OFFICE OF SPECIAL MASTERS

No. 03-2787V

(Filed: September 13, 2005)

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STEPHANIE HIDALGO, as the Mother and representative of the estate of ADAM CADE HIDALGO,	*
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Petitioner,	*
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v.	*
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SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*
	*
Respondent.	*
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ORDER[1]

On 12 September 2005, Petitioner filed a Response to an Order to Show Cause issued by this Court concerning a supplemental expert report requested in the above captioned case.

In an Order dated 13 April 2005, after finally receiving a report from Dr. John J. Shane, a pathologist, the Court requested that Petitioner add some flesh to the report, namely that Dr. Shane file a supplemental report providing a "logical sequence of cause and effect" that connects the vaccination(s) to the injuries alleged. The Court did not think the Order particularly onerous and gave Petitioner through 19 May 2005 to file the supplemental report and granted numerous extensions thereafter. Finally, on 29 August 2005, the Court set a final deadline, stating that Petitioner shall file the supplemental expert report by close of business on 12 September 2005 or be dismissed for failure to prosecute.

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[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Therefore, as provided by Vaccine Rule 18(b), 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, "the entire decision" will be available to the public. *Id.*

The report was not filed. Instead, Petitioner filed a response requesting a further extension and a clarification of the special master's request in light of the recent decision passed down from the Federal Circuit in Althen v. Secretary of HHS, 2005 WL 1793399, slip op. (Fed. Cir. July 29, 2005).

In Causation-in-fact cases such as this, where the injury is not one recognized by the Vaccine Injury Table, the Federal Circuit in Althen recently stated that Petitioner's burden is to prove by a preponderance of the evidence (more probably than not) that the vaccine(s) in question caused the injury alleged by showing: "(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, slip op. at *5. Moreover, Althen further recognized that "requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes—is merely a recitation of this court's well established precedent." at *10.

In toto, Althen does not represent a sea change in the way this particular special master addresses Causation-in-fact. The Federal Circuit in Althen held that a claimant cannot be required to provide medical literature. Althen, slip op. at *8. This special master does not require that petitioners submit peer reviewed literature in support of their theory as a prerequisite for proving causation. Instead, this Court has long recognized that the plausibility of a medical theory can be bolstered in any number of ways including, but certainly not limited to (1) evidence that at least a sufficient minority in the medical community has accepted the theory as to render it credible; (2) epidemiological studies and an expert's experience, while not dispositive, lend significant credence to the claim of plausibility; (3) articles published in respected medical journals, which have been subjected to peer review, are also persuasive; however, publication "does not necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993). Even so, petitioners are often encouraged to submit such literature where available in order to meet their burden of proof – that the vaccine in question more likely than not caused the injury alleged.

Dr. Shane is an expert in pathology. He asserts, unless the Court is mistaken, that an encephalopathic event appears to have dealt a blow to Adam's central nervous system that resulted in pulmonary edema which resulted in death. Petitioner's Exhibit ("Pet. Ex.") 11. Dr. Shane says, "The timing of this event as relates to the administration; the unexplained shaking on the evening before his death; and his death 24 hours after the immunization clinically correlate with the pathological findings to confirm a diagnosis of vaccine related encephalopathy with central nervous system mediated pulmonary edema." Pet. Ex. 11 at 3.

Petitioner states that "the medical theory that vaccines can cause encephalopathy is nothing new to this program and has been stated many times before." Petitioner's Response to the Order to Show Cause at 3.

While it has been stated many times before, Petitioner's specific medical theory – that these vaccine(s) in particular caused the encephalopathy alleged – is far from proven. To hold otherwise would be to afford Petitioner's a presumption of causation allowed only in Table Injury claims.

The Vaccine Injury Table recognizes that an "acute encephalopathy" may occur within 72 hours of a vaccine containing pertussis. 42 C.F.R. § 100.3. Petitioner is not arguing that Adam suffered an "acute encephalopathy" as defined by the Qualification and Aids to Interpretation that accompany the Vaccine Injury Table. *Instead, Petitioner is asserting that a combinations of vaccinations caused an afebrile encephalopathic event that resulted in the death of a six month old baby.*

Petitioner must convince the Court that her theory is plausible and must eliminate any alternative cause(s) identified in the medical records.

According to the reasoning in Althen, a petitioner may not be required to proffer epidemiological studies or corroborating medical literature. And, for the reasons previously stated, this Court agrees. However, while Petitioner is not required to submit such evidence, she is given every opportunity and is encouraged to do so as such evidence goes to the plausibility of the medical theory and the weight to be afforded an expert's testimony.

