In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Case No. 14-319V

Filed: January 27, 2015

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MARKUS HEINZE and CANDACE HEINZE, as the Parents and Natural Guardians of J.H., a Minor,	Special Master Nora Beth Dorsey
Petitioners,	
v.	Entitlement; Decision Without a Hearing; Ruling on the Record; Measles-Mumps-Rubella (MMR) Vaccine; Vaccine-Induced Immune Dysregulation; Erythema Multiforme; Type 1 Diabetes.
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	
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Mark Theodore Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for petitioners.
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

I. Introduction

On April 21, 2014, Markus and Candace Heinze ("petitioners"), filed a petition for compensation on behalf of their daughter, J.H., under the National Vaccine Injury Compensation Program ("the Program" or the "Vaccine Act")[2], alleging that a measles-mumps-rubella (MMR)

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, 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). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

vaccine administered to J.H. on April 22, 2011, caused her to develop "vaccine-induced immune dysregulation resulting in erythema multiform[e] and Type 1 diabetes." Petition at 1. The medical records and information in the record, however, do not support a finding that petitioners are entitled to compensation under the Vaccine Act.

In this case, petitioners allege a "causation-in-fact" injury, thus a medical opinion as to causation is required. See § 300aa-13(a)(1). Petitioners have not offered such an opinion. For the reasons discussed below, petitioners have failed to demonstrate that they are entitled to compensation and, therefore, the petition is dismissed for insufficient proof.

II. Procedural History

Petitioners filed their petition on April 21, 2014. Medical records and a Statement of Completion were filed over the next four months. On July 21, 2014, respondent filed her report pursuant to Vaccine Rule 4(c), stating that the medical personnel of the Division of Vaccine Injury Compensation reviewed the petition and medical records and concluded that the case was not appropriate for compensation under the Vaccine Act. See Respondent's Report ("Resp't's Rep't"), filed July 21, 2014, at 1. Respondent stated that petitioners' claim that J.H. suffers from "immune dysregulation" is unsupported by the records. Id. at 5. Furthermore, regarding petitioners' claim that J.H.'s diabetes was caused by her vaccine, respondent notes that a number of cases alleging a connection between diabetes and vaccinations have been denied compensation in the Vaccine Program. Id. Respondent also challenges the diagnosis of erythema multiforme ("EM").[3] The medical records document J.H.'s diagnosis of EM while describing the same rash as "morbilliform."[4] Id. at 6. Finally, respondent states that there is insufficient information in the record to establish that any of J.H.'s injuries, which may have been caused by the MMR vaccine, lasted for more than six months. Id.

The Rule 5 status conference was held on August 7, 2014. The undersigned reviewed the medical records and the information set forth in the Rule 4(c) report, and provided petitioners with time to determine how they wanted to proceed with their case.

On November 20, 2014, petitioners filed a Motion for Judgment on the Administrative Record ("Motion for Judgment") requesting that the undersigned rule on the record as it now stands. Respondent filed a response to the Motion for Judgment on December 15, 2014, stating that respondent does not oppose having the Special Master rule on entitlement on the current record, and relying on the arguments set forth in the Rule 4(c) report.

This case is now ripe for a decision on the record.

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[3] Erythema multiforme is defined as either of two conditions (minus or majus) "characterized by sudden eruptions of erythematous papules, some of which evolve into target lesions consisting of a central papule surrounded by a discolored ring or rings." Dorland's Illustrated Medical Dictionary, 643 (32nd ed. 2012).

[4] A morbilliform rash is defined as having an appearance "like measles; resembling the eruption of measles." Id. at 1180.

III. Summary of Relevant Evidence

a. Medical Records

J.H. was born on [redacted]. Other than a diagnosis for anisocoria (unequal sized pupils), J.H.'s medical history was otherwise unremarkable. See Petitioner's Exhibit (Pet's Ex.) 2 at 18. On March 11, 2011, J.H. had her three-year well-child examination and the results were consistent with normal health and development. Pet's Ex. 2 at 111. About six weeks later, on April 22, 2011, J.H. received the MMR vaccine. Pet's Ex. 2 at 1, 115.

