, given a year earlier, did not result in an earlier injury (or at least by Alexander's pediatric visit on October 18, 2005). Moreover, while petitioners state that the onset of Alexander's symptoms occurred "[s]hortly after" the 2005 influenza vaccinations, they prefer to rely on the medical record addressing his symptoms in April of 2006 as the first evidence of Alexander's speech problems in their response to respondent's argument that their claim is untimely. Petitioners' theory of causation, specifically that the thimerosal component in the received vaccines caused Alexander's autism, has been considered and rejected by three autism test cases, see supra p. 2, and petitioners have presented no additional scientific or medical evidence demonstrating that thimerosal caused Alexander's autism. Nor is there any notation in Alexander's medical records to suggest that the implicated vaccinations caused his autistic condition.

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 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 of causation.

Accordingly, it is clear from the record in this case that petitioners have failed to demonstrate that Alexander suffered a “Table Injury” or that his injuries were “actually caused” by a vaccination.

For the reasons set for above, **this case is DISMISSED. The Clerk of the Court is directed to enter judgment accordingly.**

IT IS SO ORDERED.

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