

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-11V

Filed: July 20, 2011

JAMES T. HOLMES, III, as Executor of
CATHERINE J. HOLMES,

Petitioner,

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Failure to Produce an Expert Report;
Lack of Evidence of Causation;
Dismissal

DECISION¹

Vowell, Special Master:

On January 6, 2011, James T. Holmes, III ["Mr. Holmes" or "petitioner"] filed a petition for compensation ["Pet."] under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² [the "Vaccine Act" or "Program"], on behalf of the estate of his mother, Catherine J. Holmes ["Ms. Holmes"]. The petition alleged that Ms. Holmes received influenza and H1N1 vaccines on or about November 23, 2009,³

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioner has 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).

³ This date was clearly an error, albeit one repeated in Petitioner's Exhibit ["Pet. Ex."] 2 at ¶¶ 3, 8, as the death certificate, Pet. Ex. 1, indicates that Ms. Holmes died on January 6, 2009.

that caused hemorrhagic encephalitis and her death. Because petitioner has been unable to find an expert linking Ms. Holmes' influenza vaccination⁴ to the encephalitis that caused her death, and because the medical records indicate that the encephalitis was caused by the herpes simplex virus, I hold that petitioner has failed to produce preponderant evidence of vaccine causation. Accordingly, the petition is dismissed.

I. Procedural History.

Some of Ms. Holmes' medical records were filed with the petition, and others were filed on January 20, 2011.⁵ At the initial status conference on February 10, 2011, I ordered petitioner to file additional records and a Statement of Completion by April 11, 2011. During that status conference I noted that my preliminary review of the filed records failed to find any record or report that attributed Ms. Holmes' illness and death to an influenza vaccine. I pointed out that the death certificate (Pet. Ex. 1), the discharge summary, an MRI⁶ report, and the treating physicians' opinions all attributed her illness and death to herpes encephalitis (e.g., Pet. Ex. 3, pp. 42, 71, 73-75, 77, 78, 82, 85, 86, 88, 98-100, 105, 112, 117; see also *id.*, pp. 34, 63, 67, 69, 72).

Petitioner filed additional medical records on April 6, 2011 and a Statement of Completion on April 12, 2011. As the newly filed medical records did not attribute Ms. Holmes' illness and death to a vaccination, on April 12, 2011, I ordered petitioner to file the report of a medical expert by June 13, 2011. Petitioner failed to comply with this order and failed to request an enlargement of time. I therefore ordered petitioner to comply with my April 12 order by June 29, 2011. Order, filed June 15, 2011. Petitioner responded with a second Statement of Completion filed on June 28, 2011, which indicated that there were no other medical records or reports available, including expert reports.

⁴ Although the petition alleged that Ms. Holmes received both the trivalent influenza and H1N1 vaccinations, only the trivalent influenza vaccine appears on the Vaccine Injury Table. 42 C.F.R. § 100.3 (2010). In 2010, the trivalent influenza vaccine incorporated an H1N1 virus. Prior to that point, allegations that H1N1 vaccinations caused injuries could not be considered as a part of the Vaccine Program.

⁵ The medical records filed with the petition were labeled as exhibits 1-3. The records filed on January 20, 2011 contained no exhibit numbers and were paginated consecutively. As the first three pages of the January 20, 2011 filing are what was previously filed as Pet. Ex. 3, I refer in this opinion to the January 20, 2011 filing as Pet. Ex. 3.

⁶ "MRI" stands for magnetic resonance imaging. MRI technology uses a magnetic field and radiofrequency signals to visualize internal structures of the body. See MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th ed. 2010) ["MOSBY'S"] at 1166.

At a July 6, 2011 status conference, petitioner's counsel confirmed that he was unable to find an expert or treating physician to opine in favor of vaccine causation. Respondent thereafter filed a Vaccine Rule 4 report on July 11, 2011, recommending against compensation.

II. Relevant Medical History.

Prior to her death at age 63, Ms. Holmes suffered from a number of medical conditions. When she received an influenza vaccination on September 30, 2008,⁷ the problem list in her records included hypothyroidism, Type 2 diabetes, high cholesterol, hematuria, and stress. The records also indicated that she had acute pharyngitis and had been exposed to meningitis. Pet. Ex. 3, p. 1.

On December 1, 2008, Ms. Holmes went to Boston Medical Center ["BMC"], complaining of chest palpitations, dizziness, body aches, cough, and cold symptoms. She was treated and released later that same day. Pet. Ex. 3, pp. 4-9, 26.

She returned to BMC via ambulance on December 27, 2008, complaining of dizziness and flu symptoms, with increased weakness and lightheadedness. She had fallen twice. Her temperature was 102.8° Fahrenheit and she was lethargic at the time of her admission that same day. Pet. Ex. 3, pp. 12-17. The following day, a BMC neurologist examined Ms. Holmes. Based on his examination, her history, and laboratory testing, he believed that she had "viral meningoencephalitis." Pet. Ex. 3, pp. 34-35.

