

OFFICE OF SPECIAL MASTERS

(E-Filed: March 22, 2007)

No. 99-409V

PUBLISHED

RICK and CHERYL BUTCHER, as)	
representatives of the ESTATE of)	
TAYLOR BUTCHER,)	
)	
Petitioners,)	Motion for Judgment on the
)	Record; Hepatitis B Vaccination;
v.)	Cardiac Arrest and Subsequent
)	Death; Failure to Offer either a
)	Medical Theory or Opinion of
SECRETARY OF THE DEPARTMENT OF)	Causation; Denial of
HEALTH AND HUMAN SERVICES,)	Compensation
)	
Respondent.)	
)	
)	

Clifford J. Shoemaker, Vienna, VA, for petitioner.

Althea W. Davis, with whom were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Vincent J. Matanoski, Acting Deputy Director, and Catharine E. Reeves, Assistant Director, United States Department of Justice, Torts Branch, Civil Division, Washington, DC, for respondent.

DECISION¹

¹Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless an issued decision contains trade secrets or commercial or financial information that is privileged or confidential, or the decision contains medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. When a special master files a decision or substantive order with the Clerk of the Court, each

On June 28, 1999, petitioners, Rick and Cheryl Butcher, as representatives of the Estate of Taylor Butcher, filed a petition pursuant to the National Vaccine Injury Compensation Program² (the Act or the Program). The petition alleges that “[o]n or about June 20, 1997, Taylor received a Hepatitis B vaccination³ and experienced an adverse reaction to this inoculation.” Petition (Pet.) ¶ 2. The petition states that “Taylor’s course was complicated, and, as a direct result of his injuries, he passed away on February 4, 1998.” *Id.* ¶ 3. The petition further states that a “fact-specific description of the claimed symptoms and the nature and extent of the injuries caused by the inoculation and the condition of [Taylor] at all relevant times is set forth in the medical records which, when filed, will be incorporated by reference herein” *Id.* ¶ 4. On February 8, 2002, petitioners filed Exhibit 1, which petitioners described as “[a]ssorted [m]edical [r]ecords from [p]revious [c]ounsel.” See Petitioners’ Exhibit 1 (Ps’ Ex. 1).

On May 13, 2002, an Order to Show Cause (Show Cause Order) issued stating:

The medical records submitted as exhibit 1 show that Taylor suffered cardiac arrest on July 11, 1997 at approximately 2:30 a.m., 21 days after receiving hepatitis B vaccine. The records also show that he had previously been healthy. He had been playful the evening before. He had been treated for conjunctivitis five days previously, and had a cough for a couple of days together with a runny nose. Med. recs. at 12, 18. He had no twitching, no fever, and no vomiting. Med. recs. at 12. No autopsy report or certificate of death was filed.

Show Cause Order at 1-2. Because “[p]etitioners have not yet submitted an expert medical report in support of their case[, and because] [i]t appears highly unlikely that petitioners will succeed in finding an expert to support the allegations of their petition, i.e., that

party has 14 days within which to identify and move for the redaction of privileged or confidential information before the document’s public disclosure.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

³ The hepatitis B vaccine is “a noninfectious viral vaccine derived by recombination from hepatitis B surface antigen and cloned in yeast cells; administered intramuscularly for immunization of children and adolescents and of persons at increased risk for infection.” Dorland’s Illustrated Medical Dictionary 1999 (30th ed. 2003).

hepatitis B vaccine caused cardiac arrest in a healthy baby 21 days after vaccination,” petitioners were directed to show cause “why this case should not be dismissed.” Id. at 2.

Petitioners responded to the Show Cause Order asking “this court to allow petitioner[s] to participate in the resolution process being created by the Hepatitis B Steering Committee.”⁴ Petitioners’ Response to Show Cause Order and Motion to Proceed with Similar Hepatitis B Claims (Ps’ Show Cause Resp.) at 1. In their response to the Show Cause Order, petitioners also moved for the inclusion of this case in the “Cardiac/Hematological group” of hepatitis B cases, which would permit petitioners to “participate in the Cardiac /Hematological group causation hearing(s).” Id. Petitioners stated in their filing “that Taylor received [his] Hepatitis B vaccine on June 20, 1997 and suffered a cardiac arrest on July 11, 1997,” twenty-one days after the receipt of his vaccination. Id. Petitioners further stated that they believed that they “w[ould] succeed in obtaining an expert to support the allegation that [Taylor’s death] was caused by the Hepatitis B vaccine.” Id. But, petitioners requested a stay of further proceedings until the cases were “ready to proceed.” Id. On February 24, 2003, an order issued staying “all future action . . . until petitioner[s] notif[y] this court that petitioner[s] [are] prepared to proceed.” Stay Order, filed February 24, 2003.

