

OFFICE OF SPECIAL MASTERS

No. 05-581V

(Filed: March 23, 2006)

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KATE MILLER, as Parent and Next Friend \*  
of SARA MILLER, a minor, \*

Petitioner, \*

v. \*

NOT TO BE PUBLISHED<sup>1</sup>

SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*

Respondent. \*

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RULING CONCERNING "ENTITLEMENT" ISSUE

HASTINGS, *Special Master.*

This is an action in which the petitioner, Kate Miller, seeks an award under the National Vaccine Injury Compensation Program (hereinafter "the Program--see 42 U.S.C. § 300aa-10 *et seq.*<sup>2</sup>), on account of an injury suffered by her daughter, Sara Miller. For the reasons set forth below, I conclude that she is entitled to such an award, in an amount yet to be determined.

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<sup>1</sup>This document will not be sent to electronic publishers as a formally "published" opinion. However, because this document contains a reasoned explanation for my action in this case, I intend to post this document on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Therefore, each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this entire document will be available to the public. *Id.* See also 42 U.S.C. § 300aa-12(d)(4)(B).

<sup>2</sup>The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2000 ed.). Hereinafter, for ease of citation, all "\$" references will be to 42 U.S.C. (2000 ed.). I will also sometimes refer to the Act of Congress that created the Program as the "Vaccine Act."

## I

### THE APPLICABLE STATUTORY SCHEME AND CASE LAW

Under the National Vaccine Injury Compensation Program (hereinafter the "Program"), compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious long-lasting injury; and has received no previous award or settlement on account of the injury. Finally--and the key issue in most cases under the Program, as in this case--the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table" corresponding to the vaccination in question, within an applicable time period also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is shown affirmatively that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury not of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists of demonstrating entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that, in fact, the vaccination caused the injury in question. *Althen v. Secretary of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Secretary of HHS*, 940 F. 2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); see also *Hines*, 940 F. 2d at 1525; *Althen*, 418 F. 3d at 1278. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *In re Winship*, 397 U.S. 358, 371 (1970) (*Harlan, J.*, concurring). The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Secretary of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, by evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F. 3d at 1278; *Grant v. Secretary of HHS*, 956 F. 2d 1144, 1148 (Fed. Cir. 1992).

In this case, there is no dispute that Sara's case meets most of the requirements for a Program award. The only question now in dispute is whether the petitioner has demonstrated the required

*causal link* between Sara’s vaccinations of June 24, 2002, and her chronic neurological condition, by making a showing of “causation-in-fact.”

## II

### FACTS AND PROCEDURAL HISTORY OF THIS CASE

#### A. *Facts*

The basic facts of this case are not in dispute. Sara Miller was born on February 20, 2002. For the first four months of her life, she generally appeared to be healthy. On June 24, 2002, at a four month well-baby check-up, she received several vaccinations, including the diphtheria-tetanus-acellular pertussis (“DTaP”) vaccine, the hemophilus influenza type B vaccine, and the inactivated poliovirus vaccine. Within 24 hours, she began to exhibit unusual shaking movements, which proved to be symptoms of a neurological disorder. Since then, Sara’s neurological disorder has proven to be a severe one, causing her to experience substantial deficits in the area of motor skills.

#### B. *Procedural history*

The petitioner in this case contends that Sara’s chronic neurological disorder was “caused-in-fact” by the vaccinations that she received on June 24, 2002. The petition was filed on May 25, 2005. After all of the relevant medical records were filed, I conducted an unrecorded telephonic status conference at which opposing counsel and I discussed the processing of the case. We agreed that the petitioner would file one or more expert reports supporting petitioner’s causation-in-fact theory, then respondent would file an expert report if respondent chose to take issue with petitioner’s theory.

Petitioner filed the expert reports of Dr. Richard Kelley on October 31, 2005, and of Dr. Martha Lusser on December 15, 2005. Both reports indicated the opinion (1) that Sara suffered an *acute* neurological reaction to her vaccinations of June 24, 2002, within 24 hours of those vaccinations, and (2) that Sara’s subsequent *chronic* neurologic disorder was caused by those vaccinations. After Dr. Kelley’s report was filed on October 31, 2005, respondent was given until December 5, 2005, in which to file an expert report, if respondent disagreed with Dr. Kelley’s opinion. (See my order of October 31, 2005.) Respondent requested and received an extension of the time for filing such a report until January 15, 2006, with petitioner’s consent. (See my order of December 6, 2005.) The January 15 deadline passed without respondent filing a report or requesting an extension, but, over petitioner’s objection, and after discussion at a conference held on February 7, 2006, I granted respondent’s request to be permitted to file respondent’s expert report no later than February 15, 2006. (See documents filed January 31, February 6, and February 8, 2006.)

