

OFFICE OF SPECIAL MASTERS

No. 03-550V

(Filed: March 22, 2006)

Sierra Howard, by Her Mother and *
Next Friend, CORALEE HOWARD, *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED¹

DECISION

HASTINGS, *Special Master.*

This is an action in which the petitioner, Coralee Howard, seeks an award under the National Vaccine Injury Compensation Program (hereinafter “the Program--see 42 U.S.C. § 300aa-10 *et seq.*”), on account of an injury to her daughter, Sierra Howard. For the reasons set forth below, I conclude that petitioner is not entitled to such an award.

¹Because I have designated this document to be published, this document will be made available to the public unless petitioner files, within fourteen days, an objection to the disclosure of any material in this decision that would constitute “medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” See 42 U.S.C. § 300aa-12(d)(4)(B): Vaccine Rule 18(b).

²The 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, 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 question in most cases under the Program--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 to demonstrate 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. *Althen*, 418 F. 3d at 1279. 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 injury or 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).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

Concisely stated, Althen's burden is to show by preponderant evidence that the vaccine 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. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F. 3d at 1278 (citations omitted). The court noted that a petitioner may not be required to supply evidence from *medical literature* supporting the petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of a qualified expert. The court stressed that a finding of causation may be founded largely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F. 3d at 1280.³

In this case, the question to be decided is whether the petitioner has prevailed via the "causation-in-fact" avenue.

II

FACTS AND PROCEDURAL HISTORY OF THIS CASE

A. *Facts appearing in the contemporaneous medical records*

Sierra Howard was born on April 8, 1999. During her first year of life she had no significant health problems, and received a number of vaccinations, including her first two hepatitis B vaccinations.

On April 10, 2000, Sierra received her third hepatitis B vaccination, along with a varicella vaccination ("com vax") and a hemophilus influenza B ("HIB") vaccination. (Ex. 4, p. 4.)⁴

³Most recently, the Federal Circuit addressed the causation-in-fact standard once again in *Capizanno v. HHS*, No. 05-5049, slip op. (Fed. Cir. March 9, 2006). That opinion cautioned Program factfinders against too narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of *Althen*.

⁴Petitioner filed Exhibits 1 through 6 on May 28, 2004, and additional, consecutively-numbered exhibits on numerous occasions thereafter. Respondent has filed Exhibits A and B. "Ex." references will be to those exhibits. "1-Tr." references will be to the pages of the transcript of the evidentiary hearing held on March 15, 2005; "2-Tr." references will be to the pages of the transcript of the hearing held on May 20, 2005.

Thereafter, she was not taken to see her pediatrician, Dr. Bianchi, or any other physician, until May 26, 2000. (Ex. 4, pp. 38-39.) At that May 26 visit, Sierra's mother reported that Sierra had been experiencing fever, rash, decreased appetite, fussiness, and frequent stools for "2 days." (Ex. 4, p. 38.) In the following days, Sierra's fever and rash worsened, she developed swelling of her hands and feet, and she was taken for medical attention again at least six times during the next 12 days. (Ex. 28, p. 38; Ex. 4, pp. 34-37; Ex. 5, p. 30.) Two different physicians at that time concluded that she was suffering from a "viral illness." (Ex. 4, pp. 34, 36, 37; Ex. 5, p. 30.) In the following weeks Sierra began to suffer leg problems--ultimately losing the ability to stand or walk--abdominal problems, and other difficulties, and she had a number of additional physician visits. By August, Sierra was diagnosed to be suffering from "eosinophilia" and, ultimately, "hypereosinophilic syndrome," also known as "HIS."⁵ (Ex. 5, pp. 13, 28.)

Since then, Sierra has continued to suffer severe leg problems and other difficulties, apparently as a result of her HIS. No cause for the HIS has ever been definitively identified.

B. Petitioner's reports of additional symptoms

In the course of this Vaccine Act proceeding, the petitioner, Sierra's mother, provided testimony that described symptoms which, according to petitioner, Sierra displayed during the period between April 10 and May 23, 2000. In this regard, petitioner provided an affidavit dated July 15, 2004 (Ex. 25), and then oral testimony at the hearing on March 15, 2005. The affidavit and oral testimony described basically the same symptoms, but only the oral testimony described *when* each symptom took place during that period.

Petitioner testified that on the evening of the day of Sierra's vaccinations, April 10, 2000, Sierra became feverish and also seemed "withdrawn" or "distant." (1-Tr. 6.) The fever lasted four or five days, then subsided, but Sierra continued to seem "withdrawn" or "depressed" until her next visit to Dr. Bianchi on May 26, 2000. (1-Tr. 7-8.)

Petitioner also testified that about two weeks after the fever subsided (thus, about three weeks after the April 10 vaccination), Sierra's feet became "puffy," meaning slightly enlarged. (1-Tr. 8.) Sierra's hands then also became puffy, and thereafter she experienced a slight "splotchy" rash on her feet, hands, and a bit on her chest. (1-Tr. 8-9, 32.) According to petitioner, the puffiness in the hands and feet, and the rash on the feet, remained until the time of Sierra's visit to Dr. Bianchi on May 26. (1-Tr. 10, 37.)

⁵"Eosinophilia" means that she had an abnormally large number of eosinophils in her blood; "hypereosinophilic syndrome" is a condition involving a massive increase in the number of eosinophils in the blood. *Dorland's Illustrated Medical Dictionary* (30th ed. 2003), pp. 624, 881. Eosinophils are cells that are part of the body's defense mechanism against invading microorganisms. Eosinophils are normally present in small numbers in the blood. Their inappropriate activation and increase, however, as in Sierra's case, can be harmful to the body. (Charles R. Janeway, et. al., *Immunobiology*, § 12-7 (5th ed. 2001).)

C. Procedural history

The petitioner in this case contends that Sierra's condition of HIS was "caused-in-fact" by the hepatitis B vaccination that Sierra received on April 10, 2000. The petition was filed on March 10, 2003, and was assigned on March 20, 2003, to Special Master E. LaVon French. On December 22, 2004, the case was reassigned to my docket, due to the impending retirement of Special Master French.

After the case was transferred to me, I determined that in order to resolve the petitioner's "causation-in-fact" contention, it was appropriate that I schedule two separate evidentiary hearings. First, I would travel to petitioner's home city and hear the testimony of the petitioner, and any other witnesses that the petitioner desired to present, concerning the symptoms that were not mentioned in the contemporaneous medical records, but were alleged to have occurred between April 10 and May 23, 2000. Then, at a separate hearing I would hear from the parties' two expert witnesses. In fact, two such hearings were held, on March 15, 2005, and May 20, 2005, respectively.

