In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0595V

Filed: 14 May 2009

ABIGAILE GOLEC, a minor, by her mother, PARIS GOLEC, and father, ALLEN GOLEC, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	**UNPUBLISHED DECISION**

RULING ON ENTITLEMENT[1]

The Court convened a series of hearings in the above-captioned case on 15 August 2007, 16 January 2008, and 5 May 2008. The Court heard fact witness testimony from the Petitioners themselves and from medical experts called to testify from each party. Ultimately, the Court ruled in favor of entitlement in a bench ruling.

The Court summarized the rudimentary factual sequence of this case in its bench ruling, made on 5 May 2008:

> Abigaile was born on 7 September 2003. The first set of vaccinations, which included DTaP, [administered] 10 November 2003. The second set of vaccinations, which are essentially what bring us here today, 18 February 2004, and the first serious seizure requiring hospitalization that is evinced in the medical records is on the 2nd of April, 2004. The next major seizure, a grand mal, and a disorder which is diagnosed is on the 8th of April, 2004.

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[1] Petitioners are reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling 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, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

This Court is authorized by the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a cognizable Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). If Petitioner had claimed to have suffered a "Table" injury, to him would §13(a)(1)(A) have assigned the burden of proving such by a preponderance of the evidence. In this case, however, Petitioner did not claim a presumption of causation afforded by the Vaccine Injury Table, and thus the Petition may prevail only if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury alleged. See § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); see also *Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit has articulated an alternative three-part causation-in-fact analysis as follows:

> [Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] 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 v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

As part of that analysis, the Federal Circuit recently explained:

> [T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.

de Bazan v. Secretary of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury, they must still proffer a plausible

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[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C. §300aa.

medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

As a matter of elucidation, the Undersigned takes note of the following two-part test, which has been viewed with approval by the Federal Circuit,[3] and which guides the Court's practical approach to analyzing the Althen elements:

> The Undersigned has often bifurcated the issue of actual causation into the "can it" prong and the "did it" prong: (1) whether there is a scientifically plausible theory which explains that such injury could follow directly from vaccination; and (2) whether that theory's process was at work in the instant case, based on the factual evidentiary record extant.

Weeks v. Secretary of HHS, No. 05-0295V, 2007 WL 1263957, 2007 U.S. Claims LEXIS 127, slip op. at 25, n. 15 (Fed. Cl. Spec. Mstr. Apr. 13, 2007).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), rehearing and rehearing en banc denied, (Oct. 24, 2006), cert. den., 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshhold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that petitioner would not have sustained the damages complained of, but for the effect of the vaccine. See generally *Shyface, supra*. "[T]he relevant inquiry ...[is]... 'has the petitioner proven ... that her injury was in fact caused by the ... vaccine, rather than by some other superseding[,] intervening cause?' ...[The petitioner need not] rule out every possible explanation ...[but]... must simply show ... that her injury was caused by a vaccine." *Johnson v. Secretary of HHS*, 33 Fed. Cl. 712, 721 (1995), aff'd 99 F.3d 1160 (Fed. Cir. 1996) (emphasis added).

Wherefore, the Court summarized the evidence and ruled as follows:

> The first record that I'm going to mention is Exhibit 9, page 1, which is the Arkansas Children's Hospital discharge record. Of course, we're talking here about the admission of 14 April 2004 and discharge on the 16th of April, 2004.
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> Under Chief Complaint, Abigaile is a seven-month-old white female with history of seizures this month. The family reported seizure on April 2, 2004. The patient was

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[3] *See Pafford v. Secretary of HHS*, No. 01-0165V, 2004 WL 1717359, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd* 451 F.3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in *Althen* and *Shyface*"), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

admitted to an outside hospital for two days. On April 8, 2004, she had what they described as a grand mal seizure, lasting 45 minutes, after which she was medicated. She was rehospitalized at that time. She was started on No. 4, Phenobarbital, or I'm sorry, IV Phenobarbital. On April 9, 2004, she had another large seizure that occurred which was more upper torso than the entire body. These seizures started with a horrible scream or screech.

In looking back, the parents feel that she has had some other screaming episodes, especially during the night, that they feel may have been seizures as well as these that go back several months. That's most puissant. That's important, that particular phrase. It says, go back several months. This is dated April. The vaccination of course is February. This begins to corroborate the parental asseverations and show a consistency.