On February 15, 2006, respondent did file an expert report, of Dr. Gerard Berry. In that report, however, Dr. Berry actually *supported* the conclusion of Drs. Kelley and Lusser that Sara had

an *acute* neurologic reaction to her vaccinations of June 24, 2002, and *did not dispute* the conclusion of Drs. Kelley and Lusser that Sara's *chronic* neurological disorder was vaccine-caused. Thereafter, an unrecorded telephonic status conference was held on March 8, 2006, at which respondent's counsel stated that while respondent had not *conceded* that petitioner is entitled to a Vaccine Act award, respondent did not have any further expert report to file.<sup>3</sup>

### III

#### ANALYSIS

Based upon all the evidence of record in this case, I conclude that it is "more probable than not" that Sara's chronic neurological disorder was caused by her vaccinations of June 24, 2006. The basis for this conclusion is simple. The basic underlying facts of this case, as set forth above at p. 3, are not in dispute. The only issue to be decided is whether the petitioner demonstrated the required *causal link* between Sara's vaccinations of June 24, 2002, and her chronic neurological disorder, by making a showing of "causation-in-fact." And I conclude that petitioner *has* adequately established that causal link, via the written opinions of Drs. Kelley and Lusser. As noted above, petitioner filed the expert reports of Dr. Richard Kelley on October 31, 2005, and of Dr. Martha Lusser on December 15, 2005. Both reports indicated the opinion (1) that Sara suffered an *acute* neurological reaction to her vaccination of June 24, 2002, within 24 hours of those vaccinations; and (2) that Sara's *chronic* neurologic disorder was caused by those vaccinations. In response, respondent filed the expert report of Dr. Gerard Berry. Dr. Berry's report, however, actually *supported* the conclusion of Drs. Kelley and Lusser that Sara had an *acute* neurologic reaction to her vaccination of June 24, 2002, and *did not dispute* the conclusion of Drs. Kelley and Lusser that Sara's *chronic* neurological disorder was vaccine-caused.

Therefore, the record of this case simply supports only one conclusion concerning the issue of causation-in-fact. Only two experts, Drs. Kelley and Lusser, have addressed the issue of whether Sara's chronic disorder was vaccine-caused, and those experts unanimously agree that it *was*. Dr. Berry's report does *not* take issue with that conclusion. Accordingly, I conclude that petitioner *has* successfully demonstrated, via the causation-in-fact route, that Sara's chronic neurologic disorder was vaccine-caused.<sup>4</sup>

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<sup>3</sup>When, on February 7, 2006, I scheduled the March 8 status conference, I remarked that at that March 8 conference we would likely talk about possible dates for an evidentiary hearing; this was based upon the assumption that Dr. Berry's report would likely *dispute* the conclusions of Drs. Kelley and Lusser. At the March 8 status conference, then, respondent's counsel stated that respondent would be willing to present oral testimony from Dr. Berry if I decided to hold an evidentiary hearing. I replied that since Dr. Berry's report in fact did *not* dispute the conclusions of Drs. Kelley and Lusser, I now saw no reason to schedule an evidentiary hearing.

<sup>4</sup>I note that it seems possible that Sara's case may fall within the "encephalitis" (not "encephalopathy") Table Injury for the DTaP vaccination. It is not necessary to resolve that issue, however, since petitioner has prevailed via the "causation-in-fact" route."

## IV

### FURTHER PROCEEDINGS

For the reasons stated above, I find it “more probable than not” that Sara’s chronic neurologic disorder was vaccine-caused. Therefore, I conclude that her mother is entitled to a Program award, on Sara’s behalf, on account of that chronic disorder. I have already scheduled a status conference for April 13, 2006, to discuss the issue of the appropriate *amount* of the award.

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George L. Hastings, Jr.  
Special Master