After the second hearing, at the request of petitioner's counsel, the parties agreed to file post-hearing briefs. Each party filed briefs on August 26 and September 16, 2005.

III

SUMMARY OF EXPERTS' OPINIONS

As noted above, both parties in this case have presented the opinions of medical experts. I will now summarize the opinions of each of the two experts.

A. Summary of Dr. Katz' opinion

Petitioner's expert, Dr. Roger Katz, submitted a written expert report (Ex. 26), and later testified at the second evidentiary hearing on May 20, 2005. Dr. Katz is a physician who is board-certified in immunology, pediatrics, and the treatment of allergies and pediatric allergies. His testimony concerning the causation issue may be summarized as follows.

Dr. Katz opined that the hepatitis B vaccination that Sierra received on April 10, 2000, caused her HIS.⁶ In forming his opinion, Dr. Katz relied upon the history of symptoms provided by Sierra's mother in this proceeding. That is, while neither his report nor his hearing testimony was very clear or precise in this regard, he seems to have assumed that Sierra experienced a fever within 24 hours after vaccination; that her fever lasted several days; that about two weeks later she

⁶At the evidentiary hearing, Dr. Katz pointed only to the hepatitis B vaccination, which Sierra received on April 10, 2000, as the cause of her HIS. (2-Tr. 20-21.) Earlier, in his written report, however, Dr. Katz had opined that it could have been either the hepatitis B vaccination or the varicella vaccination that she also received on the same day. (Ex. 26, p. 2.)

experienced puffiness of the hands and feet as well as a rash; and that she was “not responding well” (2-Tr. 23) to her parents and was “not her usual self” (2-Tr. 25) during the period between April 10 and May 26. (Ex. 26, p. 1; 2-Tr. 12-13, 23-29.)

Dr. Katz pointed to two articles in the medical literature which, he opined, indicate that the hepatitis B vaccine can cause HIS. (2-Tr. 19.) He opined that the hepatitis B vaccine stimulated Sierra’s immune system, provoking an “autoimmune response,” *i.e.*, a response in which the body’s immune system inappropriately attacks parts of the body itself, rather than attacking some invading agent as the immune system is designed to do. (2-Tr. 16-21.)

Dr. Katz opined that the symptoms that Sierra’s mother described as occurring in the first few weeks after her hepatitis B vaccination of April 10, 2000--*i.e.*, the fever, rash, and puffiness of hands and feet--were the first symptoms of Sierra’s HIS. He concluded that this timing of the symptoms supports the proposition that the vaccine caused the symptoms. In this regard, he noted the fact that this was Sierra’s third hepatitis B vaccination, so her immune system would react immediately to the vaccine.⁷ (*E.g.*, 2-Tr. 12-13, 21.)

Dr. Katz also noted, in support of his theory, that other likely causes for HIS had been investigated and ruled out in Sierra’s case. (Ex. 26, pp. 1, 2.)

B. Summary of Dr. Berger’s opinion

Respondent’s expert, Dr. Melvin Berger, also submitted an expert report (Ex. A, first filed on December 22, 2004, and then refiled in corrected form on January 7, 2005), and also testified at the evidentiary hearing on May 20, 2005. Dr. Berger is a physician who is board-certified in pediatrics, allergy, and immunology. Dr. Berger opined that the available evidence does *not* justify a conclusion that the hepatitis B vaccination caused Sierra’s HIS. Rather, Dr. Berger believes that Sierra’s HIS was caused by a viral infection, the first symptoms of which occurred on or about May 24, 2000.

Dr. Berger relies on the fact that the medical records made in 2000 indicate the *abrupt onset* of an acute illness in Sierra on or about May 24, 2000. Those records indicate a progression of Sierra’s symptoms from that time until her diagnosis of HIS. In Dr. Berger’s view, that acute illness which began about May 24, likely a viral infection, resulted in Sierra’s HIS.

Dr. Berger testified that he did not disregard the testimony of petitioner describing certain symptoms in Sierra between April 10 and May 23 of 2000. He opined, however, that any symptoms

⁷At the hearing, Dr. Katz referred to this type of immediate response to a repeat vaccination as an “amnesic” response, and, upon inquiry, spelled the word that way. (2-Tr. 21.) Reference to a medical dictionary, however, indicates that the word that Dr. Katz apparently had in mind was “anamnesic.” See *Dorland’s Illustrated Medical Dictionary* (W.D. Saunders Co., 27th ed. 1988), p. 72.

occurring during that period were likely not of much significance, since Sierra's family never took her to see a physician during that time period. Dr. Berger also explained that he could not understand how the hepatitis B vaccination of April 10 could produce only very mild symptoms during the first several weeks after vaccination, and then suddenly produce an abrupt, acute activation of Sierra's immune system more than six weeks later, about May 24.

IV

PRIMARY ANALYSIS

Based upon all the evidence of record in this case, I conclude that petitioner has *failed* to demonstrate that it is "more probable than not" that Sierra's HIS was caused by her hepatitis B vaccination of April 10, 2000. My reasons for this conclusion can be divided into two different primary lines of analysis. First, I find it unlikely that Sierra in fact experienced the alleged symptoms, during the period between April 10 and May 23, 2000, upon which Dr. Katz based his opinion. Second, even if I were to assume the accuracy of the petitioner's testimony concerning the alleged symptoms between April 10 and May 23, 2000, I would still find the analysis of Dr. Berger to be more persuasive than that of Dr. Katz.

A. The symptom history relied upon by Dr. Katz

After fully considering the testimony of Sierra's mother, the petitioner, and comparing that testimony to the evidence contained in the medical records, I find it unlikely that Sierra in fact experienced the set of symptoms, during the period between April 10 and May 23, 2000, upon which Dr. Katz relied. The chief reason is that none of the many medical records made during the year 2000--or any medical records made within two years of the time period in question--make any mention of those alleged symptoms.

1. The contemporaneous records do not mention any symptoms prior to May 24

When Sierra was taken to see Dr. Bianchi on May 26, 2000, the notes of that visit indicate that Sierra had been experiencing a rash and fever for *two days*, and also that she had a decreased appetite, frequent stools, and was "fussy," with no vomiting. (Ex. 4, p. 38.) No mention was made of *any* symptoms over the previous six weeks, from April 10 through May 23. Over the next 12 days after that May 26 visit, Sierra was taken to see physicians at least six more times, and again no notation was ever made in the medical records of any symptoms during the period from April 10 to May 23. (Ex. 25, p. 38; Ex. 4, pp. 34-37; Ex. 5, p. 30.) More visits occurred over the following weeks, and again no mention was made of any symptoms occurring prior to the rash and fever that began about May 24.