To go back to the record, the patient also has had several previous 30-second to two-minute episodes with the same scared look and body language as the larger seizures that likewise exhibit the same.

All right. By the way, several of the records for Abigaile, the baby records, indicate the reference to food issues and the question of whether there was an allergy. That is never diagnosed or sustained. It's an issue that is proffered, a little bit like the issue of sweats that is also indicated and the mother, who made an association or the possible association with rice cereal. The Court ultimately is not going to make anything out of that. The Court is not going to make anything out of that because neither of the experts made anything out of that.

If we look at Dr. Keller's Exhibit 21, I guess it's pages 7 to 9, this is dated August 16, 2004, under assessment, at the bottom of page 8, "past history of seizures, with mother noting temporal association between administration of immunizations and subsequent development of seizure activity, certainly association with the second immunization received at age four months. There was a prolonged period between immunization and subsequent development of seizure activities. There was also significant generalized edema noted by mother, with mother being unaware of specific etiology for the generalized edema."

In the notes of Dr. Bernadette Lange, this would be Exhibit 22, page 1 and 2, and this would be dated September 3, 2004, on page 1, they make an association of staring, flexing her arms to the chest, eyes to the right, lasting 15 to 30 seconds. That may be of minimal consequence for our purposes, but the Court noted it.

We also have Arkansas Children's Hospital record, Exhibit 24, pages 1 and 3, dated September 16, 2004. She was "seen following your request for consultation related to the question of a possibility of vaccine-related seizures and possible food allergic reactions and mild rhinitis. Both parents were present for the appointment and

provided the history. They state that they have noted that Abigaile had onset of seizures that occurred approximately two weeks after her second and four-month sets of immunizations."

Now this is Dr. Amy Scurlock. Dr. Scurlock says in her conclusions, page 3, "Again, I feel that her seizures are likely not mediated by food allergic reaction and are likely not related to an allergic vaccine reaction." Of course, the key word there may be "allergic". "However, I would like to discuss with Dr. Bernadette Lange our findings on the rest test and then formulate a plan together for her future vaccine administration." That may or may not be of consequence.

This is Exhibit 45, and, of course, it's Dr. Wheless in his evaluation. The date of the report was 16 November 2006. Of course, we know that he's at the University of Tennessee and is a pediatric neurologist and a Director of I guess that said department at St. Jude's Hospital. He concluded that she was developing normally when she received her DPT immunization along with other immunizations. Presumably, he's referring there to the first set.

In the evening, the parents noted episodes of intermittent eye deviation to the right. These occurred that day and then a couple times a day after this for a short period of time. He also makes association with screaming and that they said she was inconsolable. He then discusses her second DTP vaccination on February 18 and the parents noting her staring off and convulsing for a minute and being cyanotic. That would be reflected to the 2nd of April.

He then concludes, "It's my opinion based on medical probability that the DTAP immunization caused Abigaile to have an encephalopathy at age five months which was manifested by the awakening and the screaming. This has left her with a chronic encephalopathy, manifested as developmental delay, which is global and includes speech, motor and cognitive function."

The Court will note for the record the diary entries that have been alluded to and Dr. Wheless's supplemental report, which is particularly making the association with the February 18, 2004, vaccination and his notation of diary entries dated February 20,

February 23, February 24 and March 2, 2004. That is the mother's diary that he relied upon. All note episodes of excessive crying and screaming and that the mother had some association at that time with her being colic-like. Then, of course, the Court notes Dr. Cohen's report, Respondent's Exhibit A, which is four pages.

All right. Now that the Court notes all that, the first thing the Court should indicate is reflected to Mr. and Mrs. Golec, because there were two hearings, part of which revolved relative to a baby book that was never found although searched for. The Court makes nothing in reference to that other than the fact that it was referenced,

that counsel made mention that such a thing existed and that Mrs. Golec on the stand said, yes, such a thing at least had existed and they could not locate that.

The Court carefully noted on the part of both Mr. and Mrs. Golec their deportment, their presentment, their demeanor, and concludes, not with every facet since that would be uncommon, but essentially that the great weight of what they had to say evinces the tin tin abulation of veracity and consequently concludes that the vast weight of the vast majority of what was stated is reliable and that the notations made on the presumed contemporaneous calendar that has been made mention of more likely than not were made at the time that the Golecs indicated they were made and that can be utilized as appropriate evidence for a contemporaneous document. Dr. Wheless does that.