Eleven days after administration of the MMR vaccine, on May 3, 2011, Markus Heinze called Pediatric Associates, PSC ("PA") to report that J.H. was vomiting and experiencing a rash on her abdomen that occurred the night before. Pet's Ex. 2 at 116. The provider stated that the symptoms could be a result of the MMR vaccine and instructed the parents to monitor the rash. Id. J.H. visited the doctor two days later, on May 5, 2011, because the rash spread to her arms and back with minor itching. Dr. Mackay diagnosed J.H. with a nonspecific rash and lymphadenopathy. Id. at 119.

On May 24, 2011 (32 days after vaccination), J.H. was seen due to a fever lasting two days, a hoarse voice, runny nose, cough, and decreased appetite. Pet's Ex. 2 at 121. That examination was normal except for an erythematic pharynx. Id. The diagnosis was acute pharyngitis. Id. at 121-22. During that same visit, the doctor noted that there were no rashes or lesions present on J.H.'s skin. Id. at 121. On June 15, 2011, J.H. was seen to check her lymph nodes, which were normal. Id. at 124. She also received the second hepatitis B vaccine on that date. Id. J.H. received the third hepatitis B vaccine on August 5, 2011, and a pneumococcal vaccine on August 26, 2011. Id. at 127-128.

Four months and 18 days after the MMR vaccine (September 9, 2011), J.H. was seen for a rash that started at her navel but spread over her whole body, which her father described as hive-like. Pet's Ex. 2 at 129. The nurse who examined J.H. noted bilateral, cloudy nose drainage, a morbilliform rash on the torso and thigh regions and clear breath sounds. Id. Despite exhibiting a morbilliform rash, the assessment was erythema multiforme ("EM"). Id. The treatment plan noted in the medical records states that J.H.'s parents should monitor J.H. for Stevens - Johnson syndrome.[5] Id. at 130.

On September 13, 2011, J.H. was seen for a possible upper respiratory infection, with symptoms starting several weeks prior with a cough. Pet's Ex. 2 at 130-131. J.H. was diagnosed with allergic rhinitis. Id. at 132. The visit included a full examination and the doctor found that J.H. had no rashes or lesions on her skin. Id. at 130. On September 16, 2011, J.H.'s father called PA and reported that J.H. was drinking an excessive amount of water. Id. at 134. Following that call, J.H. was seen for runny nose, cough, and congestion on September 28, 2011. Id. at 135.

[5] Stevens-Johnson syndrome or erythema multiforme majus is defined as: "A respiratory prodrome precedes characteristic mucocutaneous lesions and other symptoms. Large areas of the skin and oronasal, genital, and colonic mucous membranes develop macules and become necrotic; hemorrhagic crusts appear on the lips." Dorland's at 1773.

She underwent testing that showed elevated levels of glucose, an upper respiratory infection, weight loss, polyuria, and Type 1 diabetes. Id. at 135-137. After the pediatrician spoke with Dr. Eader, a pediatric endocrinologist, J.H. was diagnosed with insulin dependent diabetes mellitus (IDDM). Id. at 137. During this visit, J.H. was referred to the emergency department at Cincinnati Children's Hospital ("CCH") for an evaluation based on the ketones in her urine and high blood glucose. Id., see also Pet's Ex. 3 at 418. J.H. was later admitted to the endocrinology department at CCH, where her diagnosis was confirmed on September 28, 2011. Pet's Ex. 2 at 160. During J.H.'s evaluation at CCH, the doctor noted the family history of diabetes. Pet's Ex. 3 at 58. J.H.'s maternal grandmother, grandfather, and cousin have diabetes mellitus. Id. After two weeks of polyuria and polydipsia, J.H. began insulin treatment. Id. at 404-405.

The months following J.H.'s diagnosis of Type 1 diabetes included strict monitoring of her blood glucose and blood sugar. Pet's Ex. 2 at 166. Doctors did not document any skin problems during this time until May 1, 2012. Id. at 154. On that day, J.H.'s mother reported that J.H. had a bump on her back that had gotten worse since December. Id. The doctor took a culture of the bump and diagnosed J.H. with folliculitis. Id.

J.H.'s diabetes has been closely monitored since her diagnosis and her doctors created a treatment plan to help manage J.H.'s condition. That management plan includes adjusting the dosage of medication as J.H. grows and develops. Pet's Ex. 3 at 789.