For example, when Sierra was first admitted to a hospital, at the Tucson Medical Center on August 17, 2000, Dr. Bianchi recorded a history of her illness, beginning with "I first saw her on May 26 with a complaint of rash and fever." (Ex. 11, p. 48.) No mention was made of any

symptoms occurring prior to the report on May 26 of a *two-day* history of rash and fever. Thus, when Dr. Bianchi admitted Sierra to the hospital on August 17, 2000, he seems to have concluded that the onset of her illness was the two-day history of rash and fever reported on May 26.

Next, when Sierra was transferred from the Tucson Medical Center to the University Medical Center on August 22, 2000, two histories of Sierra's illness were recorded on the same page, in two different handwritings.⁸ (Ex. 5, p. 54.) In the notes on the left side of the page, the history begins with "3 mth PTA [3 months prior to admission] → fever, rash." (*Id.*) This record, thus, again seems to indicate that the rash and fever reported to have begun about May 24, 2000--almost exactly 3 months prior to the 8-22-00 admission--were the first symptoms of Sierra's illness. Similarly, the notes in a different handwriting, on the right side of the page, list, as the earliest symptom of Sierra's illness, a "purple-red rash" occurring "3 mo. ago," which was treated by "steroids [for] 15 days." (*Id.*) This history, too, seems also clearly to describe the rash that appeared about May 24, 2000, which was in fact treated by steroids, as the first symptom of Sierra's overall illness.⁹ In addition, when Sierra first visited the rheumatologist, Dr. Hollister, on September 25, 2000, he wrote that Sierra "first became ill approximately four months ago with fever and rash," prompting treatment by steroids. (Ex. 7, p. 16.) Thus, not only is the notation of "four months ago" consistent with onset at around May 24, but Dr. Hollister, again, describes the onset of the disease as beginning with a fever and rash, prompting steroid treatment. Again, this description seems clearly to describe the abrupt onset of fever and rash on *May 24*, first reported to Dr. Bianchi on May 26.

In short, the medical records made in the year 2000 make no mention at all of the symptoms now described by petitioner, making it seem doubtful that such symptoms occurred.¹⁰

⁸At the bottom of pages 54 and 55 of Exhibit 5 appears the name of a resident physician, Dr. Colleen K. Cagno. It would seem likely, then, that Dr. Cagno wrote one of the two histories on p. 54, and that the other was recorded by someone else.

⁹Interestingly, this history, on the right hand side of the page, notes that "3 ½ months ago" Sierra's grandmother "returned from China," but, conspicuously, fails to note any *symptoms* in Sierra until "3 mo. ago." (Ex. 5, p. 54.)

¹⁰Numerous Program decisions have noted the general principle that contemporaneously-recorded records should ordinarily be given greater evidentiary weight than witness recollections offered long after the event in question. See *Cucuras v. Secretary of HHS*, 26 Cl. Ct. 537, 542 (1992), *aff'd*, 993 F. 2d 1525, 1528 (Fed. Cir. 1993); *Beddingfield v. Secretary of HHS*, 50 Fed. Cl. 520, 523-524 (2001); *Estate of Arrowood v. Secretary of HHS*, 28 Fed. Cl. 453, 458 (1993); *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 523 (1993); *Murphy v. Secretary of HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F. 2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992). See also the same principle noted in non-Program decisions such as *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947); *Montgomery Coca Cola Bottling Co. v. United States*, 222 Ct. Cl. 356, 615 F. 2d 1318, 1328 (Ct. Cl. 1980).

2. *The records which estimate a certain number of months of illness*

Next, I note that there were several histories recorded in August or September of 2000 that simply list Sierra as having been sick for a certain number of months, without giving any additional detail. These histories are not of crucial evidentiary weight, since they are so nonspecific. That is, if a person estimates that something began “about three months ago,” that estimate usually does not mean *precisely* three months ago. It is an *estimate*; the person is not usually attempting to be specific. It could mean 2 ½ months ago or 3 ½ months ago, or even two months or four months ago. So, such histories obviously have limited evidentiary value for purposes of pinpointing the *precise* onset of an occurrence. Nevertheless, the histories of this type contained in the record here are still worth a brief mention.

Several histories recorded in late August state that Sierra became sick about *three months* prior. I have already mentioned above the two different histories recorded at the hospital on August 22, at Ex. 5, p. 54, both indicating onset three months beforehand. There is another report of a “three month” history, also apparently made on August 22, at Ex. 5, p. 57. Other reports of “three-month” histories were recorded on August 24 (Ex. 5, p. 81); August 25 (Ex. 5, p. 85); and September 1 (Ex. 5, p. 138). Similarly, in the discharge summary from Sierra’s hospitalization that began on August 22, it is stated that she was “admitted after a three-month history” of illness. (Ex. 5, p. 43.) All these histories, describing during late August (or on September 1) a “three month” history, would be consistent with onset about May 24, as indicated by Dr. Bianchi’s first history taken on May 26. In addition, as also mentioned above, when Sierra first visited Dr. Hollister on September 25, 2000, he recorded the illness as beginning “four months ago,” again consistent with onset about May 24. (Ex. 7, p. 16.)¹¹

On the other hand, three of the general histories recorded in August diverge somewhat from the histories described above. First, on August 8, 2000, Sierra visited Dr. Shehab, a pediatric infectious disease specialist. In the notes of that visit, it was recorded that Sierra was “still sick--now almost three months” (Ex. 5, p. 11), which prompted Dr. Shehab to write that Sierra had been sick “over the past three months” (Ex. 5, p. 8). Of course, onset *exactly three months* earlier than August 8 would place the onset somewhat earlier than the May 24 date indicated by the record of Dr. Bianchi on May 26. However, at this August 8 visit, Sierra’s mother estimated onset “almost” three months earlier (Ex. 5, p. 11), the word “almost” indicating onset perhaps somewhat *less* than three months beforehand. Given this use of the word “almost,” coupled with the fact that this was an *estimate*, I conclude that the history really does not seriously contradict the conclusion that Sierra’s illness had its onset about May 24.

¹¹Also, Dr. Walden Browne recorded, in three notations in late August, that Sierra’s symptoms had begun “2-3” months beforehand. (Ex. 5, pp. 82, 101, 112). This estimate again, is completely inconsistent with petitioner’s current testimony concerning when the onset of symptoms began.

