

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
01-263V
Not for Publication
August 29, 2007**

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| MEGAN HELZNER, | * | |
| | * | |
| Petitioner, | * | Ruling on the Record; |
| | * | Hepatitis B; |
| v. | * | Statute of Limitations |
| | * | |
| SECRETARY OF THE DEPARTMENT OF | * | |
| HEALTH AND HUMAN SERVICES, | * | |
| | * | |
| Respondent. | * | |

Clifford Shoemaker, Esq., Shoemaker & Associates, Vienna, VA, for the petitioner.
Althea Davis, Esq., U.S. Department of Justice, Washington, DC, for the respondent.

VOWELL, Special Master:

DECISION¹

On April 30, 2001, Mrs. Paula K. Helzner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² [the “Vaccine Act” or “Program”] on behalf of her minor daughter, Megan Helzner [“Megan”]. The case was recaptioned after Megan reached the age of majority.

The original petition alleged that the hepatitis B vaccination she received on April 28, 1998,³ caused Megan to develop arthritis and lupus-like symptoms. Petition, ¶ 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¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). 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 Hereinafter, for ease of citation, all “§” references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000).

³ Section 300aa-16(a)(2) requires a petition to be filed within three years of onset. I judicially note that April 28, 2001, the date the statute of limitations would have expired if computed from the earliest possible date of onset (the date of vaccination), was a Saturday. In accordance with Vaccine Rule 19(a),

Two amended petitions were filed on October 25, 2006, clarifying petitioner's theory of liability.⁴ These revised petitions contended that the third hepatitis B vaccination Megan received on April 28, 1998, significantly aggravated the pre-existing conditions caused by the first two hepatitis B vaccinations she had received. Second Amended Petition, ¶¶ 46. Petitioner's theory of recovery was based on this significant aggravation claim, because the first two vaccinations and the alleged onset of her symptoms in September 1997 all fell outside the Vaccine Act's statute of limitations. See § 300aa-16(a)(2).

On June 29, 2007, I issued an onset ruling that set forth the procedural history of the case and the facts surrounding Megan's hepatitis B vaccinations, onset of symptoms, and treatment of her illness. The onset ruling is incorporated by reference into this decision.

Petitioner has requested judgment on the record without a lengthy discussion of her medical history. Motion for Judgment on the Record, filed August 24, 2007. Respondent's counsel orally indicated that she did not oppose the motion. The facts, as set forth in the onset ruling, establish that Megan received a vaccine listed on the Vaccine Injury Table in the United States on April 28, 1998 and thereafter experienced an aggravation of some earlier symptoms with illness persisting for longer than six months after this third hepatitis B vaccination. Although the Motion for Judgment on the Record indicates that petitioner was unable to find an expert to support her claim of vaccine causation of her medical condition, I find that the petition was filed in good faith.

To be eligible for compensation under the Vaccine Program, a petitioner must either demonstrate a "Table" injury, to which a statutory presumption of causation attaches, or prove by a preponderance of the evidence that a vaccine listed on the Vaccine Table caused or significantly aggravated an injury. *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Because the injuries alleged, arthritis and a lupus-like condition, are not ones listed on the Vaccine Injury Table (42 C.F.R. § 100.3), Megan has the burden to establish by a preponderance of the evidence, that: (1) she received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) she sustained or had significantly aggravated an illness, disease, disability, or condition

RCFC, Appendix B, when a deadline is on a weekend or holiday, the filing is due the next day that is not a weekend or holiday. In 2001, the next business day was Monday, April 30, 2001.

⁴ The two amended petitions are nearly identical. The only difference is that the second amended petition includes ¶¶ 14-16, which allege a date for Mrs. Helzner's contact with the vaccine manufacturer, as well as information regarding Megan's summer activities, her deteriorating health, and the impact of her health on her school attendance during the first semester of her 7th grade year.

caused by the vaccine; and (4) that the condition has persisted for more than six months.⁵

Based on a review of the entire record,⁶ I conclude that she has failed to establish a *prima facie* case. Although the record establishes all the other statutory requirements by preponderant evidence, she has failed to show that the vaccine caused her injury.

In an off-Table case, a petitioner must show, “by preponderant evidence that the vaccination brought about her injury by providing: (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*, 418 F.3d at 1278. See also, *Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006).

Petitioner need not show identification and proof of specific biological mechanisms, as “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen*, 418 F.3d at 1280. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition; showing that the vaccination was a “substantial factor” in causing the condition and was a “but for” cause is sufficient for recovery. *Shyface v. Sec’y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). See also, *Pafford v. Sec’y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Petitioners may not be required to show “epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect... .” *Capizzano*, 440 F.3d at 1325. Causation is determined on a case by case basis, with “no hard and fast *per se* scientific or medical rules.” *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see, Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden).

At best, Megan’s medical records show that she and her mother believed that her condition was caused by the hepatitis B vaccine. Some medical histories recite that

⁵ Section 300aa–13(a)(1)(A). This section provides that petitioner must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1). Section 300aa–11(c)(1) contains the four factors listed above, along with others not at issue in this case.

⁶ See § 300aa–13(a): “Compensation shall be awarded...if the special master or court finds on the record as a whole...” See also, § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

belief, and one of her treating physicians indicated that her condition was possibly related to the hepatitis B vaccination. Petitioner's Exhibit 1, p. 2. This "possibility" does not rise to the level of proof required under the Vaccine Act and under *Althen*, because it fails to provide a medical theory connecting the vaccine and injury, fails to demonstrate the logical sequence of cause and effect, and fails to explain the temporal relationship between vaccine and illness, other than by stating that the vaccine preceded the medical condition.⁷ In the absence of a medical opinion establishing the *Althen* factors, I cannot conclude that petitioner has met her burden in this case.

Petitioner has not demonstrated by a preponderance of the evidence that her condition was either caused or significantly aggravated by the hepatitis B vaccination she received in April 1998. She has thus failed to establish a *prima facie* case for compensation. The petition for compensation is therefore DENIED. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Special Master

⁷ I note that the physician who wrote this statement may have been relying on something other than the contemporaneous medical records to establish the temporal connection between vaccine and onset of symptoms in Megan's case. In the onset ruling, I issued factual findings that differed from those provided in some of the medical histories, but my findings were generally consistent with those found in the contemporaneous medical records.