Petitioner appears to be arguing that she need put forth nothing more than medical records or a medical opinion. Certainly it is clear from the language of the Act that, at the *very least*, medical records or a medical opinion must accompany a petition in order for a special master to find on the claimant's behalf. In fact, a special master could not so find "based on the claims of petitioner alone, *unsubstantiated* by medical records or by medical opinion." 13(a)(1) (emphasis added). However, the Act goes on to say that the special master "s*hall* consider, in addition to all other relevant medical and scientific evidence contained in the record – (A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." 13(b)(1) (emphasis added). Moreover, the special master is to accord each item its proper weight based upon considerations of "the *entire* record and the course of the injury." *Id* (emphasis added). Therefore, medical records and/or a medical opinion are only one part of the entire record that a special master must consider.

In this particular case, the medical records provided and Dr. Shane's report raise significant questions as to the plausibility of Petitioner's theory.

First of all, which vaccination(s) caused the injury? Or does Petitioner allege that all three worked in some combination to cause the alleged encephalopathy? On the day of vaccination, Adam was seen for cough, congestion, and a runny nose. Pet. Ex. 11 at 1. Has Petitioner adequately accounted for this potential alternate cause for the alleged encephalopathy as identified in the medical records? Granted, Petitioner must by no means eliminate every possible alternate cause, but where there is evidence in the

medical records of a possible alternate cause, that must be addressed, and Petitioner bears the burden of proof.

Furthermore, the Court questions whether there exists any evidence in the record – aside from Dr. Shane's asseverations – which indicates that DTaP, Prevnar, or Hib can cause an afebrile encephalopathic event within 24 hours of vaccination.

Moreover, the Court questions whether Dr. Shane, as a pathologist and not a pediatric neurologist, is best suited (or qualified at all) to opine as to whether the encephalopathy alleged was vaccine-related.

For argument sake, let us assume that Dr. Shane is right – as he very well may be – that according to his expert pathological opinion, an encephalopathy created serious damage to Adam's central nervous system including "neuronal degeneration, gliosis, and severe cerebral edema" which then led to "severe and extensive pulmonary edema." Pet. Ex. 11 at 2. Even so, that does not prove that the vaccination(s) were responsible for the encephalopathy.

Petitioner may argue that, given temporal proximity and a lack of alternative causes, the vaccinations more likely than not caused the alleged encephalopathy. However, that argument essential boils down to a *post hoc ergo propter hoc* assertion which is "neither good logic nor good law." Frianco v. Secretary of HHS, 22 Cl. Ct. 796, 800 (1991). Neither temporal proximity nor absence of alternate etiology by themselves or in tandem satisfy petitioner's burden of proof.

Furthermore, when the Court talks about temporal proximity, it is talking about "a medically acceptable temporal relationship" between the vaccination and the injury. Althen at *10. Therefore, the Court asks, what proof does Petitioner proffer that the injury alleged, an afebrile encephalopathic event resulting in Adam's death within 24 hours of the vaccination(s), occurred within a medically acceptable time frame?

Finally, the Federal Circuit in Althen appears to indicate that the process of establishing causation-in-fact under the Vaccine Act has become increasingly and unnecessarily complicated. Therefore, this Court recommends a return to the basics, which includes asking and answering elementary questions such as: How do you know? Says who? and How do they know?

The Court hopes this acts by way of clarification for Petitioner. If anything has been missed or if Petitioner's counsel has any further questions or disagrees entirely with certain points of this Order, the Court encourages further dialogue in the argumentative briefs that will undoubtedly follow in this case. The application of the law has been described as a dialogue, and the Court appreciates the substantial contribution of Petitioner's counsel in the conversation concerning the appropriate interpretation of the Vaccine Act.

As for the above captioned case, it is apparent to the Court that Dr. Shane may not be best suited

to opine as to the underlying questions of causation surrounding the case. He has offered his medical opinion as an expert in pathology, that an encephalopathy (as opposed to SIDS or some other etiology) was the root cause of Adam's death. If Petitioner feels that Dr. Shane is qualified to opine as to the questions raised in this Order, she may continue to seek a supplemental report from him. Otherwise, she may wish to pursue an opinion from a neurologist or some other qualified expert that the vaccinations in question caused the encephalopathy indicated by Dr. Shane. The Court assumes that Respondent will most likely take umbrage both with Dr. Shane's pathological report and with the underlying theory that the vaccinations in question caused such an injury.

As it presently stands, were the Court asked to rule on the record as presented, it could not find, based on the record as a whole including Dr. Shane's report, that Adam's death was more likely than not attributed to the vaccine(s) administered.

It is well established precedent 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 v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Therefore, in order to prevail, Petitioner must provide a plausible medically theory that connects, via a logical sequence of cause and effect, the vaccine(s) in question with the injury alleged by Dr. Shane.

The status conference scheduled for 14 September 2005 at 11:00 a.m. will be held as scheduled in order to set an appropriate schedule. If the parties have any non-substantive issues or queries, please contact my law clerk, David Lee Mundy, Esq., at 202-357-6351.

IT IS SO ORDERED.

s/ Richard B. Abell

Richard B. Abell
Special Master