Second, on August 25, 2000, Sierra was seen by Dr. Michael Schumacher, who wrote that Sierra's "history started 4-5 m ago [with] rash on feet." (Ex. 5, p. 52.) Presumably the "m" after "4-5" stands for months, but if so, this history would seem to be nothing like any other piece of evidence in the record. Five months prior to August 25 would indicate onset about late March, which would be even *earlier* than the vaccination in question, while four months prior to August 25 would mean late April. Of course, an indication of onset "four to five months ago," in any event, obviously indicates that the person providing the history was not trying to be precise, but was providing a very gross *estimate* or *guess*. Moreover, the first few lines of the history recorded at that visit--"history started 4-5 m ago [with] rash on feet → U[pper] and L[ower] extremities → hives → Rx'd [with] oral steroids x 2 weeks" (*id.*)--seems to describe Sierra's history *beginning on May 24* as described in Dr. Bianchi's records of May 26 through June 16. Therefore, this history does *not* seem to describe any of those symptoms that Sierra's mother now describes as taking place prior to the rash and fever experienced about May 24. Accordingly, I conclude that the "4-5 month" estimate given to the physician at this visit was an aberration, and, does not provide substantial support to petitioner's current testimony concerning symptoms between April 10 and May 23.

Third, I note that Dr. Bagatell took a history on August 17, 2000. (Ex. 5, p. 17.) This history starts by stating that Sierra was "well until 3 ½ mo. ago presented [with] marked swelling of feet and hands. Then developed hive-like rash wax/wane all over body--reddish in color." (*Id.*) This history possibly could be interpreted as providing support to petitioner's description of symptoms predating May 24. That is, "3 ½ months" prior to August 17 would be at the beginning of May, right around the point at which, according to petitioner's current testimony, Sierra experienced the onset of "puffiness" in her hands and feet. However, there are also considerable problems with such an interpretation of this history. The use of the words "marked swelling," written by Dr. Bagatell, does *not* fit with petitioner's current description of Sierra as experiencing around May 1 only "puffiness" that was so slight as to be imperceptible to most people who looked at Sierra's hands and feet at the time. The "marked swelling" phraseology, rather, would seem to better describe the swelling in Sierra's hands and feet that Dr. Bianchi first observed on May 30. (Ex. 4, p. 37.) Further, the use of the word "presented" indicates that Sierra *came to a physician* with that "marked swelling," which again seems to refer to the visit with Dr. Bianchi on May 30, not to some very slight "puffiness" one month earlier which was *never reported to a physician*.

In sum, this "3 ½ mo. ago" history recorded by Dr. Bagatell does give me pause. But the use of the words "marked swelling" and "presented" is simply not consistent with petitioner's current testimony. Overall, this history of Sierra's illness still does not sound much like petitioner's current description. Therefore, considering this note in the context of all of the records made in the year 2000, I simply cannot find that this record supports petitioner's current description of Sierra's symptom history. More likely, the "3 ½ mo. ago" reference was simply an estimate made by petitioner's mother, and not intended to be exact.

3. Testimony that symptoms were reported to physicians

Petitioner testified that during Sierra's visit to Dr. Bianchi on May 26, 2000, she told Dr. Bianchi that Sierra's feet had been "puffy" and "mottled." (1-Tr. 12, 41.) Yet Dr. Bianchi did not record that such symptoms had been reported to him, even though he *did* note the mother's reports of fever, rash, decreased appetite, fussiness, and frequent stools. (Ex. 4, p. 38.) This makes me believe that the petitioner is now mistaken in her current recollection. Dr. Bianchi wrote down a number of fairly trivial symptoms, including "fussy" and "frequent stools;" it seems quite likely that if Sierra's mother also reported that Sierra's feet and/or hands had been puffy or mottled, he would have recorded that report, even if he did not notice such alleged conditions himself.

Similarly, petitioner testified that she described the symptoms that Sierra allegedly experienced between April 10 and May 23 to the physicians at the University Medical Center in August of 2000. (1-Tr. 42-43.) Yet the records of that hospitalization do not contain any mention of those symptoms. Again, it seems quite likely that if these physicians, who were struggling to determine why Sierra was so ill, and who were recording such trivial details as when her grandmother returned from a trip (Ex. 5, p. 54), had been told of any symptoms that predated May 24, then they would have recorded such a report in their notes.

In sum, petitioner now testifies that she reported the alleged pre-May 24 symptoms to Dr. Bianchi on May 26 and to other doctors in August, but the absence of any such notations in the medical records makes it appear unlikely that she made such reports. The fact that she is mistaken on this point adds further reason for me to conclude that she is mistaken in her testimony that the symptoms occurred at all prior to May 24.

4. History of prior physician visits by Sierra

Another factor is that, as Dr. Berger emphasized, during Sierra's first year of life, her mother seems to have taken Sierra to see Dr. Bianchi fairly often, even for relatively mild illnesses. (Tr. 82-83; see also Ex. 4, pp. 40-50.) This makes petitioner's current testimony seem even more unlikely. That is, it seems unlikely that Sierra could really have been "withdrawn" or "depressed" for six weeks, and had "puffy" hands and feet for more than three weeks, and yet petitioner did not take the infant to the doctor during that time period.

5. No conclusion of false testimony

In this regard, I stress that I certainly do *not* conclude that Sierra's mother gave deliberately false testimony in this case. Rather, I note a pattern that I have observed in a great many Program cases, in which family members' statements about the *timing* of an infant's symptoms in relation to an inoculation often change, sometimes abruptly, months or years after the vaccination. In these situations, the family's change in story quite often seems to have corresponded to the family's exposure to articles, television programs, a physician's suggestion, or some other source of information suggesting that a vaccination might be capable of causing the type of problem from

which that family's child has suffered. After such an exposure, the family begins for the first time to "remember" in hindsight that the infant's symptoms first occurred soon after a vaccination. In the large majority of these cases, I do not think that there is any dishonesty involved in such changes of story. Rather, in most cases it is likely that a family whose child has a serious disorder, having been told that no one knows the cause of that disorder, simply reacts when later informed about a possible cause--*i.e.*, the possibility that a vaccination could cause the disorder. To me, it seems understandable that loving families, desperate to pinpoint a cause for an awful disorder, will often begin in such circumstances to "remember" the onset of symptoms as having occurred closer in time to a vaccination than actually was the case.

I think it possible that such a phenomenon, as described in the paragraph above, explains the petitioner's testimony in this case. Based upon her own testimony and the medical records, it appears that sometime many months after the onset of Sierra's illness--probably sometime in 2002, about two years after the onset¹²-- petitioner heard a remark from Dr. Schumacher suggesting the possibility that a vaccination could cause an illness like Sierra's. Petitioner then discussed that possibility with Dr. Bianchi, which prompted Dr. Bianchi to fill out a VAERS report on August 12, 2002. (A VAERS report (Vaccine Adverse Event Reporting System) is to be filed when a patient suffers an adverse event soon after a vaccination. (See footnote 18, p. 18, below.) In his VAERS report, Dr. Bianchi reported that Sierra had experienced fever, rash, and later HIS, after a hepatitis B vaccination on April 10, 2000, with the "onset date" listed as May 24, 2000. See Ex. 38, p. 50.) Soon thereafter, petitioner contacted her current counsel about the possibility of filing a Vaccine Act claim, and, at her counsel's suggestion, she asked Drs. Schumacher, Bianchi, and Bagatell to provide letters addressing the issue of whether Sierra's illness was vaccine-caused.¹³ (1-Tr. 17-18.) That request resulted in a letter written by Dr. Schumacher on November 21, 2002, which contains the first written notation in any medical record mentioning any symptoms in Sierra *prior* to May 24, 2000. (Ex. 6, p. 1.)