On February 8, 2006, this case was reassigned to the undersigned. See Order of Reassignment, filed February 8, 2006. By Scheduling Order dated March 29, 2006, petitioners were directed to file all medical records and an expert opinion on causation on or before July 31, 2006. Petitioners filed no additional medical records. Petitioners did not file an expert opinion.

Subsequently, petitioners filed a Motion for Judgment on the Record (Ps’ Mot.). Petitioners’ motion requests judgment on the record “as it stands” because “[p]etitioners do not feel that they can prove causation.” Ps’ Mot. at 1. Petitioners state that they “cannot find an expert to support causation in their case.” Id.

⁴ After the filing of numerous petitions seeking compensation for injuries alleged to have occurred as a result of hepatitis B vaccinations, the Office of Special Masters explored with representative counsel for petitioners and respondent the possibility of resolving the various claims by addressing claims involving similar injuries through omnibus proceedings that would first consider the issue of whether a hepatitis B vaccination could cause the particular type of injury alleged.

In response to petitioners' motion, respondent filed a combination Rule 4(c) Report⁵ and a Response to Motion for Ruling on the Record (R's Resp.). Respondent does not object to the motion or to the entry of a decision in this case. Respondent asserts that "petitioners have presented no evidence regarding Taylor's death, including the cause of his death, and have failed to present evidence linking Taylor's death to his alleged vaccine-related injury." R's Resp. at 6. Respondent urges the dismissal of petitioners' claim because petitioners "[l]ack[] supportive evidence in the medical records . . . and [l]ack[] support . . . from a medical expert" that would enable them to meet their requirements for proving entitlement to compensation. Id.

The record in this case consists of the petition and petitioners' Exhibit 1. Petitioner's motion for judgment on the record is ripe for decision.

II. Discussion

A. The Factual Record

Petitioners' adopted son, Taylor, was born on October 11, 1996.⁶ Pet. ¶ 2. Taylor received his first hepatitis B vaccination on October 12, 1996, the day after his birth, in the hospital. Ps' Ex. 1 at 93. Taylor received his second hepatitis B vaccination on November 11, 1996. On June 20, 1997, at eight months of age, Taylor received his third hepatitis B vaccination. Id. On July 11, 1997, twenty-one days after his vaccination, Taylor suffered cardiac arrest. See id. at 19, 130-131.

The filed records pertaining to Taylor's emergency room visit on July 11, 1997, contain a "[h]istory of [p]resent [i]llness" provided by Mrs. Butcher, Taylor's mother, that Taylor awakened his parents at "approximately . . . 2:40 [a.m.], seemed to be crying and gasping for respiration, seemed poorly responsive . . ." Id. at 18. Taylor's condition prompted his parents to call an ambulance. Id. On arrival at Pascack Valley Hospital,

⁵ Rule 4(c) of the Vaccine Rules requires that respondent file a report "after petitioner has satisfied all required documentary submissions" that sets forth "a full and complete statement of respondent's position as to why an award should or should not be granted." Vaccine Rule 4(c), Appendix B of the Rules of the Court of Federal Claims. The Rule 4 report must contain respondent's medical analysis of petitioner's claims and any legal arguments that respondent may have in opposition to the petition. Id.

⁶ The medical records indicate that "at 2 days of age," Taylor's birth mother "put [him up for] adoption." Ps' Ex. 1 at 13, 18. Petitioners subsequently adopted him. See id. at 18, 93.

Taylor's mother related to the emergency room staff that Taylor "had no recent illness," but had been "treated for conjunctivitis 5 days ago." Id. She also noted that Taylor had been "playful" the prior evening. Id. After intubation⁷ at Pascack Valley Hospital, Taylor was transferred to Westchester County Medical Center. Id. at 12-13.

Taylor's emergency room "admit note[s]" at Westchester County Medical Center indicate that he had a two day history of a "cough" and a "runny nose." Id. at 12. The records from Westchester County Medical Center include the following notation:

Toxicology screen "(qualitatively) positive for glutethimide (sedative) used for insomnia. Child supposedly watched by an aunt who had been on this medication. Poison control called - half life is 12-14 hours

. . .

Have called C[hild]P[rotective]S[ervices] in light of positive tox screen for sedative (a drug used by child's aunt) and parents told nite charge nurse that child had problems sleeping at nite. CPS worker is here this a[.]m[.] waiting to speak with parents.