Now, if you take the weight of what Dr. Wheless had to say, and Dr. Wheless essentially was found rather persuasive, perhaps in the context of this argument more persuasive than Dr. Cohen, Dr. Wheless ultimately does show a medical theory connecting the vaccination and the injury, a logical sequence of cause and effect, and a proximate temporal relationship, which is to say that his presentation meets the requisites found in the Offen test.

Now there has been much said about the food allergy issue, the mold issue. The Court must indicate that ultimately they are both found as the proverbial red herring. Could in fact they have had some bearing? Perhaps, but there's no preponderance of evidence, and certainly no medical expert relied upon either one of those issues.

You find that Respondent's expert appears to be putting a certain amount of reliance, or Respondents are, on a factor unrelated if that would be the correct terminology or certainly an alternative reasoning, which is essentially cryptogenic, and its cryptogenic delays of unknown etiology is Respondent's factor unrelated. Per se, that has to be considered an idiopathic explanation. Etiology unknown simply is not going to function as an alternative explanation when Petitioners have proffered an explanation that meets the minimum needs.

We find that Dr. Wheless is relying upon, as indicated in his report, an association of indicia which go back to within a couple of days particularly of the February 18 vaccination but also indicates the prior November vaccination, of the eye darting, screaming, inconsolable screaming, subsequent seizures. No one says that the eye darting themselves are seizures except that Mrs. Golec indicated that she was told later that since those items were identical to what was seen later, that they were more likely than not or they probably were seizure events. She may be correct.

She indicated she was told that. Dr. Wheless does not specifically mention that. He puts the weight of his argument that there was an acute encephalopathy, which begins within days particularly of the second vaccination or administration of the second

vaccination, and then eventually manifests itself in early April with the very dramatic seizures that we find there. He winds all that together.

Dr. Cohen simply does not accept the testimony of Mr. and Mrs. Golec and says we see what we see in early April and that's not associated with the vaccinations of February.

Well, the Court finds that we can rely on the testimony of the Golecs, and therefore, that goes to the heart of the presentation of both experts. The Court also accepts more likely than not that the phone calls that Mrs. Golec referenced as having occurred contemporaneously because of her concern over Abigaile that are noted in what the Court accepts as a contemporaneous document of the diary more likely than not did occur.

She proffers that she did take Abigaile, but it was a nurse that saw Abigaile, and therefore, that was not entered on the records, nor were the phone calls entered on the records. But the Court accepts her testimony that in fact these phone calls and presumed visitations occurred essentially when she says they occurred and which is also shown on the contemporaneous diary.

The Court found it most puissant, as previously indicated, that on the discharge summary at the Arkansas Children's Hospital, there was at that time an association made with the screaming as being identical or similar or as had occurred several months prior. Several months of course puts us in the time period before, during and after the administration of the second set of vaccinations. That becomes very important when the mother then testifies and the father as to when that occurred.

There have been notations of alteration in behavior and that that behavior first became manifest almost immediately after the second set of vaccinations.

Essentially the Court cannot accept cryptogenic issues which are based on etiology unknown as a probable alternative causation. They were addressed by the parents. There could have been other issues but nothing on which the Court could find reliance. Ultimately, the Court has to rely and does rely on the parental testimony, the parol testimony, on the discharge evidence of Arkansas Children's Hospital and on Dr. Wheless's testimony, which also is based on the parents and on the diary.

Consequently, this Court would find in the affirmative for the Petitioners and consequently would then not dismiss the petition and would instruct the Petitioners to proceed towards the process of securing a life care planner so as to delineate precisely what the damages in actuality are....

The Court did not come to conclusive findings on any matter not addressed in the above-stated findings. The Court ruled on the weight of evidence presented in this case. If further dispute

arises between the parties, further proceedings may be scheduled if necessary to take additional evidence.

Any queries or problems encountered by the parties in this matter should be addressed to my law clerk, Isaiah Kalinowski, Esq., at 202-357-6351.

IT IS SO ORDERED.

Richard B. Abell
Special Master