Thus, in this case, it appears that in late 2002, about 2 ½ years after the onset of Sierra's illness, petitioner, now focused on the possibility of a vaccine cause for Sierra's illness, *for the first time* described to a physician symptoms in Sierra that were closer in time to her April 10 vaccinations than the fever and rash that began about May 24. It seems dubious to me, however, that petitioner in late 2002 could suddenly "remember" accurately a history of Sierra's symptoms that

¹²At the hearing, petitioner testified at one point that Dr. Schumacher suggested the possibility of a vaccination as the cause of Sierra's illness about *one year* after the onset of that illness. (1-Tr. 56.) Later, however, she acknowledged that it could have been later than that. (1-Tr. 59.) She also stated that soon after she received that suggestion from Dr. Schumacher, she contacted Dr. Bianchi, causing him to file the VAERS report. (1-Tr. 57, 60.) Thus, since the VAERS report was created in August of 2002 (Ex. 38, p. 50), it appears that petitioner's focus on the vaccination as a possible cause actually began just prior to August of 2002--that is, about *two years* after the onset of Sierra's illness.

¹³The letters of Drs. Schumacher, Bianchi, and Bagatell, and the VAERS report filed by Dr. Bianchi, will be discussed in more detail below (at pp. 17-19).

she never related to any physician in 2000. In such circumstances, I simply must be skeptical of whether the symptoms “remembered” at such a late date really are accurate. I am much more inclined to credit the histories provided by petitioner to the physicians at the time that Sierra’s illness began, in the year 2000.¹⁴

6. Changes in petitioner’s descriptions of Sierra’s symptoms

As explained above, Dr. Schumacher’s letter of November 21, 2002, seems to be the first mention in any medical record of any symptoms of Sierra that predated May 24, 2000. It is noteworthy, however, that this history, apparently provided by petitioner to Dr. Schumacher in November of 2002, nevertheless *differs* in three significant ways from petitioner’s *current* representations. First, in that November 2002 letter, Dr. Schumacher states that along with the “puffiness” about three weeks post-vaccination, it also became painful for Sierra to walk. No such leg pain at that time, however, has been described by petitioner in this proceeding. Second, that November 2002 letter makes no mention of “puffiness” in Sierra’s *hands*, in contrast to petitioner’s recent testimony. Third, in the November 2002 letter Sierra is described as becoming “withdrawn” *after* the onset of the feet puffiness about three weeks post-vaccination, whereas now petitioner testifies that Sierra became “withdrawn” beginning the *first evening* after the vaccination on April 10. (1-Tr. 6-8.)

Thus, apparently, the petitioner’s descriptions of Sierra’s symptom history have *changed more than once*. In 2000, no mention at all of symptoms predating May 24; in November of 2002, with the petitioner now focused on vaccination as a possible cause, the first report of symptoms predating May 24; then later, in her July 2004 affidavit and March 2005 testimony, a description of the pre-May 24 symptoms that is significantly different from the description provided to Dr. Schumacher in November of 2002.

The fact that petitioner’s descriptions of Sierra’s symptoms have changed in these ways over the years gives me *additional* reason to doubt whether her current description is an accurate one.

7. Summary concerning symptom history upon which Dr. Katz relied

For the reasons discussed above, I find it *unlikely* that Sierra experienced the set of symptoms now described by the petitioner as occurring during the period between April 10 and May 23, 2000. Therefore, the opinion of Dr. Katz, based on a history which seems unlikely, simply cannot be of any assistance to petitioner. Accordingly, petitioner’s causation case thus fails for this reason alone.

¹⁴I note also that the medical records make it clear that Sierra *did* suffer the *type* of symptoms that petitioner now describes as occurring during the April 10-May 23 period; that is, she suffered such symptoms in the days *after* May 24. Therefore, it seems likely that petitioner is simply misremembering the *timing* of the symptoms.

B. Dr. Berger's analysis was more persuasive

Moreover, as noted above, even if I were to *assume* the accuracy of the petitioner's testimony concerning the alleged symptoms between April 10 and May 23, 2000, I would still find the analysis of Dr. Berger to be more persuasive than that of Dr. Katz.

1. Strengths of Dr. Berger's testimony

In this regard, I found persuasive the testimony of Dr. Berger that even assuming that Sierra did experience symptoms of the type now described by her mother during the period between April 10 and May 23, such symptoms were likely not of much significance. As stressed above, Sierra's family never took her to see any physician during that time period, even though they had frequently taken Sierra to the pediatrician during the prior year. Moreover, even when Sierra was taken to see physicians, on May 26 and numerous times over the following days, none of the records made at those visits makes any mention of any symptoms occurring prior to May 24. Thus, as Dr. Berger argued, it is a major weakness in the theory of Dr. Katz that he bases his analysis of Sierra's illness substantially upon the timing of symptoms that, if they occurred at all, were at the time *not* considered significant enough to be noted in any medical records. In contrast, Dr. Berger bases his analysis of the case on the timing of symptoms--*i.e.*, the onset of fever and rash about May 24, and the numerous symptoms that occurred over the following days--that *did* result in Sierra being taken to a doctor and that *were* clearly recorded in medical records.¹⁵

Next, Dr. Berger's analysis is supported by the contemporaneous medical records in another way--that is, Sierra's treating physician at the time did note, in the contemporaneous medical records, the conclusion that Sierra was likely experiencing a *viral infection* that caused her symptoms of May 24-26 and the following days. Sierra's treating pediatrician at the time, Dr. Bianchi, stated in his records on four occasions--May 30, June 1, June 6, and June 13--that he believed that Sierra was suffering from a viral illness. (Ex. 4, pp. 33, 34, 36, 37.) In addition, Dr. Shehab, in the notes of a visit with Sierra on June 6, also indicated the view that Sierra's rash ("erythema multiforme") was "most likely the result of a viral infection." (Ex. 5, p. 30.)