A brain MRI performed on December 29, 2008, had findings "suggestive of herpes encephalitis." Pet. Ex. 3, p. 42. Her condition deteriorated the following day. She was unresponsive and required intubation. Two brain CT scans⁸ showed evidence of hemorrhage and edema, which were interpreted as "[h]erpes encephalitis, right temporal bleed" (Pet. Ex. 3, p. 48). *Id.*, pp. 44, 73, 76. She had a positive test for herpes simplex virus, and an infectious disease specialist commented that her presentation was "classic" for herpes encephalitis. Pet. Ex. 3, p. 86.

Ms. Holmes remained in critical condition in the intensive care unit at BMC until her death on January 6, 2009. Her physicians attributed her death to complications

⁷ This is apparently the vaccination petitioner alleged to be causal, although the date of the vaccination does not correspond to the November date appearing in the petition.

⁸ A CT scan refers to a computed tomography scan of the brain, a test used to diagnose central nervous system disease, including tumors, aneurysms, and hemorrhages. It consists of a computerized analysis of x-rays of the brain. MOSBY'S at 1080-82.

from herpes encephalitis (Pet. Ex. 3, p. 112⁹), and her death certificate reflects her cause of death as hemorrhagic encephalitis and herpes (Pet. Ex. 1).

III. Failure to Establish Vaccine Causation.

In order to receive compensation, a petitioner must prove either a “Table” injury¹⁰ or that a vaccine listed on the Table actually caused or significantly aggravated an injury. Because the influenza vaccine has no associated injuries listed on the Table, petitioner must demonstrate that it caused or significantly aggravated Ms. Holmes’ illness or death. See § 300aa-11(c)(1)(C)(ii). This requires preponderant evidence of “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). See also *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). No reliable evidence submitted in this case links the vaccine as the cause in fact of any illness, disability, injury, or condition, or of Ms. Holmes’ death. There is preponderant evidence that Ms. Holmes’ death was the result of brain inflammation and hemorrhage caused by a virus unrelated to any vaccine.

Under the Vaccine Act, a special master cannot find a petitioner has proven his case by a preponderance of the evidence based upon “the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a)(1). Petitioner is “required to substantiate [this claim] with independent evidence.” *Lett v. Sec’y, HHS*, 39 Fed. Cl. 259, 262 (1997). Failure to substantiate a claim will result in dismissal. See *Tsekouras v. Sec’y, HHS*, 26 Cl. Ct. 439 (1992), *aff’d per curiam*, 991 F.2d 810 (Fed. Cir. 1993); *Sapharas v. Sec’y, HHS*, 35 Fed. Cl. 503 (1996); Vaccine Rule 21(b). In our initial status conference, I informed petitioner’s counsel that, given that the medical records did not substantiate this claim, an expert medical opinion would be required in order to avoid dismissal. I then reminded petitioner in my June 15, 2011 order that failure to file an expert medical opinion would result in dismissal of this claim. Petitioner was unable to find a medical expert willing to opine in favor of vaccine causation.

⁹ This page appears in the medical records between Pet. Ex. 3, p. 112 and Pet Ex. 3, p. 113. It is also labeled p. 112, and it is the doctor’s death note, dated January 7, 2009, 12:00 AM.

¹⁰ A “Table” injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2010), corresponding to the vaccine received within the time frame specified.

The only evidence of vaccine causation here is petitioner's affidavit that he was informed by an unidentified physician that an influenza vaccine administered "shortly" before Ms. Holmes' illness manifested "could have" caused her illness and death. I cannot find that a vaccine-related injury occurred based solely on the claims of a petitioner. Even if I could do so, a statement by an unidentified physician that something "could have" caused injury is insufficient. The statute requires preponderant evidence of causation; mere possibilities are not enough. See § 300aa-13(a)(1)(A); see also *Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1322-23 (Fed Cir. 2010) (noting a causation-in-fact petitioner is the equivalent of a tort plaintiff and must prove his case under the same standards applied in traditional tort litigation). I also note that the term "shortly" as used in the affidavit refers to a vaccine in November possibly causing an illness in December, but Ms. Holmes received her vaccine in September, not November. The treating physician may not have been aware of the true facts at the time any statement to Mr. Holmes regarding vaccine causation was made.

IV. Conclusion.

Petitioner has failed to demonstrate that Ms. Holmes' illness and death were caused by a vaccine. He has failed to comply with an order to produce an expert medical opinion to support his claim. **Accordingly, this case is dismissed for failure of proof and for failure to prosecute. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/Denise K. Vowell

Denise K. Vowell
Special Master