

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-395V

January 22, 2010

Not to be Published

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TYLER HARRISON and JESSICA HARRISON, \*  
as parents and legal representatives of their minor \*  
daughter, EMILY HARRISON, \*

Petitioners, \*

v. \*

SECRETARY OF THE DEPARTMENT OF \*  
HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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Ramon Rodriguez, III, Richmond, VA, for petitioners.

Chrysovalantis P. Kefalas, Washington, DC, for respondent.

Entitlement: hepatitis A  
vaccine; acute hepatitis;  
no petitioners' expert opinion;  
ruling on the record

**MILLMAN, Special Master**

## DECISION<sup>1</sup>

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision is filed, the parties have 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioners filed a petition on June 17, 2009 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis A vaccine caused their daughter Emily acute hepatitis or, in the alternative, significant aggravation of an underlying disorder.

The undersigned and the parties held telephonic status conferences on September 23, 2009 and October 23, 2009. During this time, petitioners' counsel endeavored to find expert medical support for his clients' allegations, but was unsuccessful.

On October 9, 2009, respondent filed her Rule 4(c) Report. Attached to it as Exhibit A is the expert report of Dr. Raymond S. Koff, a hepatologist and Clinical Professor of Medicine at the University of Connecticut Health Center, dated August 15, 2009. Dr. Koff states Emily did not have a systemic or local reaction to either of her first two hepatitis A vaccinations on March 26, 2002 or July 30, 2003. Ex. A, p. 1. Emily received her third hepatitis A vaccination on June 21, 2006. This is the vaccination at issue in the case. Emily had subsequent acute liver failure. Ex. A, p. 2. Dr. Koff states that in 49% of acute liver failure cases, no cause could be identified. In children, no known cause occurs in nearly 50% to 70% of cases. Ex. A, p. 3. Dr. Koff states that hepatitis A vaccine is an inactivated vaccine unassociated with actual infection. *Id.* He concludes that Emily's onset of illness 13 days after vaccination was coincidental. *Id.*

On January 13, 2010, petitioners filed a Motion for a Ruling on the Record, stating that they could not obtain a medical expert who would provide an opinion establishing a reasonable medical theory to support their claim of entitlement. Motion, p. 1. The undersigned grants petitioners' motion.

The telephonic status conference set for Thursday, February 4, 2010, at 10:30 a.m. is hereby cancelled.

## **FACTS**

Emily was born on November 30, 1995.

On March 26, 2002, she had her first hepatitis A vaccination. Med. recs. at Ex. 4, p. 8.

On July 30, 2003, she had her second hepatitis A vaccination. *Id.*

On June 21, 2006, she had her third hepatitis A vaccination. Med. recs. at Ex. 4, p. 10.

On July 20, 2006, she went to the doctor with a history of having yellow eyes and diarrhea starting two days previously. Med. recs. at Ex. 5, p. 6.

On July 21, 2006, Emily went to Children's Hospital and Health Center where she was diagnosed with hepatitis. Med. recs. at Ex. 6, pp. 2., 4. Her eyes had been yellow the last three days. She had slight diarrhea, but no fever and no vomiting. Med. recs. at Ex. 6, p. 4. She did not have autoimmune hepatitis. Med. recs. at Ex. 6, p. 16.

On August 13, 2006, Emily went to Lucile Packard Children's Hospital for a liver transplant. Med. recs. at Ex. 8, p. 19.

On November 16, 2006, Emily saw Dr. Kenneth L. Cox, a gastroenterologist at Lucile Packard Children's Hospital, who diagnosed her with hepatitis of unclear etiology. Med. recs. at Ex. 10, pp. 28, 29.

On April 16, 2007, a liver biopsy final report was issued which stated that no features specific for autoimmune hepatitis were identified. Med. recs. at Ex. 10, p. 56.

## **DISCUSSION**

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence "(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. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal

Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” Grant, *supra*, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148.

Petitioners must show not only that but for the hepatitis A vaccine, Emily would not have had hepatitis, but also that the vaccine was a substantial factor in bringing about her hepatitis.

Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In the instant action, however, petitioners were not able to provide an expert opinion to satisfy the three Althen prongs. On the contrary, respondent filed an expert report from Dr. Koff, a hepatologist, who opined that Emily’s hepatitis onset was coincidental to rather than caused from her third hepatitis A vaccination. Recognizing the weakness in their case, petitioners moved for a ruling on the record. The undersigned grants their motion and dismisses for their failure to present a prima facie case of causation in fact.

Petitioners have failed to make a prima facie case that hepatitis A vaccine caused Emily’s hepatitis and liver failure.

## CONCLUSION

Petitioners' petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.<sup>2</sup>

**IT IS SO ORDERED.**

January 22, 2010  
DATE

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s/Laura D. Millman  
Laura D. Millman  
Special Master

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<sup>2</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.