IV. Standard for Adjudication—Causation

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. REP. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation under the Vaccine Act, a petitioner must prove either: (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered a "causation-in-fact" injury, that is an injury that was actually caused by the vaccine she received. See §§ 300aa-13(a)(1)(A) and 11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that a vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Shyface, 165 F.3d at 1352-53 (Fed. Cir. 1994)).

To establish causation in fact, a petitioner must show by a preponderance of the evidence that but for the vaccination, petitioner would not have been injured, and that the vaccination was a substantial factor in bringing about the injury. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the

explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly, 592 F.3d at 1321 (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49); see also Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (medical theory must support actual cause). "[A] petitioner must demonstrate the reliability of any scientific or other expert evidence put forth to carry this burden . . . . Expert testimony, in particular, must have some objective scientific basis in order to be credited by the Special Master." Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54-55 (2011) (citing Moberly, 592 F.3d at 1322; Cedillo, 617 F.3d at 1339; Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

"The special master…may not make [] a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

If there is no Table Injury, petitioners must prove that the vaccine caused J.H.'s injury. To do so, they must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and the injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that a vaccine was the reason for his injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and injury ("Althen Prong Three"). Althen, 418 F.3d at 1278; § 300aa–13(a)(1) (requiring proof by a preponderance of the evidence).

a. The Evidence Does Not Prove Causation Under the Althen Prongs

This case does not involve a Table injury for the MMR vaccine, or any other vaccine. Thus, petitioners must prove that the MMR vaccine was the cause-in-fact of J.H.'s injuries and any injuries she suffered as a result of that vaccine persisted for more than six months. The petitioners have failed to do so.

Petitioners allege that the MMR vaccine caused J.H. to suffer immune dysregulation resulting in erythema multiforme. The medical records do not demonstrate that J.H. was diagnosed with immune dysregulation. J.H. was diagnosed with erythema multiforme on September 9, 2011 (four months and 18 days after vaccination). It is unclear if J.H. had an erythema multiforme rash or a morbilliform rash as both were documented during that visit. Regardless of the correct characterization of the rash, it was gone by September 13, 2011, after persisting for four days. Prior to that diagnosis, J.H. experienced a nonspecific, papular rash on May 3, 2011, eleven days after receiving the MMR vaccine. By May 24, 2011, J.H.'s skin was clear of any rashes or lesions. The doctor suggested that the rash in May could have been a reaction to the MMR vaccine. Assuming, without deciding that the doctor was correct, J.H. suffered from that rash for no more than 21 days. Thus, neither the erythema multiforme rash nor the nonspecific papular rash meet the threshold requirement of an injury lasting six months, as required by the Vaccine Act, and are therefore not compensable injuries. See 42 U.S.C §300aa-11(c)(1)(D)(i).

In addition, the medical records do not indicate any connection between the non-specific papular rash, which occurred in May 2011, and the morbilliform rash or erythema multiforme that was diagnosed in September 2011. During the time between May and September 2011, J.H. had several medical appointments, none of which recorded skin rashes or lesions. Further, even if the two rashes were the result of the same cause, the latest rash ended on September 13, 2011, which is four months and 22 days after vaccination, falling short of the six month requirement. See 42 U.S.C §300aa-11(c)(1)(D)(i).

Petitioners also claim that the MMR vaccine caused J.H. to develop Type 1 diabetes. J.H. does have Type 1 diabetes but there is no medical expert opinion that suggests the MMR vaccine caused her injuries. In addition, prior case law has not supported claims that the MMR vaccination can be causally linked to Type 1 diabetes. See Crutchfield v. Sec'y of Health and Human Servs, No. 09-39V, 2014 WL 1665227, at *22 n.25, Fed. Cl. Spec. Mstr. (Apr. 7, 2014) (involving the MMR vaccine)(citing other cases denying allegedly vaccine-related Type 1 diabetes claims). Accordingly, J.H.'s Type 1 diabetes is also not a compensable injury under the Vaccine Act. See 42 U.S.C §300aa-11(c)(1)(D)(i).

V. Conclusion

For the reasons discussed above, the undersigned finds that petitioner has not established entitlement to compensation and his petition must be dismissed. **Therefore, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Special Master