Another point made by Dr. Berger also strongly supports his theory over that of Dr. Katz. Dr. Berger argued that, even accepting the petitioner's description of the alleged symptoms during the period from April 10 to May 23, it seemed extremely unlikely that the hepatitis B vaccination of April 10 could have produced only those relatively mild symptoms during the first several weeks after vaccination, symptoms not serious enough for Sierra to be taken to a physician, and then would suddenly produce an abrupt, acute activation of Sierra's immune system *more than six weeks later*. (2-Tr. 54-55, 83.) And, when I offered petitioner's counsel an opportunity to have Dr. Katz offer

¹⁵Note that according to petitioner's testimony, she did point out to Dr. Bianchi on May 26 that Sierra's feet had been "puffy" and "mottled" (1-Tr. 12, 41), yet Dr. Bianchi did not record such symptoms in his notes. Thus, if these symptoms did exist at all at that time, they must have been *very* insignificant if Dr. Bianchi failed to observe them or found them too trivial to write down.

rebuttal of Dr. Berger's testimony, petitioner's counsel, after conferring with Dr. Katz, chose not to present any rebuttal, on this or any other point of Dr. Berger's testimony. (Tr. 92-93.)

Dr. Berger also made other important points in his written report and at the hearing. He noted that Dr. Katz was positing an "anamnesic response" by Sierra's immune system; however, Dr. Berger argued, Sierra's alleged symptom of the appearance of "puffiness" about *three weeks* post-vaccination would *not* be consistent with an "anamnesic response," which would happen very soon after vaccination. (2-Tr. 64, 80.) Dr. Berger also noted that, according to the medical records, Sierra gained weight at a normal rate between her April 10 and May 26 pediatrician visits, indicating that she was not likely seriously ill during that time. (Ex. A, p. 5; Tr. 50-51.) Again, Dr. Katz did not rebut either of these points.

Dr. Berger also pointed out that there was no evidence from the testing of Sierra--*i.e.*, "no laboratory evidence or other studies of [Sierra], such as hypersensitivity to gelatin or other constituents of [her vaccination] or demonstration of excessive antibody responses or circulating antigen antibody complexes" (Ex. A, p. 4)--that would offer support to Dr. Katz' causation theory. To be sure, this absence *by itself* would *not* mean that petitioner could not establish a sufficient causation-in-fact claim. That is, causation-in-fact certainly may be established, in appropriate circumstances, based on *circumstantial* evidence alone. See *Althen, supra*. However, the absence of such evidence is *one factor* to be considered in evaluating the causation-in-fact question, and, in this case, constitutes one factor that does *not* support petitioner's claim.

2. Analysis of medical literature

Next, I note that an analysis of the *medical literature* submitted in this case fails to offer any substantial support for petitioner's causation-in-fact theory. With his written report (Ex. 26), Dr. Katz attached five exhibits, tabbed as A through E.¹⁶ Later, petitioner submitted two more medical articles, Ex. 43 and 44.

As to the exhibits tabbed as A through E, at the evidentiary hearing Dr. Katz did *not* rely upon them as support for his causation theory. Moreover, upon my own examination of these materials, I cannot see how they afford any substantial support to petitioner's case. The article at Tab E concerns possible reactions to the *varicella* vaccine, and thus seems irrelevant to Dr. Katz's theory, which ultimately seems to have focused only on the *hepatitis B* vaccination. Tab D seems to be a copy of the package insert for a hepatitis B vaccine. In the "adverse reaction" section, the insert indicates that some recipients have experienced "hypersensitivity" reactions, but none of the listed hypersensitivity reactions involve HIS or eosinophilia, nor do those listed reactions otherwise seem relevant to petitioner's case. The articles at Tabs A through C describe individuals who had possible allergic reactions to hepatitis B vaccinations, but again these articles do not seem to be of

¹⁶On the second page of his report (Ex. 26), Dr. Katz seems to refer to *four* medical articles as [1], [2], [3], and [4]. But at the end of his report there was no citation to any numbered articles, only a description of references A through E.

much relevance to petitioner's cases. The Tab A article describes a dramatic generalized reaction 30 minutes after vaccination, which resulted in immediate hospitalization. Sierra, in contrast, suffered no such immediate generalized reaction. The articles at Tabs B and C describe six persons who experienced either *urticaria* or *angioedema* after hepatitis B vaccination. The experiences of these patients, then, seem to be of little relevance to the case of Sierra, since none of the patients in any of the three articles are listed as having experienced HIS, eosinophilia, or anything similar.

Accordingly, I cannot find that the articles at Tabs A through E lend any significant support to Dr. Katz' causation theory.

The other two medical articles filed by petitioner were Exs. 43 and 44. Exhibit 43 described an adult who experienced eosinophilia three days after a hepatitis B vaccination. Exhibit 44 described an adult who experienced eosinophilia after an unusual *intradermal* hepatitis B inoculation. Dr. Katz did mention these two exhibits very briefly at the evidentiary hearing, indicating that he found them supportive of his causation theory concerning Sierra. (2-Tr. 19.)

Dr. Berger, however, indicated disagreement with the proposition that Exs. 43 and 44 support petitioner's causation theory. He noted that in Ex. 43 the vaccinee experienced eosinophilia only *three days* after vaccination, obviously in contrast to Sierra's case, in which Sierra did not exhibit major symptoms for more than six weeks after vaccination. (2-Tr. 56.) Dr. Berger also noted that Ex. 44 involved a patient who received a very unusual series of *intradermal* hepatitis B vaccinations, rather than the typical *intramuscular* vaccination. He explained that intradermal vaccinations are inherently much more likely than intramuscular immunizations to cause reactions. (*Id.*) Accordingly, he indicated doubt that any lesson from Exs. 43 and 44 "applies to the case of Sierra Howard." (*Id.*)

After reviewing Exs. 43 and 44, and the brief discussions of those articles at the hearing, I am persuaded that, as Dr. Berger suggested, those articles afford no significant support to petitioner's causation theory. As he suggested, the onset in Ex. 43 of eosinophilia *three days* after vaccination seems quite unlike Sierra's case, in which she experienced no strong symptoms for more than *six weeks* after vaccination. And Ex. 44 involving the unusual *intradermal* immunizations, seems to be of little relevance to Sierra's case involving the common *intramuscular* vaccination. I also note that Dr. Katz' comments concerning Exs. 43 and 44 at the hearing (2-Tr. 19) were so brief as to be completely unenlightening, and Dr. Katz declined the opportunity to respond to Dr. Berger's critique of those articles.