Id. at 21.⁸

The medical records from Westchester County Medical Center indicated that the results of a computed tomography of Taylor's head were "compatible with severe anoxic injury."⁹ Id. at 75. During his hospitalization, Taylor was "maintained on [Phenobarbital] and Dilantin for possible seizures." Id. at 69. The filed medical records did not indicate Taylor's condition on his discharge from the hospital.

⁷ Intubation is the "insertion of a tube into a body canal or cavity." Dorland's at 947.

⁸ The records also include a subsequent analysis in July or August 1997 by toxicologist Dr. Frederic Reiders of samples of Taylor's blood, serum, and urine that were dated July 11, 1997, the date of Taylor's emergency room admission for cardiac arrest, and that were received from Westchester County Medical Center. See Ps' Ex. 1 at 87-88. Although the record does not indicate why the analysis was performed, Dr. Reiders stated in a letter to Mr. Eric Kleiner, an attorney, that "no Glutethimide was administered to this individual at or around the time of the initial incident." Id. at 88.

⁹ An anoxic injury is caused by a lack of oxygen to human tissues. See Dorland's at 96.

Petitioners allege that Taylor died on February 4, 1998 as “a direct result” of his vaccine-related injuries. Pet. ¶ 3. However, the filed records contain no records pertaining to Taylor’s death.

B. Legal Standard and Analysis

The Vaccine Act permits petitioners to prove entitlement to compensation by showing that either: (1) the vaccinee suffered an injury listed on the Vaccine Injury Table within the prescribed time period, commonly referred to as an “Table” case, see § 300aa-14(a); or (2) the vaccinee suffered an injury that is not listed on the Vaccine Injury Table but is caused in fact by the received vaccination, commonly referred to as an “off-Table” case, see § 300aa-11(c)(1)(C)(ii)(I). By either method, petitioners bear the burden of proving their claim by a preponderance of the evidence. § 300aa-13(a)(1).

In a “Table” case, petitioners benefit from a presumption of causation. See § 300aa-14(a); 42 C.F.R. § 100.3(a). The filed medical records in this case indicate that Taylor suffered cardiac arrest twenty-one days after receiving his third hepatitis B vaccination. See Ps’ Ex. 1 at 19, 122. Taylor’s parents allege that as a direct result of Taylor’s hepatitis B vaccination, his “course was complicated . . . and he passed away on February 4, 1998.” Pet. ¶ 3. The record in this case does not support a finding that a Table injury occurred.

To establish entitlement to compensation for their “off-Table” claim, petitioners must prove by a preponderance of the evidence that the vaccination that Taylor received caused his cardiac arrest and subsequent death. Petitioners satisfy their burden of proof “by providing: (1) a medical theory causally connecting [Taylor’s] vaccination and [his] injury; (2) a logical sequence of cause and effect showing that [Taylor’s] vaccination was the reason for [his] injury; and (3) a showing of a proximate temporal relationship between [Taylor’s] vaccination and injury.” Althen v. Sec’y of Dept. of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In this case, petitioners have failed to supply evidence of a causal connection between Taylor’s vaccination and his death. Taylor’s medical records do not demonstrate that Taylor suffered an injury as a result of his third hepatitis B vaccination on June 20, 1997. Taylor’s medical records do not establish any relationship between his vaccination and his cardiac arrest. Taylor’s medical records do not indicate that Taylor suffered any adverse reaction following the administration of any of his hepatitis B vaccinations, and petitioners have produced no documentary evidence pertaining to Taylor’s death. Nor have petitioners provided an expert opinion offering a medical theory causally connecting Taylor’s vaccination to his cardiac arrest and subsequent death. Instead, petitioners have conceded that they are unable to find an expert to support their claim of causation. Ps’ Mot. at 1. The Vaccine Act prohibits a special master from making a finding of entitlement

to compensation based on the claims of petitioners alone, without substantiation by medical records or by a medical opinion. See § 300aa-13(a)(1). In this case, petitioners claim is not substantiated by either the filed medical records or an offered medical opinion. Under the Vaccine Act, petitioners' claim must fail.

III. CONCLUSION

The medical records in this case do not establish a causal connection between Taylor's hepatitis B vaccination, his cardiac arrest, and his subsequent death. Petitioners have offered no medical opinion causally connecting Taylor's vaccination and his injury. Because petitioners have failed to establish entitlement to compensation under the Vaccine Act, petitioners' claim is **DISMISSED**. The Clerk of the Court shall **ENTER JUDGMENT** accordingly.¹⁰

IT IS SO ORDERED.

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

¹⁰Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.