Thus, for the reasons set forth above, I find that the medical literature submitted in this case fails to offer any significant support for petitioner's causation theory.¹⁷

¹⁷To be sure, the fact the the medical literature does not significantly support petitioner's causation theory does *not by itself* mean that petitioner could not establish a sufficient causation-in-fact claim. That is, causation-in-fact certainly may be established, in appropriate circumstances, based on circumstantial evidence alone, without any medical literature support for the claim. See

3. Weaknesses of Dr. Katz' testimony

Finally, I note that I simply found both Dr. Katz' written report and his written testimony to be quite vague, unfocused, and unenlightening. Dr. Katz did clearly indicate the opinion that Sierra's HIS was caused by her hepatitis B vaccination, and that he believes that an abnormal immune response was involved; beyond that, however, he did very little to *explain the basis* for his opinion. Both his written report and his oral testimony were very short and non-detailed. His written report consisted of two pages (Ex. 26), while his direct oral testimony, once he had recited his credentials, was transcribed in only 13 pages (2-Tr. 9-21). Moreover, Dr. Katz' presentations on a number of individual points were incomprehensible or unenlightening. For example, his one-paragraph discussion of the medical literature was so brief as to be completely unhelpful. (Tr. 19.) He never explained at all why in his written report he attributed Sierra's HIS to *either* the hepatitis B vaccination or the varicella vaccination (Ex. 26, p. 2), but in his oral testimony he referred only to the hepatitis B vaccine (2-Tr. 20-21). He never explained why he disagreed with Dr. Berger's theory that a *viral infection* triggered both the symptoms that began on May 24, 2000, and ultimately Sierra's HIS. And, as noted above, Dr. Katz never explained why he believes that the hepatitis B vaccine would produce only very mild symptoms between April 10 and May 23, 2000, and then suddenly produce strong symptoms beginning on May 24.

In short, I simply did not find Dr. Katz to be a persuasive witness.

4. Summary

In sum, for the reasons stated above, even if I were to assume the accuracy of petitioner's testimony concerning the alleged symptoms between April 10 and May 23, 2000, I would still find that petitioner has failed to demonstrate "causation-in-fact," because I find the analysis of Dr. Berger to be far more persuasive than that of Dr. Katz.

V

OPINIONS OF TREATING PHYSICIANS

Petitioner has argued that the theory of causation advanced by Dr. Katz in this case is supported by certain documents provided by three of Sierra's treating physicians. (Pet. Br. 8-26-05, p. 23; Pet. Br. 9-16-05, pp. 10-11.) I have thoroughly considered the documents in question, however, and conclude that they do *not* persuade me that petitioner's causation theory has merit.

First, it is useful to review the circumstances in which those documents were created. As explained above (p. 12), it appears that sometime around mid-2002, about two years after the onset

Althen, *supra*. However, in this case Dr. Katz did attempt to rely on medical literature, in part, to support his theory, so that is necessary for me to evaluate the submitted literature to see whether it does support petitioner's theory.

of Sierra's illness, petitioner began to focus upon the possibility that a vaccination could cause an illness like Sierra's. Petitioner talked about that possibility with Dr. Bianchi, which prompted Dr. Bianchi to fill out the VAERS report on August 12, 2002. Soon thereafter, petitioner contacted her current counsel about the possibility of filing a Vaccine Act claim, and, at her counsel's suggestion, she asked Drs. Schumacher, Bianchi, and Bagatell to provide letters addressing the issue of whether Sierra's illness was vaccine-caused. (1-Tr. 17-18.) That request resulted in letters written by all three physicians. The question, then, becomes to what extent the VAERS report filed by Dr. Bianchi, and the letters supplied by the three physicians, provide support to petitioner's causation theory in this case. My short answer to that question is that these documents provide only very limited support to petitioner's theory, not enough to make a substantial difference in the case. The chief problem is that in none of the documents does the author actually indicate the view that a vaccination even "probably" caused Sierra's HIS.

First, I note that by the act of filing the VAERS report, Dr. Bianchi was *not* necessarily indicating the opinion that Sierra's HIS was vaccine-caused. VAERS reports are to be filed when a patient suffers an adverse event soon after a vaccination; the reporting physician need *not* know whether the event was *causally* connected to the vaccination.¹⁸ So, the mere fact that he filed the VAERS report does not tell us whether Dr. Bianchi believed that there was a *causal* connection. Interestingly, in the VAERS report Dr. Bianchi wrote that the "onset" of the adverse event occurred on May 24, 2000, so he clearly did *not* agree with Dr. Katz' view of Sierra's case, which relied upon symptoms that allegedly occurred *prior* to May 24. Moreover, it is also noteworthy that Dr. Bianchi did *not* file a VAERS report on his own in 2000, but only two years later, after petitioner related to him her new focus on the possibility of a causal connection between Sierra's vaccination and the HIS.

Similarly, the letters supplied by Drs. Bianchi and Bagatell clearly do *not* indicate that either physician believes that Sierra's HIS was vaccine-caused. Dr. Bianchi's letter, dated November 25, 2002, states only that one of the vaccines that Sierra received on April 10, 2000, "may have" caused her HIS. (Ex. 4, p. 73.) Likewise, in her letter, dated January 14, 2003, Dr. Bagatell could only go so far as to say that "whether the vaccines have a causal relationship to the eosinophilic syndrome or not, the temporal relationship is thought-provoking, and merits further study." (Ex. 7, p. 50.)

Finally, Dr. Schumacher, in his letter dated November 21, 2002, was willing to go a little bit farther than Drs. Bagatell and Bianchi, but not much farther. Dr. Schumacher stated that: "The rarity of the hypereosinophilic syndrome and its onset soon after the vaccination *suggests* an etiologic relationship between the injection and the disease." (Ex. 6, p. 1, emphasis added.) The use of the word "suggests" seems to indicate that Dr. Schumacher believes that it is *possible* that the

¹⁸See the highlighted excerpts from the VAERS website that I placed into the record of this case on February 6, 2006, including the following language, at page 3: "VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine * * *. You should report clinically significant adverse events even if you are unsure whether a vaccine caused the event."

vaccination caused the HIS, but was not able to go so far as to say that causation was “probable” or “likely.” Moreover, in writing this letter Dr. Schumacher was assuming a set of facts, concerning symptoms that Sierra allegedly displayed between April 10 and May 23, that not only seem unlikely based on the whole record, but, as discussed above (p. 13), were significantly different even from the petitioner’s *current* description of Sierra’s course during the April 10-May 23 period.

Of course, the fact that these physicians were willing to write letters, entertaining even the *possibility* of a causal connection between Sierra’s vaccination and her HIS, can be said to provide some *slight* support for petitioner’s case, in the sense that those doctors find the theory of a causal connection to be at least *plausible*. But this is very slight support indeed, since none of the physicians offered an opinion even to the level of “probable,” and none of the letters gave us any idea about the *reasons* for each physician’s opinion. Moreover, the letters of both Dr. Bagatell and Dr. Schumacher indicate assumptions of fact, concerning the alleged symptom history between April 10 and May 23, that, based upon the whole record, I find to be unlikely. Further, it is noteworthy that in his *medical records*, Dr. Bianchi referred to Sierra’s HIS as “idiopathic”—*i.e.*, of *unknown* cause. (Ex. 4, p. 22.) Similarly, Dr. Bagatell in her records referred to Sierra’s HIS as “of ?? etiology.” (Ex. 5, p. 114.) And I note that Sierra’s medical records demonstrate that a number of Sierra’s *other* treating physicians repeatedly described Sierra’s HIS as “idiopathic” or “of unknown cause” or “of unknown origin.” See, *e.g.*, notations of Dr. Grogan (Ex. 5, pp. 77); Dr. Hollister (Ex. 7, p. 16); Dr. Talwar (Ex. 8, p. 2); Dr. Browne (Ex. 5, pp. 82, 101, 112); and Dr. Cagno (Ex. 5, p. 133). See also notations to the same effect of physicians whose names are unclear. (Ex. 5, pp. 119, 138). And note that Dr. Villa speculated that a “viral agent” might have been the cause. (Ex. 5, p. 75).

Therefore, while in Program cases I am always very respectful of the opinions of the vaccinee’s treating physicians,¹⁹ in this case, for the reasons stated above, I cannot find that the documents in question created by Drs. Bianchi, Bagatell, and Schumacher offer persuasive support to petitioner’s causation theory.

¹⁹Of course, I am aware that in the recent *Capizzano* opinion, the Federal Circuit stressed the importance of opinions of treating physicians. *Capizzano v. HHS*, No. 05-5049, slip op. at 15 (Fed. Cir. Mar. 9, 2006). Indeed, in many a case, I have relied upon the opinions of treating physicians as an important factor supporting a finding of causation in a petitioner’s favor. See, *e.g.*, *Roper v. HHS*, No. 00-407V, 2005 WL 3597255 (Fed. Cl. Sp. Mstr. Dec. 9, 2005). In the particular circumstances of this case, however, for the reasons set forth above, I conclude that the cited statements of Drs. Bianchi, Bagatell, and Schumacher do not provide persuasive support to petitioner’s causation theory.

VI

PETITIONER'S CASE FAILS THE *ALTHEN* TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the “causation-in-fact” issue in Vaccine Act cases. The court stated as follows:

Concisely stated, *Althen*'s burden is to show by preponderant evidence that the vaccine 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. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

Althen, 418 F. 3d at 1278 (citations omitted). This statement in *Althen* could be interpreted as establishing a four-part test for proving “causation-in-fact” in Vaccine Act cases--that is, the first three parts being those enumerated in the *Althen* excerpt set forth above, with the fourth element being the requirement, set forth in the second sentence of the excerpt, that the evidence *not* show that the injury was caused by “factors unrelated to the vaccine.” There are difficulties with this apparent four-part test,²⁰ but interpreting this formulation as such a four-part test, the petitioner's presentation in this case clearly *fails* that test, because it fails to satisfy the *third and fourth elements* thereof.

The third element of the *Althen* test, set forth above, requires “a showing of a proximate temporal relationship between vaccination and injury.” That is, under this third element of the *Althen* test, the petitioner must demonstrate that the first symptom of Sierra's injury occurred in a time frame that would be consistent with causation by the vaccination in question.²¹ Petitioner in this case has failed to so demonstrate.

²⁰For example, I myself find it somewhat unclear as to exactly what is the difference between the *first* and the *second* of the three enumerated elements in the *Althen* excerpt set forth above. Also, concerning the fourth element, while the above-cited language at p. 1278 seems to imply that the burden is on the *respondent* to demonstrate that a non-vaccine factor caused the injury, additional language at p. 1281--“the elimination of other causes”--suggests that the burden may be on the *petitioner* to rule out non-vaccine causes. Any such difficulties with the four-part test, however, are not relevant in this case, since petitioner's case clearly fails the *third and fourth elements* of the *Althen* test.

²¹In other words, the petitioner must demonstrate the existence of a “scientific temporal relationship” as discussed in *Pafford v. HHS*, 64 Fed. Cl. 19, 29-30 (2005). Petitioner so acknowledged, at Pet. Br. 8-26-05, p. 22.

In this case, Dr. Katz did not indicate his view as to when, *in general*, the appropriate time frame for the appearance of a vaccine-caused injury of this type would be. He merely seemed to indicate vaguely that when, as here, a vaccinee was experiencing a *repeated* hepatitis B vaccination, he would expect the first symptom to occur *soon* after vaccination. He also opined that the appearance of Sierra's symptoms, *as described by her mother's testimony*, occurred in an appropriate time frame consistent with causation by the hepatitis B vaccination of April 10, 2000.

However, as explained above, I have concluded that the factual scenario assumed by Dr. Katz was *unlikely*--that is, that Sierra probably did *not* experience the symptoms, during the April 10 to May 23 time period, now described by her mother. Therefore, the first symptoms of Sierra's HIS likely did *not* occur during the time period soon after vaccination that Dr. Katz apparently deems appropriate. Accordingly, petitioner clearly has *failed* to satisfy the third element of *Althen*, because she has failed to establish that Sierra's first symptoms of HIS occurred within an appropriate time frame after vaccination.

Moreover, petitioner's case also fails for a *second* reason under the *Althen* test. The fourth part of the *Althen* test, set forth in the second sentence of the *Althen* excerpt quoted above, states that the petitioner fails to demonstrate "causation-in-fact" if the respondent shows, "by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." And in this case, as noted above, Dr. Berger has persuaded me that it is likely that Sierra's HIS was caused by a *viral infection*, unrelated to the vaccination, the first symptoms of which appeared about May 24.

Therefore, it is clear that petitioner's causation theory fails under the test set forth in *Althen*.²²

VII

CONCLUSION

The record of this case demonstrates plainly that Sierra Howard and her family have been through a tragic and painful ordeal. The entire family is certainly deserving of great sympathy. Congress, however, designated the Program to compensate only the families of individuals whose injuries can be linked causally, either by evidence or by a Table Injury presumption, to a listed

²²I note that I do *not* conclude that Dr. Katz made an adequate showing as to the *first two* elements of the *Althen* test. See, *e.g.*, my discussion at p. 17 above. However, it is unnecessary for me to analyze the first two elements, since petitioner's case so clearly fails the *third and fourth* elements of the *Althen* test.

vaccination. In this case, as described above, no such link has been demonstrated. Accordingly, I conclude that the petitioner in this case is *not* entitled to a Program award.²³

George L. Hastings, Jr.
Special Master

²³In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.